

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. _____

MILLIE LAND, on behalf of herself, all
others similarly situated, and the general
public,)

Plaintiff,)

vs.)

UNIVERSAL HANDICRAFT, INC., d/b/a)
"Deep Sea Cosmetics" d/b/a "Adore Organic)
Innovations;" and SHAY SABAG SEGEV,)

Defendants.)

_____)

COMPLAINT – CLASS ACTION

DEMAND FOR JURY TRIAL

/

Plaintiff MILLIE LAND (“Plaintiff”), individually and on behalf of herself, all others similarly situated, and the general public, brings this action against SHAY SABAG SEGEV and UNIVERSAL HANDICRAFT, INC., doing business as "Deep Sea Cosmetics" doing business as "Adore Cosmetic Innovations" ("Adore"). The factual contentions in this complaint have evidentiary support or will likely have evidentiary support after a reasonable opportunity for further investigation or discovery. Plaintiff intends for the exhibits filed with this complaint to become a part of this complaint for all purposes. Plaintiff alleges the following on information, belief, or by investigation of her counsel, formed after an inquiry reasonable under the circumstances, as set forth in the preceding paragraphs:

JURISDICTION AND VENUE

1. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because Plaintiff is domiciled in Florida, Defendants are domiciled in Florida, and the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

2. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) (the Class Action Fairness Act of 2005 or "CAFA") because the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interest and costs, and at least one class member is a citizen of a different state than one of the Defendants.

3. This Court has personal jurisdiction over the Defendants because each defendant has certain minimum contacts with this forum and the assertion of jurisdiction over the Defendants would not offend traditional notions of fair play and substantial justice. Each of the Defendants have purposefully availed themselves to the laws and benefits of conducting business with residents of this forum and each of the Defendants have conducted substantial business in this forum. Moreover,

the exercise of personal jurisdiction is proper pursuant to the Constitution and laws of the United States as well as California's "long-arm" statute, California Code of Civil Procedure § 410.10.

4. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district because Plaintiff purchased the products at issue in this action from Defendants' retail store that is located within this judicial district at an Adore Organic Innovations store in Ft. Lauderdale, FL in or around the summer of 2015. Plaintiff purchase approximately \$550 total for her purchases of Adore products.

NATURE OF THE ACTION

5. Defendants manufacture, distribute, market, advertise, and sell a line of super premium cosmetics under their "Adore Organic Innovation" Product line. According to Defendants, "Adore Organic Innovation uses the highest concentration of its proven Plant Stem Cell formula, combined with a blend of vitamins, essential oils, and organic plant extracts, to enable your skin's own stem cells to renew and slow the aging process. **It's the most advanced breakthrough in anti-aging skin care today. And it's yours exclusively to adore.**" (emphasis in original).

6. Included in the "Adore Organic Innovation" Product line are the Adore CELLMAX Products. The Adore CELLMAX Products are touted as a "remarkable formula" that are "proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."

7. The CELLMAX Products include the "CELLMAX Redefining Facial Cream" ("Cream"), the "CELLMAX Elite Facial Serum" ("Serum"), and the "CELLMAX Superior Supplement Facial Thermal Mask" ("Thermal Mask") (collectively the "CELLMAX Products"). The

CELLMAX Products are also sold together in a single kit called the "CELLMAX Kit." See Screenshots of Defendants' Website attached hereto as Ex. 1.



8. Defendants market and sell at least twenty-two (22) cosmetics products under is "Adore Organic Innovation" Product Line that are substantially similar to the ADORE CELLMAX Products because they contain the same types of "plant stem cells" and make almost identical labeling claims that tout the anti-aging benefits of the Products by way of the purported "plant stem cells." The CELLMAX Products and the substantially similar products, which are more fully defined in this complaint, are collectively referred to as the "Adore Products."

9. Defendants sell the Adore Products direct-to-consumers through their brick and mortar retail locations and through their website, <http://www.adorecosmetics.com/>.

10. Defendants claim through a comprehensive marketing campaign that their "exclusive Plant Stem Cell Formula" is "proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."

11. Defendants' representations, however, are false and misleading. The Adore Products do not "halt the aging process" nor are the Adore Products "Proven to restore youthful appearance." Moreover, the plant stem cells within the Adore Products are not "exclusive." Instead, the "plant stem cells" in the Adore Products are really a proprietary ingredient called PhytoCellTec™ that is manufactured by Mibelle Biochemistry of Switzerland. PhytoCellTec™ is also an ingredient in several other cosmetics products, many of which are far less expensive than the super-premium Adore Products. *See Ex. 2.*

12. Indeed, the purported "plant stem cells" contained in the Adore Products do not provide any type of anti-aging benefits because Mibelle admits that its PhytoCellTec™ *Malus Domestica* "is a patented liposomal preparation of apple stem cells derived from the 'Uttwiler Spätlauber', a rare Swiss apple variety." *See Ex. 2.*

13. All credible evidence shows that Defendants' claims about plant stem cells in the Adore Products and their ability to interact with human skin stem cells to provide anti-aging benefits are false and deceptive. Moreover, Dr. Daniel Schmid, the research director of Mibelle, has actually admitted that "[t]he anti-ageing benefit for the skin after topical application could not be confirmed in a clinical trial." *See Could the extract from a rare Swiss apple REALLY get rid of your wrinkles? THE DAILY MAIL (Nov. 2009), attached hereto as Ex. 3.*

14. Despite this statement from the research director of the company that manufactures the "plant stem cells" contained in the Adore Products, Defendants continue to market the Adore Products as containing a "proven Plant Stem Cell formula...to enable your skin's own stem cells to renew and slow the aging process." *See Ex. 1* (emphasis added).

15. In the liposomal preparation employed by Mibelle, intact plant stem cells simply no longer exist. The plant stem cells are essentially "pulverized" by "homogenization" —application of mechanical force, such as with a rotary blender, to create a suspension that Mibelle describes as a "cell broth." Various ingredients are then added to this "cell broth," which results in only a mere "essence" of the original plant stem cells. According to Mabelle's patent application for PhytoCellTec, "the great advantage of this method is its simple and low-cost application." Moreover, the patent application itself concedes that "use for stimulation and protection of skin stem cells is not envisaged." *See Patent Application for PhytoCellTec attached hereto as Ex. 4.*

16. In short, there is no possible way that the so-called "plant stem cells" in the Adore Products can "enable your skin's own stem cells to renew and slow the aging process." Nonetheless, Defendants charge a super-premium price for what is really a "simple and low-cost" cream that it describes as "the most advanced breakthrough in anti-aging skin care today."

17. Worse yet, the Adore Products are being sold unlawfully. The United States Food and Drug Administration has warned the marketers of a similar cosmetics products containing PhytoCellTec that their products violate federal law. *See FDA Warning Letter to Crescent Health Center, Inc., WL #28-16 (April 20, 2016), attached hereto as Ex. 5; FDA Warning Letter to Jaba Labs, LLC, (March 1, 2011), attached hereto as Ex. 6.*

18. Plaintiff Mollicone was misled by Defendants advertising and labeling of the Adore Products and would have not purchased the products (or would have only been willing to pay significantly less for the Products) if she would have known that the Products do not provide the touted anti-aging benefits.

19. Plaintiff Mollicone now seeks redress on behalf of herself and all other similarly situated consumers. Plaintiff Mollicone seeks to represent the consumer classes, or alternate subclasses, that are more fully defined in this complaint. Plaintiff Mollicone is alleging intentional fraud and deceit, fraud by omission, negligent misrepresentations violations of California's Unfair Competition Law, CAL. BUS. & PROF. CODE §§ 17200 *et seq.*, California's False Advertising Law, CAL. BUS. & PROF. CODE §§ 17500 *et seq.*, California's Consumers Legal Remedies Act, CAL. CIV. CODE §§ 1750 *et seq.*, Breach of Express Warranties under the laws of ten jurisdictions, Breach of Implied Warranties, violations of the New Jersey Consumer Fraud Act, and violations of the New Jersey Truth-in-Consumer Contract Warranty and Notice Act ("TCCWNA"). Plaintiff Mollicone also seeks rescission of all purchase contracts for the Adore Products, restitution, and injunctive and declaratory relief.

PARTIES

20. Plaintiff is a resident of Minneola, Florida.

21. Defendant Universal Handicraft, Inc. is a for-profit corporation organized under the laws of Florida that maintains its principal place of business at 1400 Alton Road, Suite 201, Miami Beach, Florida. *See Ex. 7.* At all times mentioned in this complaint, Defendant Universal was a seller, distributor, manufacturer, and advertiser of the Adore Products.

22. Defendant Shay Sabag Segev is an individual believed to be residing in the State of Florida. Defendant Segev is the President of Defendant Universal Handicraft, Inc. and personally participated in, directed, and controlled the sales, distribution, manufacturing, and advertising of the Adore Products. According to the Articles of Incorporation for Universal Handicraft, Inc., Defendant Segev is the incorporator of Defendant Universal and also serves as one of its directors. See Universal Handicraft Inc.'s Articles of Incorporation attached hereto as Ex. 8.

FACTUAL ALLEGATIONS

A. Defendants Capitalize on the Anti-Aging Products Market

23. Since 2001, Defendant Universal has manufactured and sold various cosmetic and skin care products. The company made a name for itself by developing products that utilize or contain, inter alia, natural Dead Sea minerals combined with complex peptides. In 2012, Universal developed a new and innovative line of products utilizing plant stem cell technology. See Emily Lambert, *The Deep Sea and Its Many Treasures*, SPECIALTY RETAIL REPORT (Fall 2010), attached hereto as Ex. 9.

24. On or about June 28, 2012, Defendants launched this new line of products under the trademark ADORE ORGANIC INNOVATION. On or about October 29, 2012, Universal filed a trademark application with the U.S. Patent & Trademark Office ("USPTO") for the trademark ADORE ORGANIC INNOVATION. See Trademark Application for "Adore Organic Innovation," attached hereto as Ex. 10.

25. "Adore Cosmetics is a leading purveyor of organic skin care products designed to harness the power of plant stem cells, botanical extracts and proven leading-edge anti-aging ingredients to restore the natural, youthful radiance of skin."

26. Products bearing the ADORE ORGANIC INNOVATION are sold through kiosks, on-line through the www.AdoreCosmetics.com website, and through retail stores dedicated to ADORE ORGANIC INNOVATION products, including self-branded stores in shopping malls operating under the mark ADORE ORGANIC INNOVATION, such as the one depicted below:

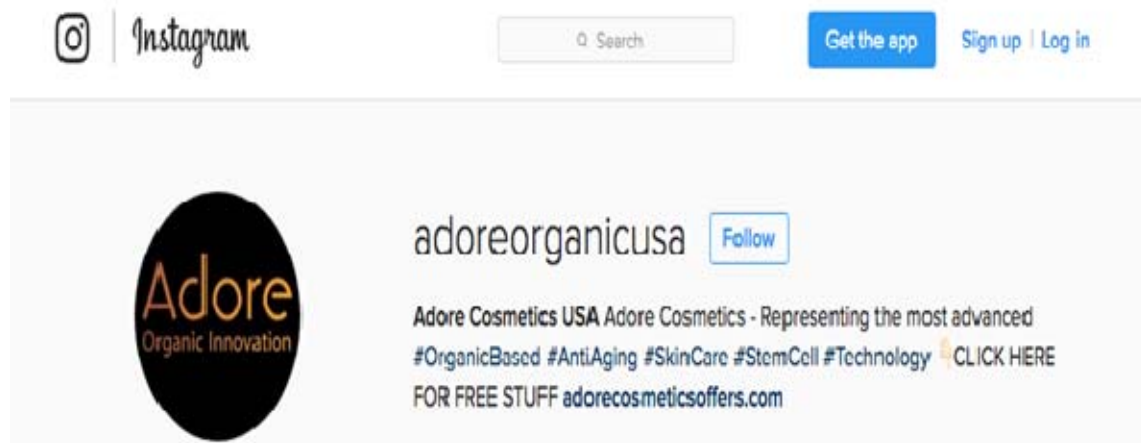


29. Defendant Segev has been called "The man behind it all" who started selling cosmetics products from a specialty retail kiosk at the Broward Mall in Plantation, Florida. "With wholesaling in mind, in 2004, Sabag returned to look for a factory and a lab that would be able to bring the most innovative high-end line of cosmetics to the market. His intention was to create cutting-edge Dead Sea cosmetics using the best technology and formulations available. Once his factory was secured, and his line was ready to market, retailers quickly jumped on board. Carts began to sprout up in Florida and spread throughout the East Coast, eventually making their way throughout the entire United States." "By the end of 2004, Deep Sea had approximately 60 carts

along the East Coast retailing their products. By the second year, that number jumped to 150. And [by 2010], during the bustling holiday season, Deep Sea carts numbered 450. The product line has also grown, from 12 products to approximately 60 by Deep Sea Cosmetics Laboratories. Retailers carry an average of 40 different products on their units." *See* Ex. 9.

B. Defendants' False and Misleading Marketing of the Adore Stem Cell Products

30. Defendants has engaged in a uniform marketing and advertising campaign designed to convince consumers that its Adore Organic Innovation Products are scientifically and clinically proven to provide consumers with dramatic anti-aging results, "Representing the most advanced #OrganicBased #AntiAging #SkinCare #StemCell #Technology," according to the Adore Instagram page.



31. These false and misleading statements are disseminated in advertising, marketing, and promotional materials designed to induce consumers to purchase Stem Cell Products through the internet, through specialty retailer cosmetic carts in shopping malls, and at Defendants' various Adore retail locations.

32. Plaintiff alleges that Defendants maintain Adore Retail Locations in approximately 24 U.S. Cities, including "Rodeo Drive Beverly Hills, California," Santa Barbara, California, San Francisco, California, and Los Angeles California. See Press Release, *Adore Cosmetics Opens New Store in Boston/Cambridge Area* (July 1, 2016), attached hereto as Ex. 11.

33. On Defendants' website, www.adorecosmetics.com, Defendants make numerous anti-aging claims, purportedly backed by exhaustive scientific research. According to the Adore Website, "Adore Cosmetic's research teams have discovered that stem cells harvested from organic produce—which is generally richer in nutrients than mass-harvested fruits and vegetables found in most supermarkets—have profound impact on our skin. Using our patented plant stem cell formula, Adore Cosmetics products take advantage of the epigenetic factors of resilient plant stem cells. In turn, this enables your skin's own stem cells to self-renew while slowing down the aging process. Stem cells have shown great potential to treat critical conditions like Alzheimer's and Parkinson's disease. Adore Cosmetics uses the same type of technology for beauty—using stem cells found in organic fruits and vegetables." See Screen Capture of Defendants' Website, *attached hereto* as Ex. 12.

34. Moreover, according to the Adore Website, "Adore Cosmetic's research team kicked off their skin studies by knowing that stem cells account for just 2% to 7% of your skin's total cells...yet they're responsible for ALL of your skin's ability to heal itself. As time passes and environmental damage mounts, these stem cells lose effectiveness—and skin loses its vitality. Scientists from Adore Cosmetics reviewed independent research that pointed out that plants also have stem cells...and that some fruit stem cells act similarly to human stem cells. The team saw the potential of applying these plant stem cells to protect human skin cells." See Ex. 12.

35. Next, according to the Adore Website, "Adore Cosmetic's researchers started experimenting by applying an extract of these organic plant cells to ethically collected human skin stem cells and then exposing them to UV light. They noticed that the skin cells experienced only a small loss of vitality—while half of those with no extract died. Adore Cosmetic's scientists also tested human skin cells for premature aging due to cellular DNA damage. While the cells incubated with the extract experienced a neutralization of the negative effects and increased their growth rate, the cells that weren't treated with the extract experienced a decrease in cellular growth." *See Ex. 12.*

36. The anti-aging effects of the Adore Products, according to Defendants, were then validated in a clinical trial (hereinafter the "Adore Clinical Trial") when "Adore Cosmetics researchers later observed the same protective effect when they applied a cream containing the extract to the crow's feet area of clinical trial volunteers. Four weeks later, wrinkle depth was reduced by as much as 15%.....Now Adore Cosmetics brings the anti-aging properties of this breakthrough to you in a luxurious line of skin care products." *See Ex. 13.*

37. According to Defendants, "A few simple steps will help you use Adore Cosmetics to put these plant stem cells to work to defend your skin against the effects of aging and sunlight. Adore Cosmetics products have a specially calibrated concentration of plant stem cell formula available, along with a rich blend of vitamins, essential oils, organic flower extracts and organic vegetable protein. By blending plant cell power with proven nutrients for the skin, the Adore Cosmetics skin care line restores healthy-looking skin by:"

- "Protecting your skin's own stem cells, the key to its regenerative ability"
- "Preventing UV stress and environmental damage"
- "Delaying skin aging processes"
- "Promoting vitality and longevity of skin stem cells."

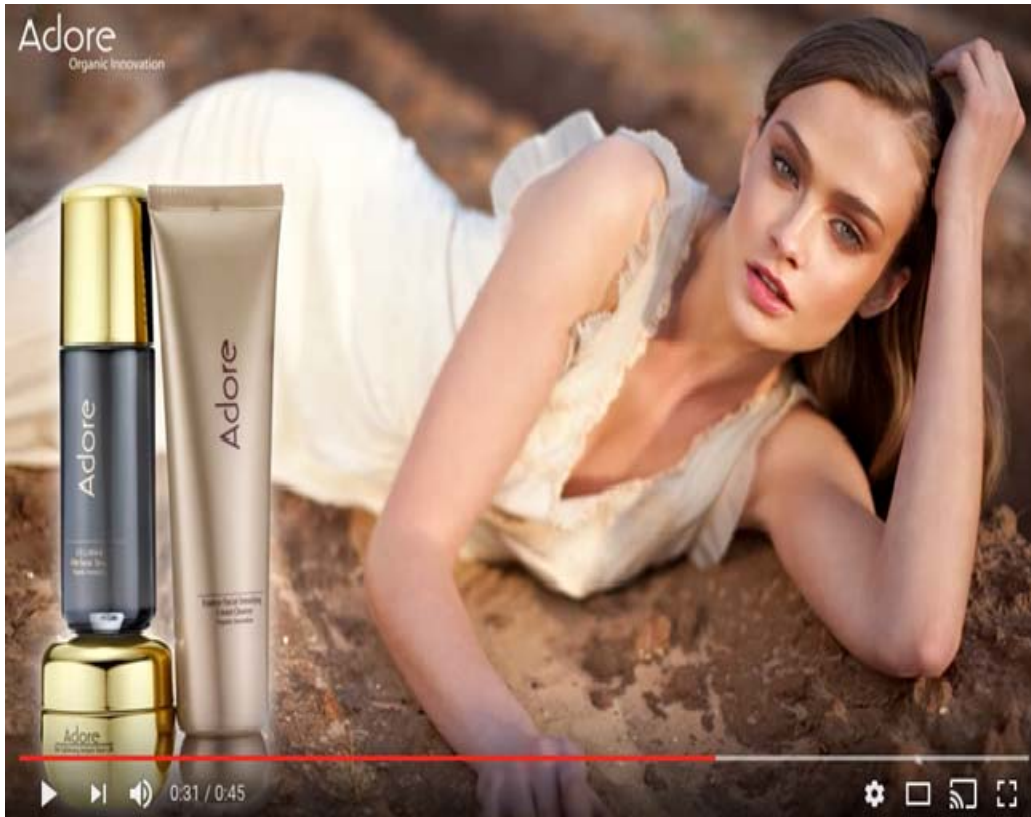
38. Finally, Defendants claim, "Adore Cosmetics represents the most advanced breakthrough in anti-aging found in the beauty industry today—and it's yours exclusively to adore."

39. Defendants also advertise and market the Adore Products on social media through YouTube videos, posts on Facebook, tweets on Twitter, and Pins on Pinterest. Defendants YouTube videos further tout the Adore products as being backed by scientific research.

Adore
Organic Innovation

ORGANIC PLANT
STEM CELLS





40. Defendants' social media pages also link to websites that further boast about the purported stem cell ingredients in the products. For example, "AdoreCosmeticsHowyouse.com" displays instructional videos to help Adore Cosmetics customers properly use the products so as to obtain maximum benefit. It also includes product overviews, video tours of Adore Cosmetics stores and reviews of products from beauty bloggers.

C. How the Plant Stem Cells in the Adore Products Work According to Defendants

41. In an effort to further promote the science behind the Adore Products, Defendants have published and distributed the "Adore Organic Innovation Science- Stem Cell Technology" Brochure (the "Adore Science Brochure"). This publication is available for download from Defendants' website and is attached hereto as Ex. 13.



42. According to the Adore Science Brochure, "Like humans, every plant has stem cells. But unlike humans, every plant cell has the potential to turn back into a stem cell and grow into an entirely new plant. If a plant is wounded, it forms what's known as callus tissue, in which normal cells become stem cells, which act to heal the wound. This is common in plants but not possible in humans. Researchers have long been interested in plants' ability to heal themselves via callus tissue, and even more so, certain plants' remarkable abilities to stay fresh long after being harvested and to protect themselves from prolonged exposure to UV rays that are harmful to living tissue. The question was, could these potent plant stem cells be used to protect human skin stem cells? The answer is yes." *See Ex. 13.*

43. Defendants reach this definitive "yes" answer because "Researchers discovered that plant stem cells contain epigenetic factors similar to those of adult human stem cells. Applied in the right way, plant stem cells have a positive impact on the vitality of skin stem cells and their proper functioning. *By growing callus cells in selected plant tissue under special conditions*, researchers have created a new biotechnology that generates plant stem cells that safely help protect human skin stem cells from chronological aging, UV stress and other environmental damage. We call this new biotechnology Plant Stem Cell formula." *See Ex. 13 (emphasis added).*

44. Furthermore, according to Defendants, "The development of a new test method, called 'progenitor cell targeting,' made it possible to isolate stem cells, which look the same as other skin cells, from the human epidermis for test purposes. *Using this method, these epidermal stem cells are grown in Petri dishes.* During this process, each healthy stem cell divides, forming a colony of cells, which is visible to the naked eye and can be counted. Stem cells that have aged and are weakened do not die, but they no longer form colonies. Researchers were thus able to prove that using plant stem cells increases the longevity and the vitality of human skin stem cells. Extensive studies have shown that Plant Stem Cell formula increases the vitality and efficiency of all essential skin cells and improves skin's resistance." *Ex. 13 (emphasis added).*

45. The Adore Science Brochure also notes that stem cells within the Adore Products are a propriety blend of plant stem cells called "PhytoCellTec™" that is manufactured by the Mibelle Biochemistry Group of Switzerland. *See Ex. 13.*

D. The Adore Products Contain the Mibelle PhytoCellTec™ Patented Active Ingredient

46. According to the Mibelle Website, "Mibelle Biochemistry Switzerland designs and develops unique, high-quality actives for the beauty industry which are based on naturally derived compounds and extensive scientific expertise."

47. Among its "unique, high-quality actives for the beauty industry" is the "PhytoCellTec™ *Malus Domestica* active ingredient that is contained in the Adore Products.

48. Mibelle claims that "PhytoCellTec *Malus Domestica* is a patented liposomal preparation of apple stem cells derived from the 'Uttwiler Spätlauber', a rare Swiss apple variety. These apple stem cells are rich in epigenetic factors and metabolites, which ensures the longevity of skin cells. PhytoCellTec™ *Malus Domestica* has been shown to protect skin stem cells while also delaying the senescence of hair follicles. PhytoCellTec™ *Malus Domestica* succeeds in delivering a revolutionary anti-aging performance for real rejuvenation." *See* Ex. 2.

49. Moreover, "PhytoCellTec™ *Malus Domestica* was the first ingredient based on plant stem cells on the cosmetic market. The topical use of PhytoCellTec™ *Malus Domestica* is patented in the USA (US 9,155,916 B2 / US 8,580,320 B2) and in Korea (10-1470632)."

E. Affirmative Evidence Shows that Defendants' Advertising of the Adore Products is Provably False and Likely to Mislead Reasonable Consumers

1. A Mibelle Researcher Admits that the Efficacy of PhytoCellTec Plant Stem Cells "Could Not be Confirmed in a Clinical Trial."

50. An article in The Daily Mail titled "Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?" featured an interview with "Dr. Daniel Schmid, research director of Mibelle Biochemistry, the Swiss lab which developed PhytoCellTec *Malus Domestica*." He "insists that his study shows his apple stem cell extracts have been 'shown to improve the maintenance of the stem cells characteristics of epidermal stem cells.'" However, "he admits: '*The*

anti-ageing benefit for the skin after topical application could not be confirmed in a clinical trial."

See Ex. 3.

51. Therefore, Defendants' claims that the Adore Products are "Proven" to provide anti-aging benefits are literally false- as was admitted by the research director at the company that manufactures the Plant Stem Cell ingredient in the Adore Products.

2. Leading Scientists Agree that Plant Stem Cells Like in the Adore Products cannot Provide Anti-Aging Benefits

52. As noted by S. Jay Olshansky, a distinguished professor at the University of Illinois-Chicago's School of Public Health who has written extensively about aging, "If someone is promising you today that you can slow, stop or reverse aging, they're likely trying hard to separate you from your money." See David Carey, Boomers will be Spending Billions to Counter Aging, USA Today (Aug. 22, 2011), attached hereto as Ex.14.

53. Professor Liam Dolan, the "Sheradian Professor of Botany at Oxford University, who specialises in studying plant cells," reviewed the advertising claims for the PhytoCellTec ingredient and concluded, "I don't see how plant stem cells could interact with human stem cells in this way." See Ex. 3.

54. Paolo U. Giacomoni, who was formerly the executive director of research at Estee Lauder, and who received a Laurea in Atomic Physics from the University of Milan and a Ph.D. in Biochemistry from the University of Paris, is critical of the role of stem cells in cosmetics. "Stem cell technology is still far from biomedical applications, let alone cosmetic ones," states Giacomoni. See Healing Beauty: More biotechnology cosmetic products that claim drug-like properties reach the market, EMBO Reports (Nov. 2008), attached hereto as Ex. 15.

55. “Stem cells that are in contact with skin are not really alive anymore,” said Margaret Foster Riley, a law professor and expert on food and drug law at the University of Virginia. “So I don’t really see how a stem cell product is working on the skin. I suppose some of them may actually work in a way that cosmetics work otherwise, because of moisturizing capability. But it’s not stem cell capability that’s working there to the degree we know how stem cells work.” See Stem cell lotions: Cutting edge or pure hype? USA Today (Sept. 1, 2015), attached hereto as Ex. 16.

56. “Potions and lotions may in fact work really well, but at the end of the day, let’s be data-driven, so the consumer doesn’t have to worry about whether they think it might work,” said Stanford professor Michael Longaker, an expert in plastic surgery and regenerative medicine.” See Ex. 14.

57. A spokesperson for yet another Plant Stem Cell cosmetics company has "conceded that if you 'put an actual human stem cell on the skin, it wouldn't do anything.'" See Ex. 16.

58. In an article that appeared in *Dermatology Today* titled *Short On Evidence*, Dr. Patricia Farris, M.D., a board-certified dermatologist and dermatologic surgeon in Metairie, La. stated, "We don't have proof in human skin yet that when these skincare products are applied to the skin that they can really boost stem cell activity, and, more importantly, make the skin look younger," Dr. Farris says “Most of the research on stem cell products has been done in vitro and needs to be translated to the clinical setting with human subjects.” See Ex. 17.

59. In an article titled *Direct-to-Consumer Stem Cell Marketing*, Professor of Biology, Dr. Douglas Sipp has stated, “Charlatans are drawn to frontiers. The scientific frontier of stem cell biology has attracted an unusual amount of dubious business activity, despite the paucity of credible

evidence for the efficacy of these cells in the treatment of indications for which they are marketed.”

Ex. 18.

60. Sam Most, a facial reconstructive surgeon at Stanford School of Medicine, says "stem-cell-related cosmetic marketing is following the time-tested tactic of climbing aboard the bandwagon of hot topics, from collagen to FDA-approved Botox injections... They don't just sit there on the shelf and last," he says. "To do any good, the ingredients would have to remain stable for weeks or months at room temperature, get past the epidermal layer, go into the right cells, and exert the proper stimulation once reaching their destination." See Bryan Nelson, A Superficial Success, NATURE REPORTS STEM CELLS (Jan.15, 2009), attached hereto as Ex. 19.

61. The totality of evidence shows that the Plant Stems Cells in cosmeceutical products are not effective at providing anti-aging benefits and thus the Adore Products are likely to mislead reasonable consumers.

3. Defendants' Claims are Patently False Because There Are No Living Plant Stem Cells in the Adore Products

62. The Adore Science Manual describes an in vitro test using live Plant Stem Cells in a "new test method, called 'progenitor cell targeting,' [that] made it possible to isolate stem cells, which look the same as other skin cells, from the human epidermis for test purposes. Using this method, these epidermal stem cells are grown in Petri dishes. During this process, each healthy stem cell divides, forming a colony of cells, which is visible to the naked eye and can be counted. Stem cells that have aged and are weakened do not die, but they no longer form colonies. Researchers were thus able to prove that using plant stem cells increases the longevity and the vitality of human skin stem cells." See Ex. 13.

63. Even assuming the above method is credible (it is not), it still fails to account for the fact that no actual Living Plant Stem Cells are in the Adore Products. Defendants' statements are not only likely to mislead reasonable consumers, but rather Defendants' advertising statements are also patently false.

64. The Mibelle patent for the PhytoCellTec Ingredient describes the production process of the PhytoCellTec ingredient and states that "In order to obtain an extract containing the Whole essence of the cultivated cells, the cells are solubilized by means of liposomes. The main component of this method is the use of high pressure homogenization of the Whole cell broth together With a liposome preparation. The great advantage of this method is its simple and low-cost application." See Ex. 4.

65. In a liposomal preparation intact cells no longer exist. Cells are disrupted by "homogenization" (application of mechanical force, such as a rotary blender, to a suspension) in the presence of various ingredients used by Mibelle, particularly lecithin, which breaks up cell membranes into small globular fragments called liposomes. Liposomes are much smaller than the extracted cells and are comprised of fragments of the cell membrane folded around microscopic cavities that contain molecules of cellular origin. Liposomes made from apple callus cultures thus may contain compounds derived from apple stem cells, as well as the chemicals used in their preparation. PhytoCellTec™ Malus Domestica does not, however, contain actual stem cells, as falsely claimed in the ingredient lists of the Adore Products.

66. The patent notes that "Suitable high pressure homogenizers are commercially available on the market" and specifically notes that destruction of the cell membranes occurs. See Ex. 4.

67. Next, "All preservative agents of natural or synthetic origin allowed for cosmetics, such as e.g. phenoxyethanol, benzoic acid, propionic acid, alcohol or silver chloride, can be used as preservative agents." However, "In order to additionally protect the extract from oxidation, antioxidants, such as e.g. ascorbic acid or tocopherol, may be added." See Ex. 4.

68. Moreover, "the described method allows the addition of still further substances useful in the preparation or cosmetic product. Once all compounds are added, the mixture has to be stirred in order to dissolve the preservative agents and other components. This may be done e.g. by means of a paddle mixer, a homogenization rod or by pumping through static mixing elements." See Ex. 4.

69. Thus, the resulting PhytoCellTec mixture does not resemble Living Plant Stem Cells whatsoever. Defendants' representations that the Adore Products somehow contain "Plant Stem Cells" that can interact with human stem cells to provide anti-aging benefits is patently false.

F. Defendants have Copied the Advertising Ideas and Style of Advertisements of the Premium J'ADORE Product Line by Christian Diore

70. Defendants' Adore products are likely to mislead reasonable consumers that the products are connected to or affiliated with the J'Adore product line by Christian Diore.

71. Dior first introduced a fragrance product under the mark J'ADORE in 1999. Today, the J'ADORE line includes not only perfume products in the form of eau de parfum, eau de toilette and voile de parfum, but also skin care products in the form of soap, shower gel, body milk and body crème.

72. Dior markets and sells its fragrance and skin care products under the J'ADORE brands throughout the United States, including through Dior boutiques and the DIOR website (<http://www.dior.com>), through third-party department stores such as Macy's and Bloomingdale's, and through specialty beauty retailers such as Sephora.

73. As a result of Dior's extensive advertising and sale of goods under the J'ADORE Marks, the marks, when used in connection with fragrance and skin care products, have become exclusively associated with Dior, and consumers recognize fragrance and skin care products bearing the J'ADORE Marks as coming from Dior.

74. Defendants are targeting the very consumers who are familiar with and who are customers of Dior's products offered under the J'ADORE brands.

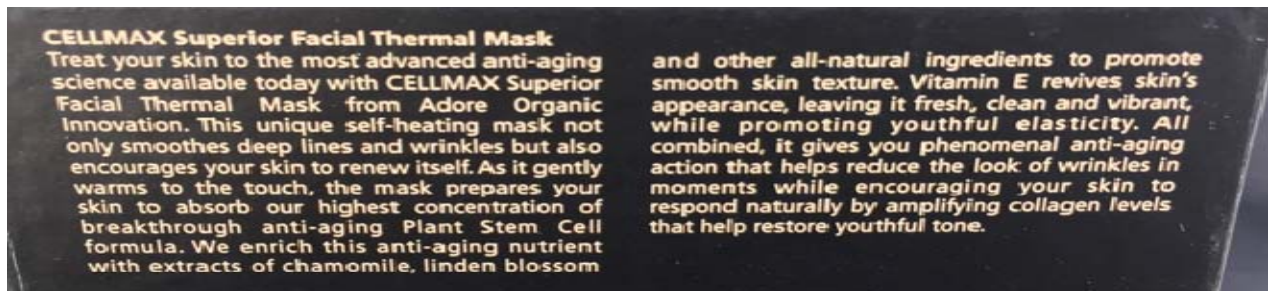
75. Defendants have copied the advertising ideas and style of advertisements of the premium J'ADORE Products to the detriment of Plaintiff and the class members.

76. Defendants' use of the Adore brand is likely to mislead reasonable consumers, who mistakenly assume that Defendants and the products offered under the Adore brand are associated with or sponsored or approved by Dior. Defendants' use of the Adore brand and trademarks is likely to continue to cause confusion, as reasonable consumers will assume that Defendants' goods are authorized by, endorsed by, associated with, or are otherwise connected with Dior or its J'ADORE products.

77. Because Defendants have no affiliation with Dior, their use of the Adore brand in connection with skin care products and related goods and services is likely to cause confusion, cause mistake, or deceive consumers as to the source, sponsorship or approval of Defendants' goods and services and, specifically, to cause consumers to believe that Defendants' goods and services are sponsored by, affiliated with, approved by or otherwise connected with Dior when such is not the case.

G. Specific Misrepresentations and Warranties on the Product Packaging

78. For purposes of this section, each statement that appears in quotation marks (“”) below create affirmative representations about the Products and also create express and implied warranties that were relied on by Plaintiff and the Class members in deciding to purchase the products. The quoted statements are hereinafter referred to as the "Representations and Warranties. The Adore CELLMAX Superior Facial Thermal Mask



79. The label of the CELLMAX Superior Facial Thermal Mask states the following:

"Treat your skin to the most advanced anti-aging science available today with CELLMAX Superior Facial Thermal Mask from Adore Organic Innovation. This unique self-heating mask not only smoothes deep lines and wrinkles but also encourages your skin to renew itself. As it gently warms to the touch, the mask prepares your skin to absorb our highest concentration of breakthrough anti-aging Plant Stem Cell formula. We enrich this anti-aging nutrient with extracts of chamomile, linden blossom and other all-natural ingredients to promote smooth skin texture. Vitamin E revives skin's appearance, leaving it fresh, clean and vibrant, while promoting youthful elasticity. All combined, it gives you phenomenal anti-aging action that helps reduce the look of wrinkles in moments while encouraging your skin to respond naturally by amplifying collagen levels that help restore youthful tone."

80. Defendants website also makes the exact same Representations and Warranties about the CELLMAX Superior Facial Thermal Mask as described in the preceding paragraph.

The Adore CELLMAX Redefining Facial Cream



81. The label for the CELLMAX redefining Facial Cream states the following:

"Formulated with revolutionary CELLMAX, featuring the highest concentration of our exclusive Plant Stem Cell formula, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin's own stem cells and encouraging

them to regenerate healthy texture. To amplify its age-defying properties, we infuse it with extracts of chamomile, linden blossom and other all-natural flora to regenerate tone and promote smoother appearance. Meanwhile, Allantoin deeply hydrates by binding moisture to dry skin. This phenomenal anti-aging cream helps erase the look of deep wrinkles and restore youthful texture, leaving skin fresher, harmonized and renewed. You'll see results with every application."

82. Defendants' website also makes the same Representations and Warranties that are quoted in the preceding paragraph concerning the CELLMAX Redefining Facial Cream.

The Adore CELLMAX Elite Facial Serum



83. The label for the CELLMAX Elite Facial Serum states the following:

"With the passage of time, skin cells suffer damage from aging and environmental elements. This extraordinary facial serum from Adore Organic Innovation helps halt and reverse the aging process using CELLMAX, a breakthrough combination of age-defying active ingredients. It features the highest concentration of our exclusive Plant Stem Cell formula, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin's own stem cells

and encouraging them to regenerate healthy texture. Its anti-aging action is increased with a special complex of Vitamin C, which regenerates the skin's appearance cell by cell, promoting production of collagen for skin firmness and elasticity. This is suspended in a formulation of jojoba seed oil, which makes it readily absorbed to minimize fine lines and wrinkles. Vitamin E revitalizes each layer of your skin, preventing damage and protecting skin from future harm, while Bisabolol soothes the skin and prevents irritation. With each application, this innovative serum promotes skin suppleness and works to restore what time and the elements take away"

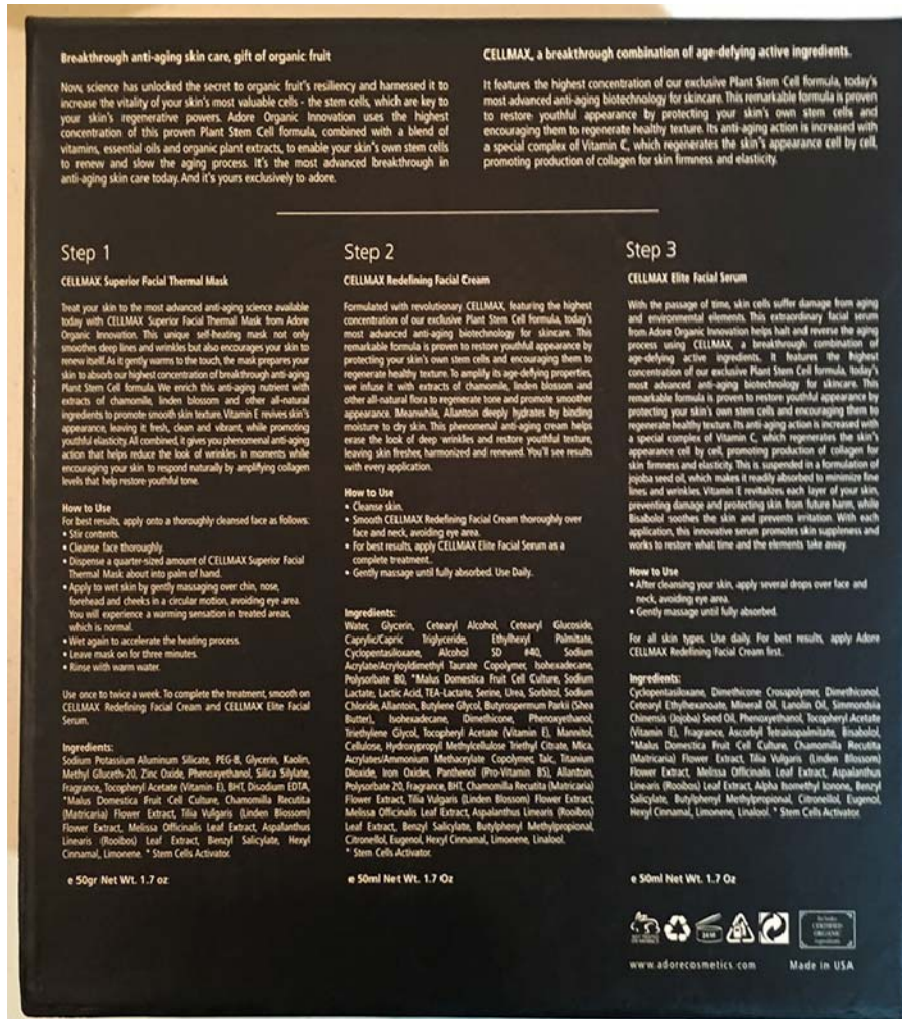
84. Defendants' website also makes the same Representations and Warranties that are quoted in the preceding paragraph concerning the CELLMAX Elite Facial Serum.

The CELLMAX Kit

85. Defendants also sell the CELLMAX Thermal Mask, Cream, and Serum in a single kit.



86. The label of the CELLMAX kit similarly makes the same Representations and Warranties that are described on the packaging for the individual CELLMAX Products.



87. Plaintiff read and relied on the above-quoted Representations and Warranties in deciding to purchase the CELLMAX Kit.

H. The "Substantially Similar" Adore Organic Innovation Stem Cell Products

88. Defendants also manufacture, market, and distribute several other products under the Adore Organic Innovation product line that also contain plant stem cells and that make substantially similar Representations and Warranties regarding the efficacy of the plant stem cells.

89. Plaintiff alleges that the following products are "substantially similar" to the

CELLMAX Products:

	Product	Substantially Similar Representations and Warranties	List Price
1	Essence Facial Detoxifying Cleansing Cream	"The key is our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to renew skin texture."	\$99.95
2	Essence Facial Toner	"It starts with our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$109.95
3	Essence Facial Milk	"The secret is our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$109.95
4	Essence Facial Cleanser	"Formulated with Adore Organic Innovation's exclusive plant stem cell formula – featuring Malus Domestica, fruit cell culture (stem cells) that are proven to protect and restore your skins own stem cells."	\$89.95
5	Snow White Facial Brightening Cream	"It begins with Adore Organic Innovation's exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$495.95
6	Dreams Multi Active Night Cream	"It starts with our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$495.95
7	Performer Sculpting Neck Serum	"The key is our exclusive Plant Stem Cell formula, which protects your skin's own stem cells and encourages them to renew texture."	\$495.95

	Product	Substantially Similar Representations and Warranties	List Price
8	Essence Facial Serum	“The key is our exclusive Plant Stem Cell formula, which protects your skin’s own stem cells and encourages them to renew texture. We amplify this breakthrough anti-aging nutrient’s action with a special compound of Palmitoyl Tetrapeptide, which regenerates the skin’s appearance, cell by cell.”	\$749.95
9	Essence Facial Hydrating Cream - normal to oily skin	“It includes our exclusive Plant Stem Cell formula, proven to protect your skin’s own stem cells and encouraging them to renew texture.”	\$199.95
10	Essence Facial Hydrating Cream - normal to dry skin	“It includes our exclusive Plant Stem Cell formula, proven to protect your skin’s own stem cells and encouraging them to renew texture.”	\$199.00
11	Advanced Firming Eye Cream	“...starts with our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin’s own stem cells and encouraging them to regenerate healthy texture.”	\$589.95
12	Advanced Firming Eye Serum	“...starts with our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin’s own stem cells and encouraging them to regenerate healthy texture.”	\$595.95
13	Skin Tightening Instant Face Lift	“By harnessing the power of these plant stem cells, we bring anti-aging effects to your own skin cells, increasing your skin’s regenerative powers.” “Within seconds of applying, fine lines and wrinkles disappear, courtesy of the innovative Plant Stem Cell Formula containing organic fruit stem cells . . .”	\$1,195.00
14	Golden Touch Magnetic Facial Mask	“This pure element triggers profound receptivity in skin cells to the renewing power of our exclusive Plant Stem Cell technology, known to restore youthful appearance by protecting your skin’s own stem cells and stimulating regeneration of luminous texture.”	\$995.00

	Product	Substantially Similar Representations and Warranties	List Price
15	Essence Facial Collagen Mask	“Proven to restore youthful appearance, advanced plant stem cells protect your skin’s own stem cells and encouraging them to regenerate healthy texture.”	\$699.95
16	Golden Touch 24k Techno-Dermis Facial Mask	“This pure element triggers profound receptivity in skin cells to the renewing power of our exclusive Plant Stem Cell technology, known to restore youthful appearance by protecting your skin's own stem cells and stimulating regeneration of luminous texture.”	\$3,300.00
17	Nourishing Hand and Body Lotion - Original	“. . . with Adore Organic Innovation’s organic Plant Stem Cell formula, proven to turn back time by protecting your skin’s own stem cells and encouraging them to restore youthful texture.”	\$34.95
18	Nourishing Hand and Body Lotion - Blossom	“. . . Adore Organic Innovation’s organic Plant Stem Cell formula, proven to turn back time by protecting your skin’s own stem cells and encouraging them to restore youthful texture.”	\$34.95
19	Nature - Intensive Body Butter	“It contains Adore Organic Innovation’s exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin’s own stem cells and encouraging them to regenerate healthy texture.”	\$89.95
20	Spirit – Calming Body Butter	“It starts with Adore Organic Innovation’s exclusive Plant Stem Cell formula, a powerful concentration proven to revitalize your skin by encouraging its own stem cells to activate new growth.”	\$89.95
21	Spirit - Calming Body Peeling Scrub	“The key is Adore Organic Innovation's exclusive Plant Stem Cell formula, designed to protect and restore your skin's own stem cells . . .”	\$79.95
22	Nature - Intensive Body Peeling Scrub	“The key is Adore Organic Innovation’s exclusive Plant Stem Cell formula, designed to protect and restore your skin’s own stem cells . . .”	\$79.95

90. Each of these products are substantially similar in that they contain, on information and belief, PhytoCellTec ingredient manufactured by Mibelle Biochemistry of Switzerland. As set forth above herein, these products are liposomal preparations derived from apple or grape callus cells and therefore do not contain any plant stem cells even if callus cells are present at the beginning of Mibelle's manufacturing process.

PLAINTIFF'S EXPERIENCE WITH THE ADORE PRODUCTS

91. Plaintiff Millie Land is a resident of Minneola, Florida who purchased the Adore Essence Facial Hydrating Cream and other Adore anti-aging products in or around the summer of 2015 from an Adore Organic Innovations retail store located at The Galleria at Fort Lauderdale shopping mall in Fort Lauderdale, Florida.

92. Plaintiff paid approximately \$550 total for her purchases of the Adore Products. Plaintiff Land would not have purchased the products at all, or would have paid less for the products, had she known the truth about the Adore products.

93. Plaintiff Land did not discover the truth about the Defendants' false and misleading advertising scheme described herein until around the time that Plaintiff sent a pre-suit notice letter to Defendants. Plaintiff and the Proposed Class Members are laypersons, lacked the knowledge and experience to understand how the Products' labels were deceptive or false, and information regarding the false or deceptive advertising was solely within Defendants' possession and control. Thus, the delayed discovery exception postpones accrual of the limitations period for all members of the putative class.

94. Defendants were constructively and actually aware that the Products were ineffective for their advertised use. Nevertheless, Defendants continued to sell the Adore Products. Therefore, at

all relevant times, Defendants had a duty to inform consumers that the Products were not effective at providing the advertised anti-aging benefits, but Defendants knowingly concealed that fact from members of the putative classes herein. Accordingly, the fraudulent concealment exception tolls the statute of limitations on all claims herein.

95. Additionally, or in the alternative, because Defendants' misrepresentations and deception continues up to the present, the continuing violation exception tolls all applicable statutes of limitations for all members of the putative classes until Defendants' unlawful advertising and labeling is corrected.

DEFENDANTS ARE JOINTLY LIABLE

96. **Agency Allegations:** At all times mentioned in this Complaint, Defendant Sagev was an agent of Defendant Universal Handicraft, Inc. and in doing the acts alleged herein, was acting within the course and scope of such agency. Defendant Universal Handicraft, Inc. had actual and/or constructive knowledge of the acts of Defendant Segev, and ratified, approved, joined in, acquiesced and/or authorized the wrongful acts, and/or retained the benefits of said wrongful acts.

97. **Aiding and Abetting:** At all times mentioned in this complaint, each Defendant knew that each and every other Defendant was engaged in the unlawful acts subject to this complaint. Each Defendant gave substantial assistance or encouragement to the other Defendant who committed the predicate unlawful acts by supplying that Defendant with the means or instrumentalities to commit the unlawful acts, which were substantial factors in causing harm to Plaintiff and the Classes.

98. **Alter Ego Liability:** Defendant Segev established Universal Handicraft, Inc. and the Adore Product Line for an illegal purpose: to perpetrate fraud. Defendant Segev utilizes Universal

Handicraft as a vehicle to commit misleading marketing practices as a means of promoting misbranded stem cell products that do not perform as advertised.

99. Defendant Segev is liable for the conduct of Universal Handicraft, Inc. because Defendant Segev abused its organizational form as corporation to accomplish fraudulent objects, namely, to fraudulently promote the sale of Adore Products, to conceal the proceeds of those frauds, and to frustrate the ability of victims to obtain redress for the fraud.

100. Defendant Segev totally dominates and controls Universal Handicraft, Inc. to such an extent that the independence of UHI is a sham. Defendant Segev founded UHI and it is essentially wholly-owned by Defendant Segev, who also completely dominates the management and control of Defendant UHI as its president.

101. Defendant UHI was incorporated in January of 2001 and is doing business as both “Deep Sea Cosmetics” and “Adore Organics Innovation.” “Shay Sabag” was the incorporator of UHI. “Shay Sabag” listed UHI’s initial principal place of business as “1901 Lee Street, Apartment 4, Hollywood, Florida 33020.”

102. There were only two initial members of the UHI board of directors, “Shay Sabag” and one Marcela Jimenez.

103. “Shay Sabag” was the initial Registered Agent for Service of Process for UHI. See RJN at Ex. 8. The only known Articles of Incorporation for UHI provide that the company is only authorized to issue 100 shares of stock at zero par value at any one time.

104. Plaintiff alleges that Defendant Segev or members of his family have at all times been the sole shareholders of UHI. Defendant Segev has complete domination and control over UHI.

105. UHI's Annual Report for the year 2002 shows that "Shay Sabag" changed the UHI principal office to an address located in Davie, Florida.

106. UHI appears to have been undercapitalized from the get-go. In fact, a written statement by Defendant "Shay Sabag" is attached to an "Application for Reinstatement" showing that Defendant requested a waiver of late fees and penalties for his alleged failure to comply with corporate formalities.

107. In 2005, "Shay Sabag" again moved the principal office of UHI to an address located in Margate, Florida. The Annual Report for the year 2005 shows that Ms. Marcella was no longer listed as a director of the corporation. Thus, "Shay Sabag" effectively became the only member of UHI's board of directors.

108. "Shay Sabag" was also the only corporate officer listed for UHI and UHI's only Registered Agent for Service of Process.

109. In 2006, "Shay Sabag" yet again moved the UHI principal office to an address located in Hollywood, Florida.

110. Then, in 2007, "Shay Sabag" decided to move the UHI principal office to 1005 Park Centre, Blvd., Miami Florida, 33169.

111. In 2010, the UHI board of directors (consisting only of "Shay Sabag") voted to add one additional member to its board—Ms. Natalie Cohen.

112. Defendant Segev has Ms. Cohen have attempted to conceal their identities as the owners of UHI. In 2013, as an alternative to changing the address of UHI, "Shay Sabag" instead changed his own name to "Shay Segev."

113. Ms. Natalie Cohen also left her position as a member of the board of directors in 2013, again leaving Defendant “Shay Segev” as the lone member of the board of directors.

114. In 2014, the UHI Board of Directors (consisting only of Shay Segev) again voted to add a second member—Ms. Tziyona Cohen.

115. Plaintiff alleges that Ms. Tziyona Cohen is the same individual as Ms. Natalie Cohen.

116. In 2016, Defendant Segev again moved UHI’s principal office to its current address that is located at 1400 Alton Road, Suite No. 201, Miami Beach, FL 33139 (the “Alton Road Address”).

117. UHI is not the only company owned by Segev that is located at the Alton Road Address though. Filings with the Florida Division of Corporations show that Defendant Segev is the President of “South Beach 18, LLC.”

118. One managing member of "South Beach 18, LLC" is “Cohen Properties, LLC.” See RJN at Ex. 3. Ms. Tziyona Cohen—the only board member of UHI aside from Segev— is also the managing member of “Cohen Properties, LLC.”

119. The Alton Road Address is also the headquarters of “Alton 14 LLC.”

120. Defendant Segev is a managing member of “Alton 14, LLC.”

121. An entity called “S&L 1003, LLC” is located at the Alton Road Address and Defendant Segev is one of the managing members of “S&L 1003, LLC.”

122. An entity called “Miami 790, LLC” is also located at the Alton Road Address; Segev serves that the President of that company as well.

123. Plaintiff alleges that Defendant Segev fails to segregate the property and funds of the entities at located at the Alton Road address and that there is an ongoing intermingling of assets.

124. Defendant Segev also sells cosmetics products under the trade name “Kristals Cosmetics,” which has opened a store in La Jolla, California.

125. It is believed that Defendant Segev operates stores throughout California—including Santa Barbara for example.

126. Defendant Segev has operated Universal Handicraft, Inc. in a manner that there is such a unity of interest and ownership between Defendant Segev and Universal Handicraft, Inc. that any sense of independence is non-existent. In fact, Defendant Segev exercises total operational control and decision-making power over all business activities at Universal Handicraft, including but not limited to product origination and development; product marketing, sales, and promotion; accounting and finance; product distribution; public and media relations; business development and strategy; vendor and third-party relationship; and contract negotiations. Defendant Segev actively manages and oversees all business operations of Universal Handicraft, Inc. and retains final decision-making power.

127. **Corporate Officer Liability:** In the Ninth Circuit, “[a] corporate officer or director is, in general, personally liable for all torts which he authorizes or directs or in which he participates, notwithstanding that he acted as an agent of the corporation and not on his own behalf.” *Transgo, Inc. v. Ajac Transmission Parts Corp.*, 768 F.2d 1001, 1021 (9th Cir. 1985) (internal quotations omitted); *see also United States v. Reis*, 366 Fed.Appx. 781, 782 (9th Cir. 2010) (citing Restatement (Third) of Agency § 7.01 (2006)); *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 734 (9th Cir. 1999) (holding that a corporate officer or director “cannot hide behind the corporation where he is an actual participant in the tort”) (internal quotations omitted)).

128. Defendant Segev actually participated in the conduct alleged in this complaint and Plaintiff alleges that Defendant Segev is personally liable for all unlawful acts described herein because he authorized, directed, or participated in such acts notwithstanding the fact that he acted as an agent of the corporation. For example, Sagev was quoted making the following Representations and Warranties about the Adore Products: "Stem Cells Prevent Aging," "Scientists have found that the stem cells of apples are similar to the stem cells in human beings," "through the use of biotechnology, science is able to utilize these fruit stem cells using them in cosmetics so they are able to penetrate the skin." See Emily Lambert, *Adore Organic: Lifting the Face*, Specialty Retail Report (Fall 2013), *attached hereto as Ex. 20*.

CLASS ACTION ALLEGATIONS

129. Plaintiff seeks to certify the following class:

The Florida Class

All persons who purchased the Adore CELLMAX Products and Substantially Similar Products within Florida for personal and household use and not for resale from the time the products entered into the stream of commerce until the date class notice is disseminated. Excluded from the Class are Defendants' officers, directors and employees.

The Direct-to-Consumer Class

All persons who purchased the Adore CELLMAX Products and Substantially Similar Products within Florida for personal and household use and not for resale from the time the products entered into the stream of commerce until the date class notice is disseminated. Excluded from the Class are Defendants' officers, directors and employees.

130. The Classes comprise of many thousands of consumers throughout the nation. The Class is so numerous that joinder of all members of the Class is impracticable. There are questions of law and fact common to the Class. The common questions include:

- (a) whether Defendants' alleged conduct violates public policy;
- (b) whether the alleged conduct constitutes violations of the laws asserted herein;
- (c) whether Defendants engaged in false or misleading advertising;
- (d) whether plaintiff and Class members have sustained monetary loss and the proper measure of that loss;
- (e) whether plaintiff and Class members are entitled to an award of punitive damages; and
- (f) whether plaintiff and Class members are entitled to declaratory and injunctive relief.

131. Plaintiff's claims are typical of the claims of the proposed Class, and plaintiff will fairly and adequately represent and protect the interests of the proposed Class. Plaintiff does not have any interests antagonistic to those of the Class. Plaintiff has retained counsel competent and experienced in the prosecution of this type of litigation. The questions of law and fact common to the Class members, some of which are set out above, predominate over any questions affecting only individual Class members.

132. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The expense and burden of individual litigation would make it impracticable or impossible for proposed Class members to prosecute their claims individually. The trial and the litigation of plaintiff's claims are manageable.

133. Unless a class is certified, Defendants will retain monies received as a result of its conduct that was taken from plaintiff and proposed Class members. Unless a class-wide injunction is issued, Defendants will continue to commit the violations alleged, and the members of the Class and the general public will continue to be misled.

134. Defendants have acted and refused to act on grounds generally applicable to the Class, making appropriate final injunctive relief with respect to the Class as a whole.

COUNT I

Breach of Express Warranty On Behalf of Plaintiff and the Class

135. Plaintiff realleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.

136. Plaintiff, and each member of the Class, formed a contract with Defendant at the time Plaintiff and the other members of the Class purchased Adore Products. The terms of that contract include the promises and affirmations of fact made by Defendants on its product labels and through its marketing campaign, as described above. This product labeling and advertising constitutes express warranties, became part of the basis of the bargain, and is part of a standardized contract between Plaintiff and the members of the Class on the one hand, and Defendants on the other.

137. All conditions precedent to Defendants' liability under this contract, including notice, have been performed by Plaintiff and the Class.

138. Defendants breached the terms of this contract, including the express warranties, with Plaintiff and the Class by not providing the product which could provide the promised benefits as described above.

139. As a result of Defendants' breach of its contract and warranties, Plaintiff and the Class have been damaged in the amount of the purchase price of Adore Products at issue.

COUNT II

Unjust Enrichment On Behalf of Plaintiffs and the Class

140. Plaintiffs reallege and incorporates by reference the allegations contained in paragraphs above as though fully set forth herein.

141. As a result of the unlawful conduct described herein, Defendant has been unjustly enriched at the expense of Plaintiffs and the other members of the Class.

142. Specifically, Defendant's unfair and unlawful actions, as described herein, have enabled Defendants to receive money and other benefits in violation of the law at the expense of Plaintiffs and the other members of the Class.

143. Defendant's receipt and retention of this financial benefit is unfair and improper under the circumstances.

144. As such, Defendant should be required to disgorge the money retained as a result of its unjust enrichment.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for a judgment:

- A. Certifying the Class as requested herein;
- B. Awarding Plaintiff and the proposed Class members' damages;
- C. Awarding restitution and disgorgement of Defendants' revenues to Plaintiff and the proposed Class members;

D. Awarding declaratory and injunctive relief as permitted by law or equity, including enjoining Defendant from continuing the unlawful practices as set forth herein, and directing Defendant to identify, with Court supervision, victims of its conduct and pay them restitution and disgorgement of all monies acquired by Defendant by means of any act or practice declared by this Court to be wrongful;

E. Awarding Plaintiff and the Class punitive damages;

F. Ordering Defendants to engage in a corrective advertising campaign;

G. Awarding attorneys' fees and costs; and

H. Providing such further relief as may be just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: May 25, 2017,

CULLIN O'BRIEN LAW, P.A.
6541 NE 21st Way
Ft. Lauderdale, FL 33308
Telephone: (561) 676-6370
Fax: (561) 320-0285

/s/ Cullin O'Brien
CULLIN O'BRIEN
Florida Bar No. 0597341
cullin@cullinobrienlaw.com

**LAW OFFICES OF RONALD
A. MARRON, APLC**
RONALD A. MARRON
ron@consumersadvocates.com
MICHAEL HOUCHIN
mike@consumersadvocates.com
651 Arroyo Drive
San Diego, CA 92103
Telephone: (619) 696-9006
Facsimile: (619) 564-6665

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.) NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.

I. (a) PLAINTIFFS Millie Land

DEFENDANTS UNIVERSAL HANDICRAFT, INC., d/b/a "Deep Sea Cosmetics" d/b/a "Adore Organic Innovations," and SHAY SABAG SEGEV,

(b) County of Residence of First Listed Plaintiff Lake County (EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) Attorneys (Firm Name, Address, and Telephone Number) Cullin O'Brien CULLIN O'BRIEN LAW, P.A. 6541 NE 21st Way, Ft. Lauderdale, FL 33308, (561) 676-6370

Attorneys (If Known)

(d) Check County Where Action Arose: MIAMI-DADE MONROE BROWARD PALM BEACH MARTIN ST. LUCIE INDIAN RIVER OKEECHOBEE HIGHLANDS

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff
3 Federal Question (U.S. Government Not a Party)
2 U.S. Government Defendant
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and incorporation status. Includes categories like Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation.

IV. NATURE OF SUIT (Place an "X" in One Box Only)

- CONTRACT: 110 Insurance, 120 Marine, 130 Miller Act, 140 Negotiable Instrument, 150 Recovery of Overpayment & Enforcement of Judgment, 151 Medicare Act, 152 Recovery of Defaulted Student Loans (Excl. Veterans), 153 Recovery of Overpayment of Veteran's Benefits, 160 Stockholders' Suits, 190 Other Contract, 195 Contract Product Liability, 196 Franchise.
REAL PROPERTY: 210 Land Condemnation, 220 Foreclosure, 230 Rent Lease & Ejectment, 240 Torts to Land, 245 Tort Product Liability, 290 All Other Real Property.
PERSONAL INJURY: 310 Airplane, 315 Airplane Product Liability, 320 Assault, Libel & Slander, 330 Federal Employers' Liability, 340 Marine, 345 Marine Product Liability, 350 Motor Vehicle, 355 Motor Vehicle Product Liability, 360 Other Personal Injury, 362 Personal Injury - Med. Malpractice.
TORTS: 365 Personal Injury - Product Liability, 367 Health Care/Pharmaceutical Personal Injury Product Liability, 368 Asbestos Personal Injury Product Liability.
PERSONAL PROPERTY: 370 Other Fraud, 371 Truth in Lending, 380 Other Personal Property Damage, 385 Property Damage Product Liability.
PRISONER PETITIONS: Habeas Corpus: 463 Alien Detainee, 510 Motions to Vacate Sentence. Other: 530 General, 535 Death Penalty, 540 Mandamus & Other, 550 Civil Rights, 555 Prison Condition, 560 Civil Detainee - Conditions of Confinement.
FORFEITURE/PENALTY: 625 Drug Related Seizure of Property 21 USC 881, 690 Other.
LABOR: 710 Fair Labor Standards Act, 720 Labor/Mgmt. Relations, 740 Railway Labor Act, 751 Family and Medical Leave Act, 790 Other Labor Litigation, 791 Empl. Ret. Inc. Security Act.
BANKRUPTCY: 422 Appeal 28 USC 158, 423 Withdrawal 28 USC 157.
PROPERTY RIGHTS: 820 Copyrights, 830 Patent, 840 Trademark.
SOCIAL SECURITY: 861 HIA (1395ff), 862 Black Lung (923), 863 DIWC/DIWW (405(g)), 864 SSID Title XVI, 865 RSI (405(g)).
FEDERAL TAX SUITS: 870 Taxes (U.S. Plaintiff or Defendant), 871 IRS-Third Party 26 USC 7609.
OTHER STATUTES: 375 False Claims Act, 376 Qui Tam (31 USC 3729 (a)), 400 State Reapportionment, 410 Antitrust, 430 Banks and Banking, 450 Commerce, 460 Deportation, 470 Racketeer Influenced and Corrupt Organizations, 480 Consumer Credit, 490 Cable/Sat TV, 850 Securities/Commodities Exchange, 890 Other Statutory Actions, 891 Agricultural Acts, 893 Environmental Matters, 895 Freedom of Information Act, 896 Arbitration, 899 Administrative Procedure Act/Review or Appeal of Agency Decision, 950 Constitutionality of State Statutes.

V. ORIGIN

- 1 Original Proceeding, 2 Removed from State Court, 3 Re-filed (See VI below), 4 Reinstated or Reopened, 5 Transferred from another district (specify), 6 Multidistrict Litigation Transfer, 7 Appeal to District Judge from Magistrate Judgment, 8 Multidistrict Litigation - Direct File, 9 Remanded from Appellate Court.

VI. RELATED/ RE-FILED CASE(S)

(Sec instructions): a) Re-filed Case YES NO

b) Related Cases YES NO

JUDGE:

DOCKET NUMBER: 1:17-cv-21486-RNS

VII. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause (Do not cite jurisdictional statutes unless diversity): Class Action Fairness Act 28 U.S.C. Sec. 1332(d)

LENGTH OF TRIAL via days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: YES NO

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE

DATE 5-25-17 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY RECEIPT #

AMOUNT

IFP

JUDGE

MAG JUDGE

EXHIBIT 1

Search product

CELLMAX

ADORE COSMETICS - CELLMAX
REDEFINING FACIAL CREAM

Formulated with revolutionary CELLMAX, featuring the m



\$699.95

Be the first to review this product

ADORE COSMETICS - CELLMAX
KIT

Includes: Superior Supplement Facial Thermal Mask, Rede



\$2,100.00

Be the first to review this product

ADORE COSMETICS - CELLMAX
ELECTRIC FACIAL SERUM

With the passage of time, skin cells suffer damage from



\$749.95

Be the first to review this product

ADORE COSMETICS - ULTRA
SONIC ANTI-AGING PREMIUM KIT

Firm Sonic is a health-oriented skin rejuvenator, which



\$2,645.99

Be the first to review this product

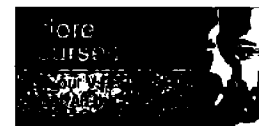
ADORE COSMETICS - CELLMAX
SUPERIOR SUPPLEMENT FACIAL
THERMAL MASK

Treat your skin to the most advanced anti-aging science



\$849.95

Be the first to review this product



MY CART

You have no items in your shopping cart

RECENTLY VIEWED PRODUCTS

Adore Cosmetics - CELLMAX Electric Facial Serum

Adore Cosmetics - CELLMAX Redefining Facial Cream

Adore Cosmetics - CELLMAX Superior Supplement Facial Thermal Mask

Adore Cosmetics - Cellmax Kit

Search product



Adore Cosmetics - CELLMAX Elite Facial Serum

Net Wt: 50ml / 1.7 Oz

With the passage of time, skin cells suffer damage from aging and environmental elements. This extraordinary facial serum from Adore Organic Innovation helps halt and reverse the aging process using CELLMAX, a breakthrough combination of age-defying active ingredients. It features the highest concentration of our exclusive Plant Stem Cell formula, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture. Its anti-aging action is increased with a special complex of Vitamin C, which regenerates the skin's appearance cell by cell, promoting production of collagen for skin firmness and elasticity. This is suspended in a formulation of jojoba seed oil, which makes it readily absorbed to minimize fine lines and wrinkles. Vitamin E revitalizes each layer of your skin, preventing damage and protecting skin from future harm, while Bisabolol soothes the skin and prevents irritation. With each application, this innovative serum promotes skin suppleness and works to restore what time and the elements take away.

Like 5 Tweet

Availability: In stock

\$749.95 Qty 1

Add to Cart

Add to Wishlist

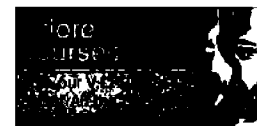
Add to Compare

Be the first to review this product

Email to a friend

Product Description Additional Information Product Reviews Custom Tab

How to Use: After cleansing your face, apply Adore CELLMAX Elite Facial Serum to your face and neck. Use daily morning and evening. For best results, use Adore CELLMAX Elite Facial Serum with Adore CELLMAX Elite Facial Cream.



MY CART

You have no items in your shopping cart

RECENTLY VIEWED PRODUCTS

Adore Cosmetics - CELLMAX Redefining Facial Cream

Adore Cosmetics - CELLMAX Superior Supplement Facial Mask

Adore Cosmetics - Cellmax Kit

Search product



Adore Cosmetics - CELLMAX Redefining Facial Cream

Net Wt: 58ml / 1.7 Oz

Formulated with revolutionary CELLMAX, featuring the highest concentration of our exclusive Plant Stem Cell formula, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture. To amplify its age-defying properties, we infuse it with extracts of chamomile, linden blossom and other all-natural flora to regenerate tone and promote smoother appearance. Meanwhile, Allantoin deeply hydrates by binding moisture to dry skin. This phenomenal anti-aging cream helps erase the look of deep wrinkles and restore youthful texture, leaving skin fresher, harmonized and renewed. You'll see results with every application.

Like 0 Tweet

Availability: In stock

\$699.95 Qty 1

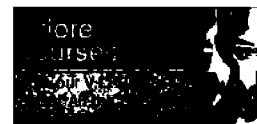
[Add to Cart](#)

[Add to Wishlist](#)

[Add to Compare](#)

[Be the first to review this product](#)

[Email to a friend](#)



RELATED PRODUCTS

CHECK ITEMS TO ADD TO YOUR CART OF SELECTION ALL



Adore Cosmetics - CELLMAX Superior Supplemental Facial Cream

\$649.95

[Add to Wishlist](#)

[Add to Cart](#)



Adore Cosmetics - CELLMAX Elixir

\$749.95

[Add to Wishlist](#)

[Add to Cart](#)

Product Description Additional Information Product Reviews Custom Tab

How to Use: 1. Dispense 1-2 pumps of product into palm of hand. 2. Gently massage into skin. 3. Rinse with lukewarm water. 4. Apply to face with fingertips. 5. Use daily.

MY CART

You have no items in your shopping cart.

RECENTLY VIEWED PRODUCTS

Adore Cosmetics - CELLMAX Elixir Facial Serum

Adore Cosmetics - CELLMAX Superior Supplemental Facial Cream Mask

Adore Cosmetics - Cellmax Kit

Search Account

Adore Cosmetics - CELLMAX Superior Supplement Facial Thermal Mask



Net Wt: 50ml / 1.7 Oz
Treat your skin to the most advanced anti-aging science available today with CELLMAX Superior Facial Thermal Mask from Adore Organic Innovation. This unique self-heating mask not only smoothes deep lines and wrinkles but also encourages your skin to renew itself. As it gently warms to the touch, the mask prepares your skin to absorb our highest concentration of breakthrough anti-aging Plant Stem Cell formula. We enrich this anti-aging nutrient with extracts of chamomile, linden blossom and other all-natural ingredients to promote smooth skin texture. Vitamin E revives skin's appearance, leaving it fresh, clean and vibrant, while promoting youthful elasticity. All combined, it gives you phenomenal anti-aging action that helps reduce the look of wrinkles in moments while encouraging your skin to respond naturally by amplifying collagen levels that help restore youthful tone.

Like 0 Tweet

Availability: In stock

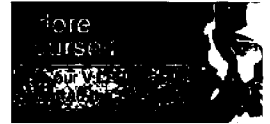
\$849.95 Qty 1 Add to Cart

Add to Wishlist Add to Compare

Be the first to review this product Email to a friend

Product Description Additional Information Product Reviews Custom Tab

How to use: 1. Wash your face with a gentle cleanser. 2. Apply a thin layer of the mask to your face. 3. The mask will heat up and create a warm, soothing effect. 4. Leave the mask on for 15-20 minutes. 5. Rinse your face with water and pat dry. 6. Apply your favorite moisturizer. 7. Use the mask 2-3 times per week for best results. 8. For more information, visit our website at www.adorecosmetics.com.



MY CART

You have no items in your shopping cart.

RECENTLY VIEWED PRODUCTS

Adore Cosmetics - CELLMAX E Facial Serum

Adore Cosmetics - CELLMAX Redefining Facial Cream

Adore Cosmetics - Cellmax Kit

EXHIBIT 2



Anti-wrinkle (<https://mibellebiochemistry.com/products/#anti-wrinkle>)

Hair / Scalp (<https://mibellebiochemistry.com/products/#hairsalp>)

Skin stem cell protection (<https://mibellebiochemistry.com/products/#skin-stem-cell-protection>)

Well-being / SPA (<https://mibellebiochemistry.com/products/#well-beingspa>)

ABOUT PHYTOCELLTEC™ MALUS DOMESTICA

PhytoCellTec™ Malus Domestica is a patented liposomal preparation of apple stem cells derived from the 'Uttwiler Spätlauber', a rare Swiss apple variety. These apple stem cells are rich in epigenetic factors and metabolites, which ensures the longevity of skin cells. PhytoCellTec™ Malus Domestica has been shown to protect skin stem cells while also delaying the senescence of hair follicles. PhytoCellTec™ Malus Domestica succeeds in delivering a revolutionary anti-aging performance for real rejuvenation.

Mibelle Biochemistry has developed a novel plant cell culture technology (PhytoCellTec™) that enables the large-scale cultivation of callus (stem) cells from rare and protected plant species, such as *Malus Domestica*. The PhytoCellTec™ technology, which was recognized at the UN






Conference Rio+20 as an Eco breakthrough, delivers a highly sustainable sourcing of this active. You can find further information on our [PhytoCellTec™](http://www.phytocelltec.ch/about.php?l=en) website (<http://www.phytocelltec.ch/about.php?l=en>).


PhytoCellTec™ Malus Domestica was the first ingredient based on plant stem cells on the cosmetic market. The topical use of PhytoCellTec™ Malus Domestica is patented in the USA (US 9,155,916 B2 / US 8,580,320 B2) and in Korea (10-1470632).



PHYTOCELLTEC™ MALUS DOMESTICA MOVIE

PROVEN EFFICACY

-  Increases the colony forming efficiency of epidermal stem cells
-  Helps skin cells to maintain the capacity to build new tissues (3D epidermis)
-  Reverses signs of senescence in fibroblasts
-  Increases lifespan of isolated hair follicles
-  Anti-wrinkle effect on crow's feet

-  In vivo study



In vitro study

CLAIM IDEAS

- Protects longevity of skin stem cells
- Delays senescence of essential cells
- Increases the vitality of skin stem cells
- Combats chronological aging

PLANT SOURCE



Uttwiler Spätlauber is a variety of a Swiss apple (*Malus domestica*) that is derived from a seedling planted in the middle of the 18th century. It was very famous for its excellent storability without shriveling. Uttwiler Spätlauber apples have especially long-living tissue stem cells, while their specific composition of metabolites leads to incredible storability and longevity properties.

INCI (EU/PCPC) DECLARATION

Malus Domestica Fruit Cell Culture Extract (and) Xanthan Gum (and) Glycerin (and) Lecithin (and) Phenoxyethanol (and) Aqua / Water

RECOMMENDED USE LEVEL

2 – 5 %

SCIENTIFIC PUBLICATIONS



MOST SEARCHED PRODUCTS

PhytoCellTec™ Malus Domestica

- Protects longevity of skin stem cells
- Delays senescence of essential cells
- Increases the vitality of skin stem cells

(<https://mibellebiochemistry.com/products/phytocelltec-malus-domestica/>)

PhytoCellTec™ nunatak®

- Protects and vitalizes dermal stem cells
- Re-densifies skin
- Fortifies skin's self-defense activities

(<https://mibellebiochemistry.com/products/phytocelltec-nunatak/>)

Snow Algae Powder

- Protects and activates longevity factors in skin cells
- Rejuvenates and protects skin at cellular level
- Safeguards skin's youthfulness by activating Klotho

(<https://mibellebiochemistry.com/products/snow-algae-powder/>)

Ameliox

- Maintains skin elasticity by fighting glycation
- Reduces wrinkles and lines
- Increases skin firmness

(<https://mibellebiochemistry.com/products/ameliox/>)

VISIT US AT

in-cosmetics Asia, Bangkok
08 November 2016 - 10 November 2016
Stand N20

in-cosmetics North America, New York
07 September 2016 - 08 September 2016
Stand C68

Cosmetic Business, Munich
08 June 2016 - 09 June 2016
Hall 3 Stand B01

SHORTCUTS

[Latest Development \(http://mibellebiochemistry.com/products/phytocelltec-nunatak/\)](http://mibellebiochemistry.com/products/phytocelltec-nunatak/)

[Our Distribution Partners \(http://mibellebiochemistry.com/wp/distributors/\)](http://mibellebiochemistry.com/wp/distributors/)

[Mibelle Group \(http://www.mibellegroup.com/en/\)](http://www.mibellegroup.com/en/)

Home (<https://mibellebiochemistry.com/>)

Disclaimer (<https://mibellebiochemistry.com/disclaimer/>)

Terms and Conditions (<https://mibellebiochemistry.com/terms-and-conditions/>)

Sitemap (<https://mibellebiochemistry.com/sitemap/>)

Contact (<https://mibellebiochemistry.com/contact/>)

EXHIBIT 3

Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?

Updated: 02:42 EST, 30 November 2009



Anti-ageing apple: It is claimed an ingredient in the Swiss apple can help people look younger

Surprisingly, it all started with an apple. A dull, sour apple, almost extinct, living quietly on a rare tree in a remote part of Switzerland.

Now, that humble apple is a big celebrity, with fans such as Michelle Obama, Helen Mirren and Jennifer Lopez.

It spends its time among beautiful people in swanky department stores. Why? Because this Swiss fruit is at the centre of what's being described as a 'revolution' in anti-ageing treatments.

It's claimed this ingredient can reverse skin ageing, increase the lifespan of human cells, and may even make it possible to grow back lost hair.

I'm used to hyperbole in the beauty world, but this new development is really getting the cosmetics companies excited.

They believe they have the science to prove that plant stem cells can be incorporated in skin creams, will interact with human skin stem cells, and can eliminate wrinkles and make skin look younger.

8/21/2016

Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?

Human stem cells can turn into any part of the body and so are big news in medical research, but the law bans the use of embryonic stem cells in cosmetics.

So, instead, researchers turned their attention to plants. These also produce stem cells throughout their lives, both to grow, as a response to an injury.

The biggest 'star' in the stem cell world is called PhytoCellTec Malus Domestica.

Derived from a rare 18th-century species of apple tree, the Uttwiler Spatlauber, it first attracted attention, as it could be kept for months without withering.

Share this article

Share

In a paper published in the cosmetics industry journal, the Journal Of Applied Sciences, Swiss scientists noted: 'These apples must have especially long-living tissue stem cells. Could we profit from these stem cells?'

'What would be the effect of an extract of such long-living stem cells on the skin?'

To find out, scientists cut pieces of the apple, which responded by forming a protective 'callous' made of plant stem cells on the surface.

These cells were grown in a liquid culture and put to the test. A solution containing one per cent apple stem cells seemed to boost cell production of human stem cells by a staggering 80per cent.



8/21/2016

Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?



Beautiful to the core: Helen Mirren, left, and Jennifer Lopez are said to be fans of the Swiss apple

The human cells were irradiated with UV light, which killed 50 per cent of those grown in a normal liquid culture, but hardly any of those protected by the apple stem cells.

Also, hair follicles kept in a solution of Uttwiler Spatlauber continued to grow for 18 days, while those kept in a typical solution died after 14.

And, in tests on 20 women, applying a cream enriched with 2 per cent PhytoCell-Tec Malus Domestica twice a day reduced crows feet by eight per cent after a fortnight, and 15 per cent after four weeks.

Skincare companies rushed to include it in their ranges. But it doesn't come cheap. 3Lab, from Urban Retreat in Harrods and Selfridges, offers its Super 'h' Serum, £215, and M cream, £185.

Both contain apple stem cells, as does the company's £70 skin firming and lifting Super C Serum. Lancome has Absolue Precious Cells, £145 for 50ml, an anti-ageing cream it claims will 'help restore the potential of skin stem cells and bring back the skin of youth'.

Grannius Smithius

The Romans brought apples to Britain. There are now more than 1,200 varieties native to the UK

Emerge Swiss Apple Stem Cell Serum (available online for £72), allegedly 'promotes the selfrenewal capacity of the skin' and in the U.S., youth-hungry celebs such as Gwyneth Paltrow and Julianne Moore all feted the launch of

8/21/2016

Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?

Cellular Lifting Serum from Clark's Botanicals, is £355 for just 30ml.

But, Professor Liam Dolan, the Sheradian Professor of Botany at Oxford University, who specialises in studying plant cells, is sceptical about the new ingredient. 'I don't see how plant stem cells could interact with human stem cells in this way,' he says.

But Dr Daniel Schmid, research director of Mibelle Biochemistry, the Swiss lab which developed PhytoCellTec Malus Domestica, insists that his study shows his apple stem cell extracts have been 'shown to improve the maintenance of the stem cells characteristics of epidermal stem cells.'

He admits: 'The anti-ageing benefit for the skin after topical application could not be confirmed in a clinical trial.'

But, he adds: 'The extract offers a promise of real skin rejuvenation.'

Further studies would be needed to prove that plant stem cells truly are as effective on faces as they are in the lab, but in our search for the elixir of youth, a new cream that can peel away the years, dreams tend to win over doubts, and this little apple looks as if it's going to bask in the limelight a little longer yet.

8/21/2016

Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?

WE RECOMMEND NIGHT CREAMS



Dr LeWinn's Private Formula Ultra R4 Regenerative Night Cream, £45, Debenhams stores nationwide

AN overnight treatment to restructure and repair skin.

Eve Lom TLC Cream, £48, spacenk.com

RICH and creamy, your skin will feel like a million dollars after applying this cream.



ESPA Regenerating Complex Intensive Night Cream, £50, espaonline.com

NOURISHING and moisturising, you'll wake with nurtured skin.



Carita Pearl of Youth Night Cream, £113.50, feelunique.com

HELPS repair the skin, re-boosting its texture and leaving it fresh and dewy.

DON'T BOTHER

Soap & Glory Night In Shining Armour Wrinkle Reducing Night Cream, £12, Boots stores nationwide

THIS smelled and felt lovely, but had little effect on fine lines as promised.



Purity Organic Overnight Moisturiser, £7.99, purityorganic.skincare.co.uk

SMELLED quite pleasant but had little deep nourishing effect.



EXHIBIT 4



US 20080299092A1

(19) **United States**
 (12) **Patent Application Publication** (10) **Pub. No.: US 2008/0299092 A1**
 Blum et al. (43) **Pub. Date: Dec. 4, 2008**

(54) **COSMETIC PREPARATION AND METHOD FOR PREPARING THE SAME**

(30) **Foreign Application Priority Data**

Apr. 27, 2007 (CH) 00701/07

(75) Inventors: **Peter Blum**, Richterswil (CH);
Cornelia Schurch, Lenzburg (CH);
Daniel Schmid, Brugg (CH); **Fred Zulli**, Kuttigen (CH)

Publication Classification

(51) **Int. Cl.**
A61K 9/127 (2006.01)
A61K 36/73 (2006.01)
 (52) **U.S. Cl.** 424/93.7; 424/450

Correspondence Address:
MAGINOT, MOORE & BECK, LLP
CHASE TOWER
111 MONUMENT CIRCLE, SUITE 3250
INDIANAPOLIS, IN 46204 (US)

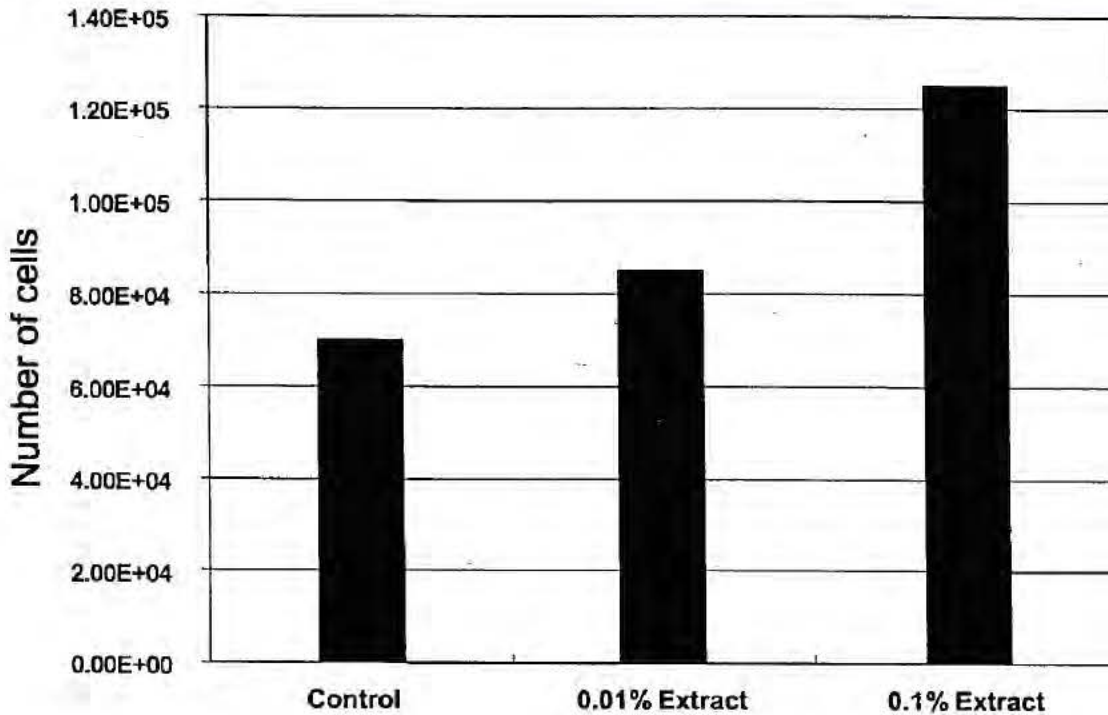
(57) **ABSTRACT**

The present invention relates to the use of dedifferentiated plant cells in cosmetic preparations for protecting of stem cells against intrinsic and extrinsic stress factors, in particular for promoting proliferation of stem cells and for protecting them against apoptosis. In particular, the invention relates to the use of dedifferentiated plant cells from fruits of *Malus domestica* (Apple) cultivar Uttwiler Spaetlauber. Further, the invention relates to a method for cultivating of dedifferentiated plant cells, as well as to the preparation of extracts of plant cell cultures which are suitable for such applications.

(73) Assignee: **Mibelle AG**, Buchs (CH)

(21) Appl. No.: **12/148,241**

(22) Filed: **Apr. 17, 2008**



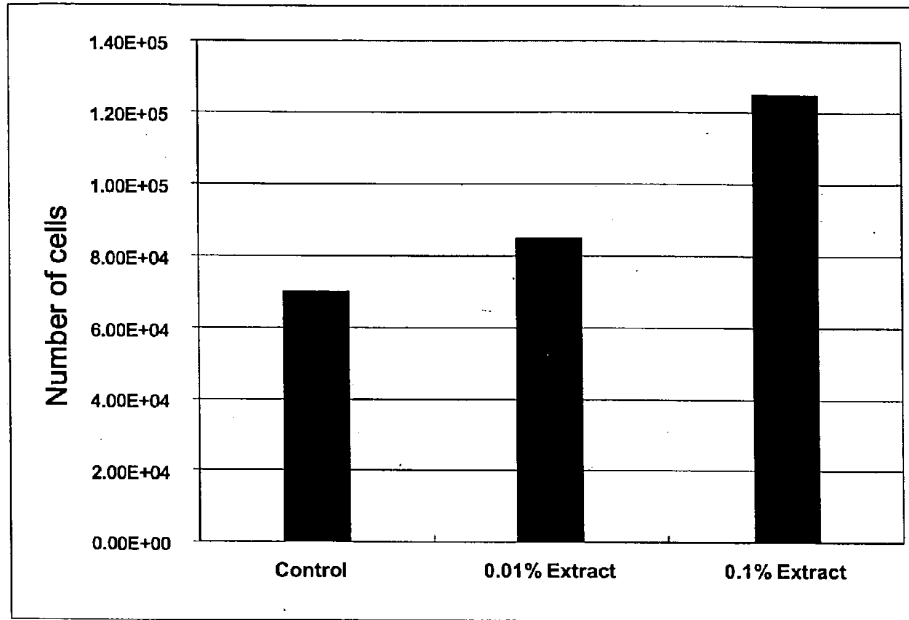


Fig. 1

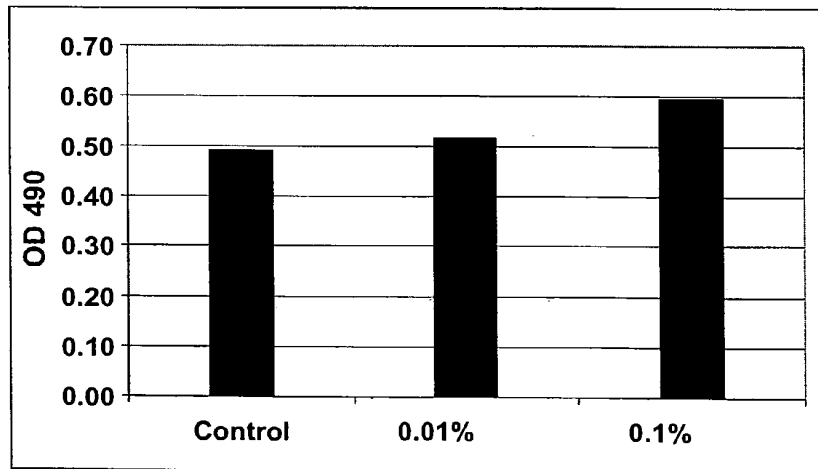


Fig. 2

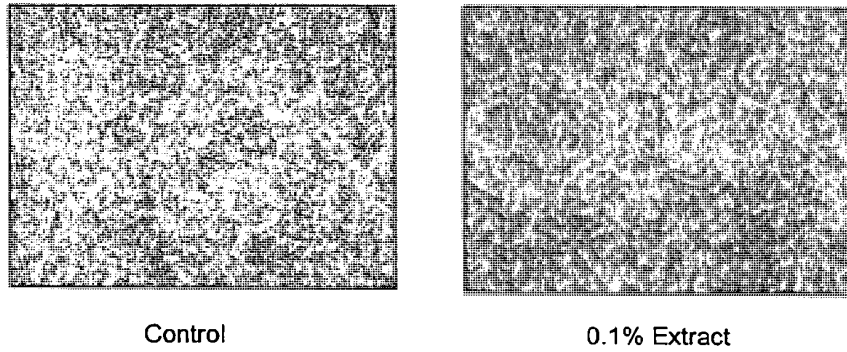


Fig. 3

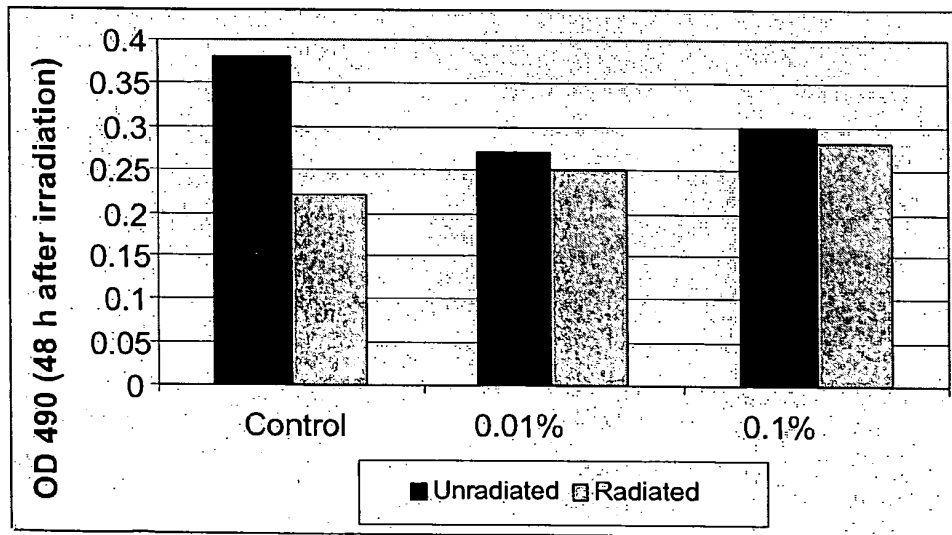


Fig. 4

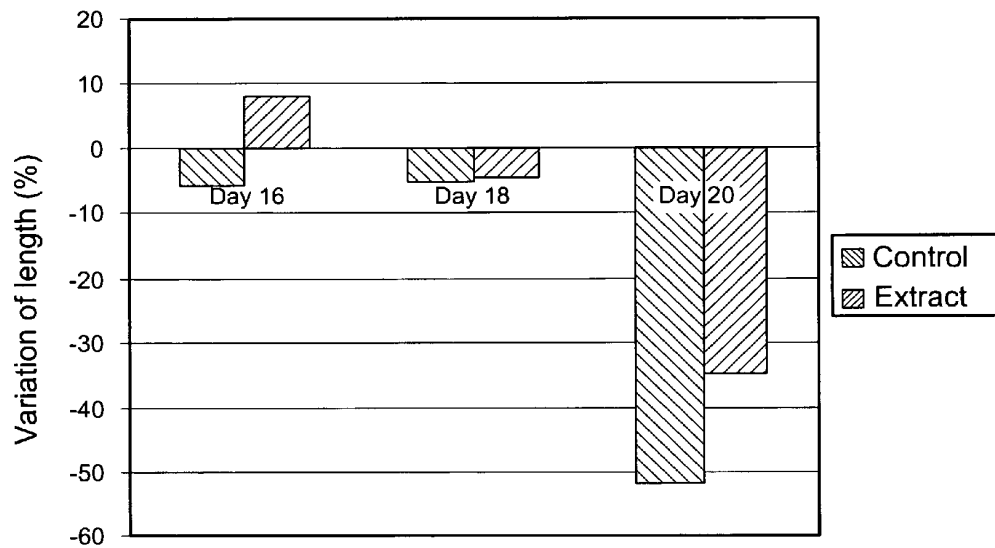


Fig. 5

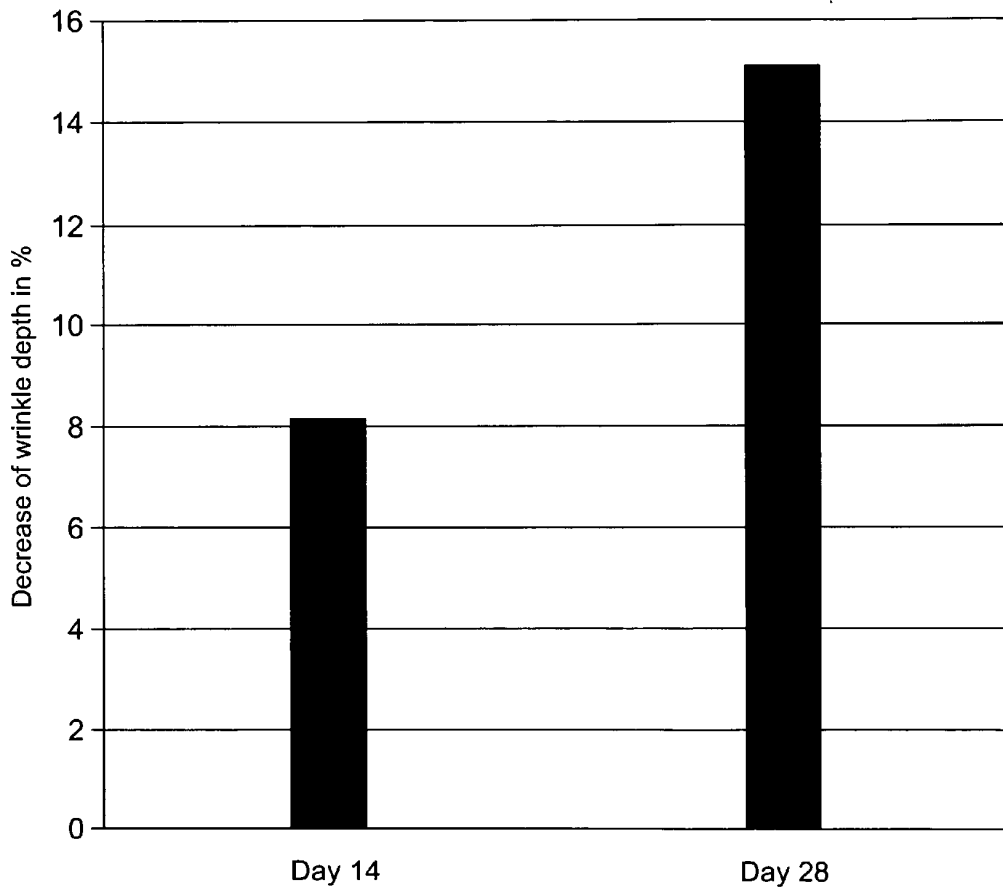


Fig. 6

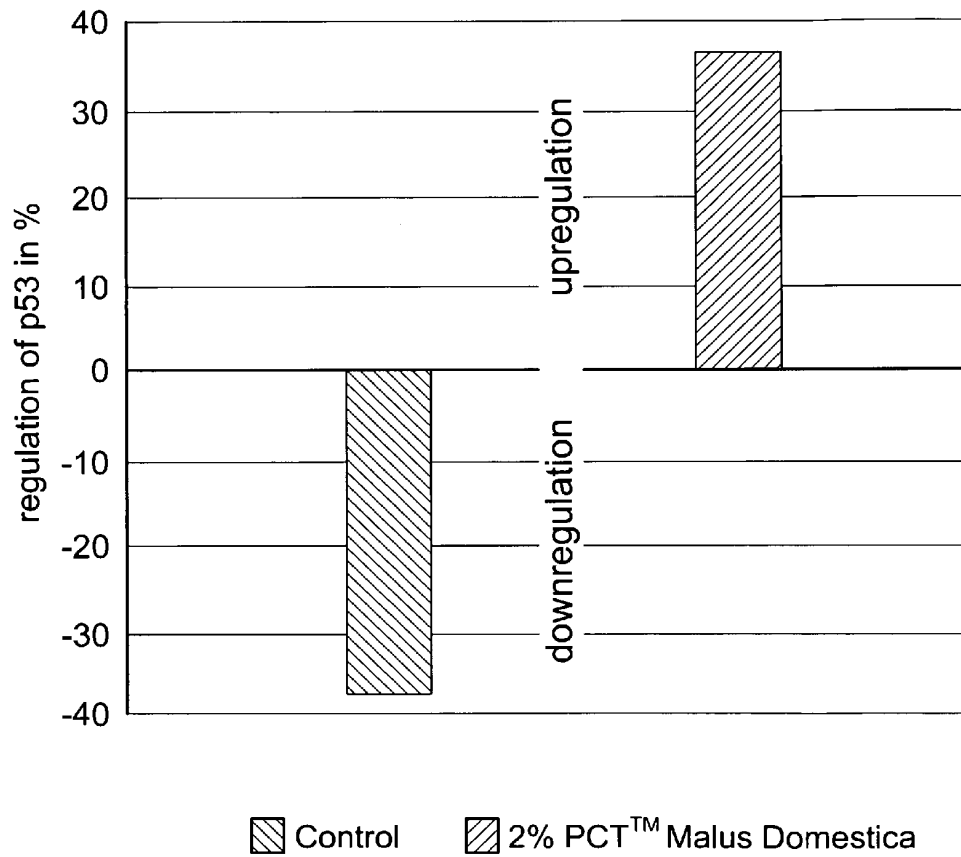


Fig. 7

US 2008/0299092 A1

Dec. 4, 2008

1

COSMETIC PREPARATION AND METHOD FOR PREPARING THE SAME

FIELD OF INVENTION

[0001] The present invention relates to the use of dedifferentiated plant cells in cosmetic preparations for protecting of stem cells against intrinsic and extrinsic stress factors, in particular for promoting proliferation of stem cells and for protecting them against apoptosis. In particular, the invention relates to the use of dedifferentiated plant cells from fruits of *Malus domestica* (Apple) cultivar Uttwiler Spaetlauber. Further, the invention relates to a method for cultivating of dedifferentiated plant cells, as well as to the preparation of extracts of plant cell cultures which are suitable for such applications.

BACKGROUND OF THE INVENTION

[0002] Stem cells (SC) are uniform undifferentiated cells having the property of constant regeneration and the unique ability of turning into any other cell type by cleavage and differentiation. By said potential, SC are a renewable source of human tissue. Thus, SC became an important object of medical research for various applications, such as gene therapy, organ transplantation, diabetes, and plastic surgery.

[0003] SC may be divided into two groups, i.e. embryonal and adult (EC). Embryonal stem cells play a key role in the first development phase of an organism. They are able to endlessly cleave and to develop every necessary type of tissue. Thus, they are able to form from a single cell a whole body, either the plant or the animal form which they originate. Due to this ability they are also called pluripotent cells. Unfortunately, for human beings this ability is restricted to the embryonal phase. In later phases of life of a subject EC are no longer present.

[0004] The second type of stem cells are adult stem cells. So far, these cells could be identified in many full-grown tissues and organs, such as bone marrow, pancreas, spine, brain, central nervous system, peripheral blood, dental pulp, blood vessel, skeletal muscles, cornea, retina, liver, cord blood, heart, epithelium of the intestinal tract, and dermis.

[0005] Compared with EC adult SC derived from such tissues have only a limited choice of differentiation. Some of them can only differentiate into one single tissue type mostly the one which is surrounding them. Thus, they are called unipotent SC. Other SC can differentiate into various tissue types and therefore are called multipotent.

[0006] Both types of adult SC are promising for medical applications since they are more easily accessible and their recovery is ethically less problematical than of ES. A survey on and their possibilities may be gleaned in Lemoni et al., 2005, Stem Cell Plasticity: Time for a Reappraisal, *Hematologica/The Hematology Journal*, 90 (3), 360 to 381.

[0007] The skin of mammals is a multilamina system which is continuously revolving. The part which is constantly in contact with the outside world is called epidermis. The major task of this specialized Tissue is to protect the body against dehydration, lesions and infections. It is composed four different laminae which are all formed by a single cell type, the so-called cerationocytes. Whereas this cell type is not much differentiated, is nevertheless has its origin in specialized skin stem cells. They are located in the lowermost lamina of the epidermis, the basal lamina.

[0008] In several papers successful isolation of such skin stem cells is reported. It even could be demonstrated that skin stem cells may be found in lower tissues of the skin, i.e. in the so-called hair follicle bulge. Contrary to the SC in the basal lamina these SC are multipotent, i.e. they are able to differentiate into every tissue type of the skin. A survey may be gleaned in: Roh et al., 2006, Cutaneous Stem Cells and Wound Healing, *Pediatric Research*, 59 (4), Pt 2, 100 to 103R; Morasso et al., 2005, Epidermal Stem Cells; The Cradle of Epidermal Determination, Differentiation and Wound Healing, *Biol. Cell.*, 97, 173 to 183; and Alonso et al., 2003, Colloquium: Stem Cells of the Skin Epithelium, *PNAS*, 100, Suppl. 1, 11830 to 11835.

[0009] Skin stem cells are crucial in the wound healing and the regeneration of skin and hair. However, the capacity of these abilities may be disturbed by genetical problems, environmental influences and the aging process. Thus, protection of these SC is extremely important. Therefore, as will be explained below more in detail, it was an object of the present invention to develop a vegetable extract able to protect and stimulate these SC in cosmetic preparations.

[0010] Vegetable extracts and the use of parts of plants, such as leaves, fruits, flowers, stems, bark, inflorescences and roots for cosmetic and medical Applications are known since ancient times. Products derived therefrom may be e.g. essential oils, fibers, starch, flavors, coloring matters, antibiotics, proteins, phenols, acids or fats. The use of plants or plant extracts in cosmetics is rampant. There are a great many of different uses, such as humidification, brighteners, tanning lotions, make-ups, sun filters, scavengers, antioxidants, immunity stimulation, detergents, preserving agents or thickening agents.

Examples of recently found uses are described in: KR20040091178, KR20040059007, US20062400129, WO2006099930, WO2006086707, US2006153792, JP2006151934, WO2006068777, WO2006053761, WO2006008418, LV13345, UA73556, CN1679498, and many others.

[0011] The spectrum of useful plants and plant component is wide and comprises e.g. algae, succulents, berries, carnivorous plants, herbs, cereals and trees. Usual well known examples of plants, however not limited to them, are: Spirulina algae, aloe vera, calendula, ginkgo, ginseng, iris, valerian, sage, lavender, thyme, peppermint, Saint-John's-wort, citrons, peach, guava, avocado, wheat, and oat.

[0012] However there are restrictions with respect to the use of plants or plant components. i.e.:

[0013] The availability may be restricted, e.g. by the seasons, limited storage capacities, protection of species, problems in cultivation, or bad harvests.

[0014] The quality is not unchanging, e.g. due to seasonal variations, different cultivation methods, geographic differences, different suppliers, clones, pollution of the environment, or physical status.

[0015] These facts often make the use of plants in cosmetic applications impossible.

[0016] Therefore, the utilization of methods of plant cell culture techniques may help to solve such problems. Said utilization comprises techniques which allow, when observing certain known process steps, to obtain uniform dedifferentiated cells, showing the following advantages as compared with cultivated whole plants:

[0017] Independency from seasons;

[0018] Continuous production;

[0019] Freedom from pollution of environment and other impurities;

US 2008/0299092 A1

Dec. 4, 2008

2

[0020] With respect to quantity and quality manageable and reproducible production of metabolites;

[0021] Protection of rare or limited plant reserves;

[0022] No limitation of market availability.

[0023] Examples for the use of plant cell cultures of various species, their cultivation and their use in cosmetic preparations may e.g. be found in: EP1244464, FR2837385, US2006021084, WO2005108596, WO2005070066.

[0024] The basic principle of cultivation of such dedifferentiated plant cells utilizes the biological fact, that every plant cell has the ability to build up the whole plant which the cell stems from. This ability is called totipotency and is comparable with the pluripotency of animal ES. Therefore, it may be accepted that dedifferentiated plant cells do have a positive influence on protection and activation of skin stem cells.

[0025] In order to achieve this effect various dedifferentiated plant cells can be used. However, further supplemental useful effects can be achieved using these plant extract as well. An investigation within several plant groups showed that apples and fruits belonging to the subfamily Maloideae of the family of Rosaceae are much promising. A known exponent of this family is the cultivated apple tree (*Malus domestica*). Apples have a long tradition in cosmetic applications. Originally, they were applied in the form of masks of pressed pulp or peelings which provided moisture and tautness of the skin. Another application is the use of apple aromas and extracts in all kinds of cosmetic preparation, such as e.g. shampoos, lotions, soaps, bath essences or toothpastes.

[0026] The main ingredients of apples are various sugars, vitamins, acids, oils, waxes and polyphenols. Recently published studies could prove that especially the overall polyphenols in apple extracts or apple juices rich in polyphenols can be useful in preventing and combating colon cancer (Eberhart et al., 2000, Antioxidant Activity of Fresh Apples, *Nature*, 405, 903 to 904; Liu et al., 2003, Antiproliferative Activity of Apples is not due to Phenolic-induced Hydrogen Peroxide Formation, *J. Agric. Food Chem.*, 51, 1718 to 1723; Kem et al., 2005, Inhibitors of the Epidermal Growth Factor Receptor in Apple Juice Extract, *Mol. Nutr. Food Res.*, 49, 317 to 328). Thereby, to a certain extent, the juices rich in polyphenols had an influence on the Wnt-pathway. This pathway is a cytobiological signaling cascade in which β -catenin is the main protein. Under normal circumstances, this protein is present in the cell on a constant level. If this level is disturbed, as in a cancer cell, the β -catenin level rises, and the β -catenin is transported into the cell nucleus, where it initiates the transcription of genes which causes an uncontrolled cleavage. Kem et al. (2006, Modulation of Key Elements of the Wnt-Pathway by Apple Polyphenols, *J. Agric. Food. Chem.*, 54, 7041 to 7046) could show that the level of intracellular β -catenin in colon cancer cells cultivated in vitro was reduced by administration of apple juice.

[0027] Furthermore, it was found that apple show a large antioxidative activity and can increase the antioxidative capacity in blood (Rezk et al., 2002, The Antioxidant Activity of Phloretin: The Disclosure of a new Antioxidant Pharmacophore in Flavonoids, *Biochem. Biophys. Res. Commun.*, 295, 9 to 13; Lee et al., 2003, Major Phenolics in Apple and their Contribution to the Total Antioxidant Capacity, *J. Agric. Food Chem.*, 51, 6516 to 6520; Vrohovsek et al., 2004, Quantitation of Polyphenols in Different Apple Varieties, *J. Agric. Food Chem.*, 52, 6532 to 6538; Lotito et al., 2004, Relevance of Apple Polyphenols as Antioxidants in Human Plasma: Contrasting in-vitro and in-vivo Effects, *Free Rad. Biol.*

Med., 36, 201 to 211; Bitsch et al., 2000, Bioavailability of Antioxidative Compounds from Brettacher Apple Juice in Humans, *Food Sci. Emerg. Technol.*, 1, 245 to 249). For this reason, apples are very interesting for establishing a dedifferentiated cell culture and its subsequent use in cosmetic preparations.

[0028] Dedifferentiated plant cells have a complex matrix of constituents of salts, acids, polyphenols, sugars, fats, proteins and other components. In addition to known components there is an unknown fraction of components which possibly is very valuable for cosmetic applications. It is known that raw plant extracts often show a better effect than identified and isolated individual components. Therefore, it is reasonable to use the entire cell lysate for application.

[0029] In order to obtain such total fraction of all ingredients special techniques are required since part of them are water-soluble whereas another part is fat-soluble. It was proposed to process plant cell culture preparations by means of lyophilization (e.g. WO2005072697, US20050265953). Thereafter, these lyophilized cells were pulverized and used in topic preparations.

[0030] Since transport of materials through the skin barrier is very limited, the technique of producing liposomes for many cosmetic applications was developed (e.g. KR20050091162, KR920005639B, GB2415375, WO2004067012, EP1498420, US2002160064, AU2388099). Application of this technique allows a better penetration of substances into the lower skin laminae. Also, a further advantage of liposomes is the encapsulation of fat-soluble ingredients in the membrane and thus their dispersion in aqueous phases.

[0031] There are various methods of liposome production. Main steps of their production comprise dissolving a phospholipid mixture in a suitable solvent (e.g. glycerol or alcohol), intermixing the dissolved lipids with an aqueous phase, applying energy (e.g. by stirring, shaking, pressure or heat) for forming the liposomes. As said above, the form of energy can be pressure. Formation of liposomes by means of high pressure homogenization is a known technique. Examples for pharmaceutical or cosmetic preparations may be found e.g. in WO9949716, NZ502840 or EP0782847. Interestingly the same technique can be used for solubilizing cells and obtaining their lysate (e.g. DE19918619). Therefore, it is possible to solubilize plant cells of suspension cultures and at the same time to extract the oil- and water-soluble agents into empty liposomes. Thereby, stability of the agents and their transportation into the skin can be improved.

[0032] From the above mentioned publication WO 2005/072697 A1 it is known to use lyophilizates of dedifferentiated plant cells for depigmenting the skin. This technique calls for the use of lyophilizates of dedifferentiated plant cells, in particular of cells of halophile plants. **A use for stimulation and protection of skin stem cells is not envisaged.**

[0033] From the publication EP 1,174,120 A1 it is known to use extracts, in particular of lyophilizates, of dedifferentiated cells of plants of the family Iridaceae (Iris-family) for stimulating immunity. Other plants or uses are not proposed.

[0034] The publication EP 1,064,932 A1 proposes the use of extracts of dedifferentiated plant cells in deodorants. Other uses are not disclosed.

[0035] The publication WO 03/077881 A discloses the use of lysates of metabolites of dedifferentiated cells of vine, which were obtained by means of a complicated method, for the preparation of cosmetics. This technique calls for the use

US 2008/0299092 A1

Dec. 4, 2008

3

of lyophilizates. A use for stimulation and protection of skin stem cells is not envisaged. Furthermore, other species of plants are not disclosed.

[0036] Furthermore, the publication WO 01/47538 A1 discloses the use of extracts of dedifferentiated cells of plants of the genus *Leontopodium* (Edelweiss) as UV filter. Other uses or other plants are not proposed.

OBJECTS OF THE INVENTION

[0037] The main object of the present invention is to create a cosmetic preparation which protects stem cells against intrinsic and extrinsic stress factors, in particular promotes the proliferation of stem cells and protects them against apoptosis.

[0038] Another object of the present invention is to provide a method for preparing an extract suitable for use in said cosmetic preparation.

SUMMARY OF THE INVENTION

[0039] The abovementioned object is achieved by using an extract of a suspension of dedifferentiated plant cells, preferably of the family of Rosaceae (Rose family), particularly of the subfamily Maloideae (Pome fruit), and more in particular of *Malus domestica* cultivar Uttwiler Spaetlauber, which is an old and rare kind of apple.

[0040] The method of preparing suitable extracts comprises the following main steps:

[0041] (a) Establishing a stable dedifferentiated cell line on a laboratory scale;

[0042] (b) Mass cultivation of the cells in an one-way bag reactor system (so-called Wave reactor), and

[0043] (c) Recovery of a total-extract by means of high pressure homogenization using empty liposomes.

[0044] Advantageously, in step (c) the following procedure is followed:

[0045] Decomposition of the plant cells by high pressure homogenization;

[0046] Extraction and stabilization of the substances of content by means of liposomes; whereby both steps are simultaneously performed as one single step.

BRIEF DESCRIPTION OF DRAWINGS

[0047] In the annexed drawings:

[0048] FIG. 1 shows the increase in the cell count of umbilical cord stem cells in dependence of different concentrations of a liposomal extract originating from dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber. For this study, the extract was centrifuged and sterilized by filtration.

[0049] FIG. 2 shows the increase in proliferation capability in a MTS-assay of umbilical cord stem cells in dependence of different concentrations of a liposomal extract originating from dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber. For this study, the extract was centrifuged and sterilized by filtration.

[0050] FIG. 3 shows microscopical pictures of umbilical cord stem cells. The left photograph shows cells cultivated in a medium without extract, the right photograph cells cultivated together with 0.1 percent of a liposomal extract originating from dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber. For this study, the extract was centrifuged and sterilized by filtration.

[0051] FIG. 4 shows the proliferation capability of umbilical cord stem cells of a control preparation and of a liposomal

extract of different concentrations originating from dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber, 48 hours after UV irradiation. For this study, the extract was centrifuged and sterilized by filtration.

[0052] FIG. 5 shows the temporal influence of a liposomal extract according to Example 10 on the length of hair follicles.

[0053] FIG. 6 shows the effect of a preparation in accordance with the present invention as anti-wrinkle cream in Test 1 described hereafter.

[0054] FIG. 7 shows the effect of a preparation in accordance with the present invention on stressed skin in Test 2 described hereafter.

[0055] In FIGS. 2 and 4 "OD" is the abbreviation of "optical density".

DETAILED DESCRIPTION OF THE INVENTION

Induction and Stabilization of Cell Line (a)

[0056] The following steps provide a dedifferentiated cell line from vegetable tissue:

[0057] (a1) Choice of a suitable tissue for the induction.

[0058] (a2) Surface sterilization.

[0059] (a3) Cladding of the explants on a suitable solid medium for callus induction.

[0060] (a4) Harvesting the callus grown on the injured surface of the explants.

[0061] (a5) Sub-cultivation of the obtained callus on the same medium until the cells are entirely dedifferentiated.

[0062] (a6) Addition of the dedifferentiated cells to a suitable liquid medium.

[0063] (a7) Homogenization of the cells in suspension until big cell clump are no longer present; and

[0064] (a8) Sub-cultivation and continuous characterization of the cell suspension.

[0065] Fundamental working protocols for plant cell cultures can be found in the standard literature (e.g. Plant Cell Culture: A Practical Approach, Editor P. A. Dixon, 1994, Oxford University Press). Protocols for the work and suitable media for initiating plant cell cultures of apples are described by Nitsch et al., 1970, Bases physiologiques de la production de chair de pomme et de poire in vitro, Bull. Soc. Bot. Fr., 117, 479 to 492; und Pech et al. 1975, Croissance in vitro de tissus et de suspensions cellulaires de pomme, Bull. Soc. Bot. Fr., 122, 183 to 194. According to these protocols, initiating and maintaining such cultures should not present a problem.

Biomass Production (b)

[0066] In the following process, the obtained suspension culture is cultivated further over several continuous steps from small laboratory flasks (Erlenmeyer flask usually having 200 ml content) to production scale of 50 to 100 liters. In this process, 5 to 10 percent, preferably 10 percent, of the next culture volume of a fully grown cell suspension is used as inoculum. The scale-up may be done in steps of e.g. 0.1/1/10/100 liter.

[0067] Cultivation volumes exceeding 1 liter necessitate the use of special bioreactors instead of culture flasks used before. Many different systems are available on the market. Execution of cultivation is done, but is not limited thereto, in agitation reactors, bubble columns, loop reactors or newly developed one-way systems suitable for plant cell cultivation. For all these cultures the influence of shearing stress which can endanger the cultures. Thus, the most important param-

US 2008/0299092 A1

Dec. 4, 2008

4

eter for selecting a suitable reactor system usually is the manner how the culture is homogenized.

[0068] Moreover, control of the culture is very important. In comparison to cultures of yeast or bacteria, measurement of the biomass is difficult, and the growth of biomass has to be measured by means of indirect parameters, such as e.g. consumption of carbon, dropping of conductivity or the pH value or the increase of optical density. Once such a control is established, the end point or the harvest moment, respectively, can be fixed.

[0069] Also important is examination analysis of secondary metabolites which are characteristic for the cell culture. Measurement of such materials can be done by HPLC-VIS/UV/MC, LC, GC-MS, e.g. enzymatically or optically. Thereby, the stable and continuous expression of such metabolites during the whole process is decisive.

Biomass Processing (c)

[0070] In order to obtain an extract containing the whole essence of the cultivated cells, the cells are solubilized by means of liposomes. The main component of this method is the use of high pressure homogenization of the whole cell broth together with a liposome preparation. The great advantage of this method is its simple and low-cost application.

[0071] In detail, the method comprises the following steps: (c1) Addition of a suitable liposome preparation to the cell broth;

(c2) Addition of a suitable preservative agent;

(c3) Addition of suitable antioxidants;

(c4) Mixing the substances; and

(c5) High pressure homogenization.

[0072] All preservative agents of natural or synthetic origin allowed for cosmetics, such as e.g. phenoxyethanol, benzoic acid, propionic acid, alcohol or silver chloride, can be used as preservative agents.

[0073] In order to additionally protect the extract from oxidation, antioxidants, such as e.g. ascorbic acid or tocopherol, may be added.

The described method allows the addition of still further substances useful in the preparation or cosmetic product. Once all compounds are added, the mixture has to be stirred in order to dissolve the preservative agents and other components. This may be done e.g. by means of a paddle mixer, a homogenization rod or by pumping through static mixing elements.

[0074] The subsequent high pressure homogenization purposes to objects:

[0075] Destruction of the cell membranes in order to release extractable substances; and

[0076] Generation of finely dispersed liposomes contained the fat- and water-soluble fractions of the cells.

[0077] Suitable high pressure homogenizers are commercially available on the market. The principle of the reaction chamber has to be selected from different possibilities and has to be previously tested. The number of passages through the reaction chamber necessary for a disintegration of all cell membranes or reaching a desired homogeneity of the extract has to be tested as well.

[0078] Afterwards, the extract obtained in this manner can directly be incorporated into cosmetic preparations, such as e.g. creams, soaps, lotions, gels or hair seras. If the extract is to be used as semi-finished good a supplemental thickening is

possible. All thickening agents of natural or synthetic origin allowed for cosmetics can be used as thickening agents.

EXAMPLES

Example 1

Production of a Dedifferentiated Plant Cell Culture

[0079] Mature apples of the cultivar Uttwiler Spaetlauber were rinsed with tap water. In cylindrical pieces of a diameter of about one centimeter diameter the score was out along the axis of the by means of a cork borer. For the surface sterilization, the cylinders were dipped for 30 seconds into 70 percent ethanol and thereafter for 10 minutes into 2.5 percent sodium hypochloride containing 0.1 percent of the surfactant Tween 40. Thereafter, the sterilized cylinders washed three times with distilled water, cut into slices of about 3 millimeter thickness, and placed on a solid medium of the following composition per liter:

Calcium chloride	332 mg
Potassium dihydrogen phosphate	170 mg
Potassium nitrate	1900 mg
Magnesium sulfate	180.54 mg
Ammonium nitrate	1650 mg
Cobalt chloride hexahydrate	0.025 mg
Copper sulfate pentahydrate	0.025 mg
Iron-Sodium-EDTA	36.7 mg
Boric acid	6.2 mg
Potassium iodide	83 mg
Manganese sulfate hydrate	16.9 mg
Disodium molybdate dihydrate	0.25 mg
Zinc sulfate heptahydrate	8.6 mg
myo-Inositol	100 mg
Nicotinic acid	5 mg
Glycine	2 mg
Pyridoxine hydrochloride	0.5 mg
Thiamidine hydrochloride	0.5 mg
Folic acid	0.5 mg
Biotin	0.05 mg
Ascorbic acid	50 mg
Thiourea	25 mg
L-Asparagine	180 mg
Saccharose	30000 mg

[0080] The ph-value was adjusted to 5.6 with sodium hydroxide solution. Agar was added in a concentration of 0.8 percent as gelling agent. All ingredients were mixed together and sterilized at 121° centigrade for 15 minutes.

[0081] The induction of the primary callus was carried out in the dark at 25° centigrade. The formed calluses were harvested after two to three weeks and further incubated on the same medium. Several sub-cultivations were carried out until the callus was fully dedifferentiated.

Example 2

Production of a Suspension Culture

[0082] Dedifferentiated cell clumps growing on said solid medium were taken, homogenized and placed into the same

US 2008/0299092 A1

Dec. 4, 2008

5

medium without gelling agent. A finely dispersed suspension was obtained which could be use for larger cultivation systems. The suspensions were grown in the dark at 25 centigrade and a shaking velocity of about 100 rpm.

Example 3

Outbreak

[0083] One tenth of a fully grown culture (percentage of cells being about 50 percent of the total weight of the culture) was used for the seeding of the next volume step. The scale-up was effected in a one-way bag reactor system of Wave Biotech AG, Tagelswangen, Switzerland (so-called Wave Reactor). The scale-up was effected in steps of 1/10/25 liter. The temperature was held at 25 centigrade and the aeration at about 0.1 vvm. Various mixing speeds were applied in dependence of the bags used. Cultivation was carried out in the dark, and it took about 20 days until a bag was completely grownup.

Example 4

Preparation of a Liposomal Extract

[0084] After cultivation, the whole cell broth was mixed with a dispersion containing empty liposomes of a size of about 50 nanometer. The mixture was then four times high pressure homogenized at a pressure of about 1200 bar ($1.2 \cdot 10^8 \text{ N m}^{-2}$) resulting in a finely dispersed extract.

Example 5

[0085]

Vanishing cream		
The percentage refers to the total quantity (weight/weight).		
Oily phase 1:	Alkyl benzoates	10%
	Dimeticone	3%

-continued

Vanishing cream		
The percentage refers to the total quantity (weight/weight).		
	Archidyl glycosides	3%
	Myristyl glycoside	2%
Oily phase 2:	Polyacrylamides	1%
Aqueous phase:	Deminerlized water	71%
	Glycerol	5%
	Phenoxyethanol	1%

[0086] Oily phase 1 and the aqueous phase were heated at 80 centigrade and blended. The mixture was chilled to 60 centigrade. Then oily phase 2 was added, and the mixture was blended. The mixture was chilled to 30 centigrade. 4 percent of the extract described in Example 4 was added and the mixture was blended again.

Example 6

[0087]

Liquid balm for the scalp	
The percentage refers to the total quantity (weight/weight).	
Ethanol	0,5%
Urea	5%
Propylene glycol	0,5%
Carbomer	0,4%
Bisabololene	0,1%
PEG-60	0,6%
D-Panthenol 75%	0,5%
Sodium hydroxide 30%	0,4%
Plant cell extract of Example 4	1%
Water	filling up to 100%

Example 7

[0088]

Intensive hair mask		
The percentage refers to the total quantity (weight/weight).		
Phase	Ingredient	Amount
Aqueous phase 1 (W1)	Water	filling up to 100%
	Citric acid	0,6%
	Sodium benzoate	0,5%
Aqueous phase 2 (W2)	D-Panthenol 75%	0,7%
Oily phase 1 (O1)	Cetearyl alcohol	4,5%
	Dicocoyl ethyl hydroxyethylmonium methosulfate	3%
	Distearoyl ethyl hydroxyethylmonium methosulfate	1,5%
	Dicapryryl ether	1%
	Glycerol stearate	1%
Oily phase 2 (O2)	Amino dimethicone	0,3%
Plant extract (A)	Plant cell extract of Example 4	2%

US 2008/0299092 A1

Dec. 4, 2008

Execution:

[0089] Aqueous phase 1 is mixed and heated to 75 centigrade. Shortly before mixing with oily phase 2 aqueous phase 2 (panthenol) is added. Oily phase 1 is heated to 75 centigrade, and shortly before mixing oily phase 2 (aminodimethicone) is added. The combined aqueous and oily phases are mixed and homogenized. The mixture is chilled to 30 centigrade, and phase A (plant extract) is added.

Example 8

[0090]

Eye Cream		
The percentage refers to the total quantity (weight/weight).		
Phase	Ingredient	Amount
Aqueous phase 1 (W1)	Water	filling up to 100%
	Citric acid	0.6%
	Glycerol	5%
	Butylen glycol	5%
	Galacto arabinane	0.3%
Oily phase 1 (O1)	Parabens in phenoxyethanol	0.8%
	Polyglyceryl-3-methylglucose distearate	2.5%
	Hydrogenated polyisobutene	3%
	Vegetable oil	4%
	Dicapryryl ether	3%
Oily phase 2 (O2)	Behenyl alcohol	2%
	Dimethicone	0.5%
	Maize phosphates	1%
Plant extract (A)	Dimethicone	0.5%
	Plant cell extract of Example 4	2%

Execution:

[0091] Aqueous phase is mixed and heated to 80 centigrade. Oily phase 1 is heated to 80 centigrade, and oily phase 2 is added. The combined aqueous and oily phases are mixed and homogenized. The mixture is chilled to 30 centigrade, and phase A (plant extract) is added, and the blend is mixed again.

Example 9

In-Vitro-Test on Stem Cells

[0092] The test was carried out on stem cells originating from the umbilical cord. The cells were grown in a complex medium containing 10 percent of fetal calf serum. The supernatant with out cell debris was used for the test. Previous to the test, the extract was sterilized by filtration.

[0093] The addition of 0.1 percent of the extract resulted in an increase of the cell count of about 44 percent (FIGS. 1 and 3).

[0094] Also, in a subsequent MTS-assay on addition of 0.1 percent of the extract an increase of the proliferation capability of the cells of 20 percent could be verified (FIG. 2).

[0095] In addition to said growth and proliferation studies umbilical cord cells together with a liposomal extract of dedifferentiated cells of Apples of the cultivar Uttwiler Spaetlauber were tested for the effects of UV radiation. Application of 0.1 percent of extract resulted in a reduction of the proliferation capability of about 7 percent, whereas the control preparation showed a loss of proliferation capability of 42 percent (FIG. 4).

Example 10

Ex-Vivo-Test on Isolated Hair Follicles

[0096] The epithelium of the hair root bulges into a supra-basal bulge which is the niche of the ceratinozyte stem cells. They consist of clonal subpopulations which regenerate skin and hair follicles. Thus, isolated hair follicles are a suitable model for analyzing the life expectancy of stem cells.

[0097] Hair follicles were isolated from skin material originating from an esthetic surgery. Then they were placed in a nutrient solution where they vived on and started growing. In

this manner, hair follicles could kept alive for about 14 days. Thereafter, the cells begin to die off, and the newly formed hair begins to shrink a control assay of 12 follicles was incubated in the nutrient solution only, Whereas a second series was incubated in a nutrient solution containing 0.2 percent of a liposomal extract of dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber. On the 16th, 18th and 20th day the length of the hair follicles was measured.

[0098] The ex vivo test showed that, as expected, the follicles of the control assay had lost about 6 percent of its length already on the 16th day. A similar shrinking could be asserted on the 18th day. Then, on the 20th day a considerable dying of 52 percent was measurable. The follicles treated with the extract remained longer in the growth phase. On the 16th day, an increase in length of 8 percent could still be measured. Not until the 18th day a slight shrinking arised. The dying on the 20th day was clearly lesser than in the control assay.

[0099] In detail, the following variations in length were detected. They are graphically represented in FIG. 5.

	Control	Extract
16th day	-5.7%	7.8%
18th day	-5.3%	-4.8%
20th day	-52%	-35%

[0100] Thus, Example 10 shows that a liposomal extract of dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber is able to prolong the expectancy of life of cerationocyte stem cells.

US 2008/0299092 A1

Dec. 4, 2008

7

Dermatologic Tests

Test 1

Anti-Wrinkle Effect of PhytoCellTec™ *Malus Domestica*

[0101] The following dermatological test was carried out by Dr. H. P. Nissen, of Derma Consult GmbH, D-53347 Alfter, Germany. PhytoCellTec™ *Malus Domestica* is the Applicant's Trade Mark for products prepared in accordance with the present invention.

Test Product

[0102] Cream containing 2.0% of PhytoCellTec™ *Malus Domestica*

Test Area

[0103] Crow's feet area

Volunteers	
Number of individuals:	20
Age:	37 to 64 years
Sex:	female

Application	
Duration:	28 days
Frequency:	twice daily

Test Parameter

[0104] Wrinkle depth by means of an apparatus PRIMO-S® 5.5 of GF Messtechnik GmbH, D-14513 Teltow, Germany

Study Design

- [0105] Day 0
 [0106] Determination of the test parameter in the test areas; first application of the test product
 [0107] Day 1 to 13
 [0108] Application of the test product twice a day
 [0109] Day 14
 [0110] Determination of the test parameter 8 to 12 hours after the last daily test product application
 [0111] Day 15 to 27:
 [0112] Application of the test product twice a day
 [0113] Day 28:
 [0114] Determination of test parameter 8 to 12 hours after the last daily test product application

Results

[0115] Two daily applications of the test cream containing 2% of PhytoCellTec™ *Malus Domestica* over 28 days resulted in a significant decrease in wrinkle depth in all of the volunteers tested. These results are represented in FIG. 6.

Test 2

Effect of PhytoCellTec™ *Malus Domestica* on Stressed Skin

[0116] The following dermatological test was carried out by F. Juchaux, of BIOalternatives, F-86160, France. PhytoCellTec™ *Malus Domestica* is the Applicant's Trade Mark for products prepared in accordance with the present invention.

Introduction

[0117] In normal skin the tumor suppressor gene p53 is upregulated by several types of stress, e.g. DNA damage (induced by UV radiation, IR radiation, or chemical agents, such as hydrogen peroxide), oxidative stress, or osmotic shock. The protein p53 plays an important role in the cell cycle as transcription regulator. In old skin this gene is no more upregulated but rather down regulated by stress.

Test Product

2.0% of PhytoCellTec™ *Malus Domestica*

Cells

[0118] Normal human dermal fibroblasts (NHDF) used at 10th passage

Assay

[0119] Fibroblasts were stressed for 2 hours with culture medium containing 600 μmole of H₂O₂. For recovery, the cells were incubated for 72 hours with a medium containing, or not containing (control), 2% of PhytoCellTec™ *Malus Domestica*. After the incubation time, mRNA was extracted and transcribed into ³³P-labeled cDNA via reverse-transcription. These labeled cDNA targets were hybridized to an "old skin" specific minichip. This minichip contained about 150 genes specific for skin aging. The content of labeled genes on the minichip was measured.,

Results

[0120] In H₂O₂-stressed fibroblasts, p53 was downregulated. H₂O₂-stressed cells treated with 2% PhytoCellTec™ *Malus Domestica* showed an upregulation of p53. These results are represented in FIG. 7.

What is claimed is:

1. A cosmetic preparation comprising at least one active component protecting stem cells against intrinsic and extrinsic stress factors, said active component originating from a dedifferentiated vegetable stem cell suspension.
2. A cosmetic preparation as set forth in claim 1, wherein said least one active component promotes proliferation of stem cells.
3. A cosmetic preparation as set forth in claim 1, wherein said least one active component protects stem cells against apoptosis.
4. A cosmetic preparation as set forth in claim 1, wherein said stem cells which are to be protected are skin stem cells.
5. A cosmetic preparation as set forth in claim 1, wherein said dedifferentiated vegetable stem cells which are to be protected are hair follicle stem cells.
6. A cosmetic preparation as set forth in claim 1, wherein said dedifferentiated vegetable stem cells originate from plants of the family of Rosaceae.
7. A cosmetic preparation as set forth in claim 6, wherein said dedifferentiated vegetable stem cells originate from plants of the sub-family of Maloideae.

US 2008/0299092 A1

Dec. 4, 2008

8

8. A cosmetic preparation as set forth in claim 7, wherein said dedifferentiated vegetable stem cells originate from plants of *Malus domestica* cultivar Uttwiler Spaetlauber.

9. A cosmetic preparation as set forth in claim 1, wherein said dedifferentiated vegetable stem cell suspension is obtained by high pressure homogenization with liposomes.

10. A cosmetic preparation as set forth in claim 1, comprising 0.01 to 100 percent by weight of dedifferentiated vegetable stem cell suspension.

11. A cosmetic preparation as set forth in claim 10, comprising 0.1 to 10 percent by weight of dedifferentiated vegetable stem cell suspension.

12. A method of preparing a dedifferentiated vegetable stem cell suspension suitable for use in a cosmetic preparation as set forth in one of the preceding claims, comprising the following procedure:

decomposition of the plant cells by high pressure homogenization; and

extraction and stabilization of the ingredients by means of liposomes;

wherein both parts of the method are simultaneously carried out in a single step.

* * * * *

EXHIBIT 5

U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

Crescent Health Center, Inc 4/20/16



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506

Telephone: 949-608-2900

FAX: 949-608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE SIGNATURE REQUIRED

April 20, 2016

WL # 28-16

Dr. Farid A. Mostamand, CEO
Crescent Health Center, Inc.
15635 Alton Parkway, Ste. 410
Irvine, CA 92618

Dear Dr. Mostamand:

From November 18 to December 2, 2015, the U.S. Food and Drug Administration (FDA) conducted an inspection of your manufacturing facility located at 15635 Alton Parkway, Ste. 410, Irvine, CA. In addition, FDA reviewed your websites at the Internet addresses www.skinbeautymall.com, www.agelessderma.com, and www.drskinspa.com in February 2016, and has determined that you take orders there for your products “Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream” and “Ageless Derma Anti-Aging Intensive Skin Brightener Cream”. Based on our inspection and review of your product labels and labeling, we have found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. You may find the Act and FDA regulations through links on FDA’s website at www.fda.gov (<http://www.fda.gov/>).

Unapproved New Drugs

The claims on your product labels and labeling establish that your “Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream” and “Ageless Derma Anti-Aging Intensive Skin Brightener Cream” products are promoted for uses that cause the products to be drugs under sections 201(g)(1)(B) and/or 201(g)(1)(C) of the Act [21 U.S.C. § 321(g)(1)(B) and/or 321(g)(1)(C)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease and/or are intended to affect the structure or any function of the human body. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the product label and labeling claims that provide evidence that your products are intended for use as drugs include, but are not limited to, the following:

Product Labels:

- “Ageless Derma Anti-Aging Intensive Skin Brightener”: “[C]linically proven to reduce all types of hyperpigmentation...to lighten the skin...”
- “Ageless Derma brand Stem Cell and Peptide Anti-Wrinkle”: “[I]mproves the firmness and elasticity of skin, removes crow’s feet...”

From your website, www.skinbeautymall.com:

On the “Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream” page:

- “Argireline reduces the depth of wrinkles...by attenuating muscle contraction...”
- “Coenzyme 10...prevents damage to collagen and elastin production...reduction in fine wrinkles... application before sun exposure protects against sun damage...”
- “Matrixyl 3000...significant decrease in wrinkle density, depth, volume roughness...”
- “PhytoCellTec Malus Domestica...decrease in wrinkle depth...”
- “Syn@-Coll is an effective and needle-free alternative to collagen injections...increased collagen synthesis (sic)...”
- “Vialox Powder significantly reduces muscle contraction as an injection-free alternative to Botox...”
- “Ageless Derma Peptide and Stem Cell Anti-Wrinkle Cream...eradicate your lines and wrinkles...”

On the “Ageless Derma Anti-Aging Intensive Skin Brightener Cream” page:

- “[C]linically proven to reduce all types of hyperpigmentation...It can even remove scars that may have been plaguing you for years”
- “This intensive skin brightener contains NET-DG-Licorice Root, a natural anti-inflammatory agent...”
- “BV-OCS...a powerful whitener...and collagen protector... increases the synthesis of collagen...”
- “Biowhite...inhibits tyrosinase activity...”
- “Belides...is a skin-whitening agent...is an inhibitor of tyrosinase...”
- “[A]lpha Arbutin...tyrosinase inhibitor...even excess tanning accidents can be reduces(sic) and lightened and thus minimize the dangerous effects of excess UV exposure...”

On the “Dynamic Ingredients Make Anti-Wrinkle Cream and Amazing Find” page which promotes the “Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream” and provides links to information about the ingredients of the product:

- “Argireline...reduction of the depth of wrinkles...” and on the linked ingredient information page: “[L]ikened to being a brief version of Botox...”
- “Coenzyme Q10...enhance the production of elastin and collagen in the skin...”
- “Syn-Coll...[W]ill increase synthesis of collagen...”
- “Vialox Powder...reduction in depth of wrinkles...” and on the linked ingredient information page: “[W]idely known to be similar to Botox...can exhibit a Botox-like reduction in wrinkles...”

- “PhytoCellTec Malus Domestica...will repair the DNA of the skin...and protect it from the sun’s harmful rays...visible reduction in wrinkles and fine lines...”
- “Matrixyl 3000...reduction of wrinkles...”

From your website, www.agelessderma.com:

On the “Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream” page:

- “[R]evitalize your body’s natural abilities to heal itself...proven in laboratory studies to stimulate growth in cultures of aged human epidermal stem cells...demonstrated measurably reduced wrinkle depth...”
- “Argireline reduces the depth of wrinkles...by attenuating muscle contraction...”
- “Vialox Powder significantly reduces muscle contraction as an injection-free alternative to Botox...”

On the “Ageless Derma Anti-Aging Intensive Skin Brightener Cream” page:

- “[F]reckles, age spots, brown spots, liver spot or changes in skin pigmentation ...Ageless Derma Anti-Aging Intensive Skin Brightener...”
- “This intensive skin brightener contains NET-DG-Licorice Root, a natural anti-inflammatory agent...”
- “BV-OCS...a powerful whitener...and collagen protector... ..”
- “Biowhite...inhibits tyrosinase activity...”
- “Belides...is a skin-whitening agent...is an inhibitor of tyrosinase...”
- “[A]lpha Arbutin...tyrosinase inhibitor...even excess tanning accidents can be reduced and lightened and thus minimize the dangerous effects of excess UV exposure...”

On the “face-whitening-cream-brown-spots” page which promotes the “Ageless Derma Anti-Aging Intensive Skin Brightener Cream” and provides links to information about the ingredients of the product:

- “[W]ill lighten and even out your skin tone within weeks...”
- “Niacinamide is an anti-inflammatory ingredient...proven to improve acne and act as a lightener on the skin...helps to protect the skin against damage from UV rays...”

From your website, www.drskinspa.com:

On the “Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream” page:

- “[W]ill diminish fine lines and wrinkles, eradicate crow’s feet...abolishing wrinkles has never been so easy...”

On the “Ageless Derma Anti-Aging Intensive Skin Brightener Cream” page:

- “[C]linically proven to reduce all types of hyperpigmentation...”

Your “Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream” and “Ageless Derma Face Brightening Cream” products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

Misbranded Cosmetics

Even if your “Ageless Derma Face Brightening Cream” and “Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream” products did not make therapeutic claims, which make them unapproved new drugs, they are misbranded within the meaning of section 602(b) of the Act [21 U.S.C. §362(b)] in that the label does not include: your firm’s

current address, and, if the distributor is not the manufacturer, a statement on the label with the qualifying phrase “manufactured for...” or “distributed by...”, as required by 21 CFR 701.12.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility and in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. You are required to comply with the Act and all applicable federal regulations.

You should respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these violations and should include documentation that would assist us in evaluating your corrections. If you cannot complete all corrections within 15 days, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to Food and Drug Administration, CAPT Daniel Cline, Acting Director, Compliance Branch, Attention: Dr. Raymond W. Brullo, Compliance Officer, FDA/Los Angeles District, 19701 Fairchild, Irvine, CA 92612

Sincerely,

/S/

CDR Steven E. Porter, Jr.
Los Angeles District Director

cc:

David M. Mazzera, Ph.D., Chief
California Department of Public Health
Food and Drug Branch
1500 Capitol Avenue MS 7602
PO Box 997435
Sacramento, CA 95899-7435

More in 2016
[\(/ICECI/EnforcementActions/WarningLetters/2016/default.htm\)](http://www.fda.gov/iceci/enforcementactions/warningletters/2016/default.htm)

EXHIBIT 6

Archived Content

The content on this page is provided for reference purposes only. This content has not been altered or updated since it was archived.

Search Archive

[Home Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters](#)
Inspections, Compliance, Enforcement, and Criminal Investigations

Jaba Labs 3/1/11

Department of Health and Human Services

Public Health Service
 Food and Drug Administration
 5100 Paint Branch Parkway
 College Park, MD 20740

WARNING LETTER

MAR 1 2011

VIA OVERNIGHT DELIVERY

Joe Adams
 JabaLabs, LLC
 14080 Nacogdoches Road
 #64
 San Antonio, TX 78247

Re: 154172

Dear Mr. Adams:

This is to advise you that the Food and Drug Administration (FDA) reviewed your web sites at the Internet addresses <http://www.stemcellfacecream.com>¹ and <http://www.synovialabs.com>² in February 2011. Based on this review, FDA has determined that your products StemCellin Intensive Emulsion, StemCellin Deep Wrinkle Serum, and Faitoz-25 are promoted for uses that cause these products to be drugs under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(C)]. The claims on your web sites establish that these products are drugs because they are intended to affect the structure or function of the human body. The marketing of these products with these claims violates the Act. You may find the Act and FDA regulations through links at FDA's home page at www.fda.gov³.

Examples of some of the claims found on your web site www.synovialabs.com⁴ include:

Claims for Faitoz-25 and its ingredients:

- "Lose your wrinkles! without painful injections"
- "The proven benefits of Faitoz-25
 - o Accelerates collagen and elastin production
 - o Restores firmness, [and] elasticity...
 - o Lose deep wrinkles in 30 days"
- "Reduce[s] expression lines & deep furrows"
- "The Argireline, Matrixyl 3000 and Snap-8 Peptides in Faitoz-25 wrinkle cream have [been] clinically shown to:
 - o Matrixyl 3000 decreases wrinkle volume
 - o Matrixyl 3000 decreases wrinkle density ...
 - o Argireline increases skin firmness
 - o Argireline increases skin thickness
 - o Argireline increases collagen production"

- "Hyaluronic acid [an ingredient of Faitoz-25] helps reduce spider veins...."
- "Argireline mimics the actions of Botulinum by ... relaxing muscle contractions...."
- "Clinical trials have shown that Matrixyl 3000 is capable of reducing ... wrinkles that add years to your appearance. It was designed to promote collagen production while strengthening the essential structure of skin tissue."
- "Snap-8 [an ingredient of Faitoz-25] is known to ... reduce the depth of wrinkles ... in the forehead and around the eyes."
- "Vitamin C and E [ingredients of Faitoz-25] help ... protect skin cells from free radical damage."
- "Argireline locally disrupts nerve signals sent to muscles, relaxing the muscles"
- "SNAP-8 is a safer, cheaper, and milder alternative to Botulinum Toxin, topically targeting the same wrinkle-formation mechanism in the very same way."
- "Our greaseless Faitoz-25 serum formula ... improve[s] the elasticity of the skin, regenerate[s] skin stem cells, and effectively combat[s] wrinkles ... inflammation, and other symptoms of prematurely aging skin."

Your www.synovialabs.com⁵ web site also contains claims in the form of personal testimonials, including:

- "I have been using your wrinkle cream [Faitoz-25] for six weeks now. The skin around my eyes ... [has] less wrinkles."
- "Faitoz-25 wrinkle cream with 25% Argireline and Matrixyl 3000 does work in reducing my wrinkles.... I am always looking for products that make me look younger but until now I had not found any that work permanently."
- "Ever since I started using Faitoz-25 with 25% Argireline and Matrixyl 3000 three weeks ago, I have noticed that the wrinkles on my forehead were less deep"

Examples of the claims found on your web site www.stemcellfacecream.com⁶ include:

Claims for StemCellin Intensive Emulsion and Deep Wrinkle Serum, and their ingredients:

- "StemCellin® with 5% PhytoCellTec™:
 - o Delays deterioration of essential skin cells
 - o Activates your own skin stem cells ...
 - o Reverses chronological aging"
- "This incredible PhytoCellTec apple stem cell cream emulsion is the first product to harness the regenerative potential of your own facial stem cells to renew skin It will actually 'rejuvenate' your skin by 'awakening' your body's own reservoir of undifferentiated stem-cells."
- "Our greaseless StemCellin PhytoCellTec stem cell cream formulas ... improve the elasticity of the skin, regenerate skin stem cells, and effectively combat wrinkles ... inflammation, and other symptoms of prematurely aging skin."
- "PhytoCellTec™ Malus Domestica is the first active [ingredient] based on plant stem cells to protect and repair skin stem cells.... The application of plant stem cell cultures to maintain and repair the function of skin stem cells is a breakthrough in anti-aging."
- "Rosehip seed oil [an ingredient of StemCellin] contains Vitamin A, which helps to delay the effects of skin aging ... and promotes collagen and elastin levels to increase. This results in firmer ... skin with greater elasticity."
- "Vitamin C [an ingredient of StemCellin] is a ... natural anti-inflammatory that helps in reversing some of the effects of sun damage."
- "Vitamin E [an ingredient of StemCellin] ... protect[s] skin cells from UV-induced damage It reduces inflammation ... by strengthening the skin's repair mechanisms."
- "PhytoCellTec™ Malus Domestica, the cosmetic ingredient in StemCellin stem cell cream, is based on an encapsulated extract of cultured apple stem cells that was tested in a clinical trial over 4 weeks with 20 subjects. This new stem cell cream ingredient was found to significantly reduce wrinkles in the crow's feet area."

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. A new drug may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products and labeling are in compliance with the laws and regulation enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in enforcement action without further notice, such as seizure and/or injunction.

Please respond to this letter within fifteen working days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot

8/21/2016

Warning Letters > Jaba Labs 3/1/11

complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Rob Genzel Jr., Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Enforcement, Office of Compliance, 5100 Paint Branch Parkway (HFS-608), College Park, Maryland 20740.

Sincerely,

/s/

Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

Close out Letter

- [Jaba Labs Close out Letter 3/30/11](#)⁷

Page Last Updated: 04/07/2011

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

[Accessibility](#) [Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA](#) [No FEAR Act](#) [Site Map](#) [Transparency](#) [Website Policies](#)

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
[Contact FDA](#)



[For Government](#) [For Press](#)

[Combination Products](#) [Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#) [Emergency Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing Education](#) [Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry Health Professionals](#) [FDA Archive](#)



U.S. Department of **Health & Human Services**

Links on this page:

1. <http://www.stemcellfacecream.com>
2. <http://www.synovialabs.com>
3. <http://www.fda.gov>
4. <http://www.synovialabs.com>
5. <http://www.synovialabs.com>
6. <http://www.stemcellfacecream.com>
7. </ICECI/EnforcementActions/WarningLetters/ucm250292.htm>

EXHIBIT 7

**FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS**

Detail by Officer/Registered Agent Name

Florida Profit Corporation

UNIVERSAL HANDICRAFT, INC.

Filing Information

Document Number	P01000005781
FEI/EIN Number	65-1066702
Date Filed	01/12/2001
State	FL
Status	ACTIVE

Principal Address

1400 Alton Road
Suite 201
MIAMI BEACH, FL 33139

Changed: 02/12/2016

Mailing Address

1400 Alton Road
Suite 201
Miami Beach, FL 33139

Changed: 02/12/2016

Registered Agent Name & Address

SEGEV, SHAY
1400 Alton Road
Suite 201
Miami Beach, FL 33139

Name Changed: 09/23/2013

Address Changed: 02/12/2016

Officer/Director Detail

Name & Address

Title P

SEGEV, SHAY
1400 Alton Road
Suite 201

8/22/2016

Detail by Officer/Registered Agent Name

Miami Beach, FL 33139

Title vp

COHEN, TZIYONA
 1400 Alton Road
 Suite 201
 Miami Beach, FL 33139

Annual Reports

Report Year	Filed Date
2014	01/14/2014
2015	01/19/2015
2016	02/12/2016

Document Images

02/12/2016 -- ANNUAL REPORT	View image in PDF format
01/19/2015 -- ANNUAL REPORT	View image in PDF format
12/18/2014 -- AMENDED ANNUAL REPORT	View image in PDF format
01/14/2014 -- ANNUAL REPORT	View image in PDF format
09/23/2013 -- AMENDED ANNUAL REPORT	View image in PDF format
03/25/2013 -- ANNUAL REPORT	View image in PDF format
01/06/2012 -- ANNUAL REPORT	View image in PDF format
03/15/2011 -- ANNUAL REPORT	View image in PDF format
07/09/2010 -- ANNUAL REPORT	View image in PDF format
02/18/2009 -- ANNUAL REPORT	View image in PDF format
01/08/2008 -- ANNUAL REPORT	View image in PDF format
07/11/2007 -- ANNUAL REPORT	View image in PDF format
03/15/2006 -- ANNUAL REPORT	View image in PDF format
02/25/2005 -- ANNUAL REPORT	View image in PDF format
01/21/2004 -- ANNUAL REPORT	View image in PDF format
01/15/2003 -- ANNUAL REPORT	View image in PDF format
10/31/2002 -- ANNUAL REPORT	View image in PDF format
01/12/2001 -- Domestic Profit	View image in PDF format

EXHIBIT 8

PO1000005781

UNIVERSAL HANDICRAFT, INC.
1901 Lee Street, Apt. 4, Hollywood, Florida 33020
(305) 877-4055

January 10, 2001

Florida Department of State
Division of Corporations
P.O. Box 6327
Tallahassee, Florida 32314

800003535808--6
-01/12/01--01065--009
*****70.00 *****70.00

SUBJECT: INCORPORATION OF
UNIVERSAL HANDICRAFT, INC.

Dear Secretary of State:

Enclosed find one original and a copy of the Articles of Corporation of UNIVERSAL HANDICRAFT, INC. and a check for:

<input checked="" type="checkbox"/> \$70.00	<input type="checkbox"/> \$78.75	<input type="checkbox"/> \$122.50	<input type="checkbox"/> \$131.25
Filing Fee	Filing Fee & Certificate	Filing Fee & Certificate Copy	Filing Fee, Certificate Copy & Certificate

ADDITIONAL COPY REQUIRED

FROM: Shay Sabag
Name (Printed or typed)

1901 Lee Street, Apt. 4
Address

Hollywood, Florida 33020
City, State & Zip

(305) 877-4055
Daytime Telephone Number

FILED
01 JAN 12 PM 4:21
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

Exhibit 8
Page 40 of 143

ARTICLES OF INCORPORATION
OF
UNIVERSAL HANDICRAFT, INC.

The undersigned incorporator, for the purpose of forming a corporation under the Florida Business Corporation Act, hereby adopts the following Articles of Incorporation.

ARTICLE I - NAME

The name of the corporation shall be: **UNIVERSAL HANDICRAFT, INC.**

ARTICLE II - PRINCIPAL OFFICE

The principal place of business and mailing address of this corporation shall be:
1901 Lee Street, Apt. 4, Hollywood, Florida 33020

ARTICLE III - SHARES

The number of shares of stock that this corporation is authorized to have outstanding at any one time is:
one hundred (100) of no par value.

ARTICLE IV - INITIAL REGISTERED AGENT AND STREET ADDRESS

The name and Florida street address of the initial registered agent are: **Shay Sabag at 1901 Lee Street, Apt. 4, Hollywood, Florida 33020**

ARTICLE V - INCORPORATOR

The name and address of the incorporator of these Articles of Incorporation are:
Shay Sabag at 1901 Lee Street, Apt. 4, Hollywood, Florida 33020

ARTICLE VI - DIRECTORS

The corporation shall have two (2) directors, and the initial directors shall be:
**Shay Sabag at 1901 Lee Street, Apt. 4, Hollywood, Florida 33020 and
Marcela Jimenez at 1901 Lee Street, Apt. 4, Hollywood, Florida 33020**

SHAY SABAG
Signature/Incorporator

1/10/01
Date

Having been named as registered agent and to accept service of process for the above stated corporation at the place designated in this certificate. I hereby accept the appointment as registered agent and agree to act in this capacity. I further agree to comply with the provisions of all statutes relating to the proper and complete performance of my duties, and I am familiar with and accept the obligations of my position as registered agent.

SHAY SABAG
Signature/Registered Agent

1/10/01
Date

FILED
01 JAN 12 PM 4:21
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

EXHIBIT 9



specialty retail REPORT

STAFFING & HIRING

RUNNING A CART OR KIOSK

MERCHANDISING RETAILER & MARKETING PROFILES

RETAILING LOCATIONS

RETAIL PRODUCTS

NEWS & PRESS



BEARFRUIT JEWELRY WHOLESALE

wholesale@bearfruitjewelry.com



Fall 2010

The Deep Sea and Its Many Treasures

by [Emily Lambert](#)

Shay Sabag, president of Deep Sea Cosmetics, in Miami, FL, not only launched a trend; he transformed it into a specialty retail mainstay.

In the constantly changing field of specialty retail, which thrives on trends and the newest “must-haves,” Shay Sabag’s story stands out. For seven years running, Sabag has been thriving in the industry with the same product concept. So what is his secret? Staying consistently new. In other words, Deep Sea Cosmetics continually offers its customers cutting-edge products in addition to the bestsellers they have been purchasing for years. And it’s not just individual products that are launched, but entire lines of cosmetics. Case in point—just last year, Deep Sea unveiled a revolutionary new line of anti-aging products (The Age

Deep Sea Cosmetics

Established 2004
 Employees 27 plus 7 franchisees
 Sales increases of 150-270% over previous years since inception on HQ Miami, FL
 Mission to be forever hope my kids will keep going with this to be in every corner of the world to serve our customers in the best way we can
 Strength Honesty People appreciate honesty Believe in yourself, stay consistent, focused Work hard
 Number of Locations 300 year round, 450 holiday
 Area United States, international (Europe,

LATEST NEWS

Online Retailer Wilkes & Riley Opening First Store Next Month...
 September 26

11 Most Profitable Mall Kiosk Business Ideas
 September 26

ThinkGeek Continues Expansion, Opening at Woodland Hills Mall
 September 23

Now Open in Edina, Vineyard Vines Aims for Niche Set...
 September 23

St. Thomas Public Library Kiosk in Elgin Mall Foregoes Fast...
 September 23

Virtual Classroom Sets up in Jackson Mall
 September 22

Ivanhoe Cambridge's Search for Ideal

Join Our Email List

to receive free & timely industry info.

enter your email address

- Specialty Retail Snapshot
- SPREE
- Visual Victories
- Specialty Leasing Designation
- Specialty Leasing Summit
- Trendspotter

We will never sell your email address.

JOIN

Perfection) that promises to turn back the clock and rejuvenate skin.

Canada, Central America, South America)

“Cosmetics are like fashion. They will never disappear. People will always want them. It’s a lifetime product, a year-round business,” Sabag says—and the number of products is infinite.

Specialty retail beginnings

The man behind it all, Shay Sabag, moved to the United States in 1999. By the following year, he had made his first foray into the field of specialty retail in the Broward Mall in Plantation, FL.

During the holiday season, he expanded to six units. For the next three years, Sabag managed his retail business, all while he completed a Bachelor’s degree in Electrical Engineering from Florida Atlantic University at the Boca Raton campus.

In 2003, Sabag moved to the Connecticut/New York border to give a colder climate’s holiday season a try. Starting in the Trumbull and Danbury Fair Malls, he expanded to eighteen carts in seven different centers, carrying an assortment of products and specializing in cosmetics.

Dead Sea products come alive

But one particular set of products changed everything: Dead Sea products. Sabag immediately recognized their potential and could see that they would have lasting impact on the industry. Subsequently, Sabag would become one of the pioneers of the industry. “At that time, no one had heard about the Dead Sea,” he says.

The first products Sabag sold at that time were Nail Kits, containing Nail Buffer, Cuticle Conditioner and Hand and Body Lotion. “That was the winning concept at the time,” he says. Then he added the Body Salt Scrub, which sold “like crazy,” and soon, he was also selling Body Butter and Facial Peeling Gel.

Sabag has been in the business for so long, that he says he can intuitively predict the next bestseller. “I got to really understand these products and knew that the Dead Sea cosmetics line of products can go as far as any other line of cosmetics in the world and even beyond due to its natural ingredients and medical benefits,” says Sabag.

Location look
September 22

DIRECTORY OF MAJOR MALLS®
Leads.

Online
1-800-898-MALL

DIRECTORY OF MAJOR MALLS®
Contacts.

On CD
shoppingcenters.com

SEARCH & B
SPECIALTY LEAS
SHOPPING CENT

casuallease.c
info@casuallease.c
advertising spa

SPREE MEETUP
February 2016
Miami, Florida

- TRENDING**
-  18th Annual Visual Victories Awards
 -  Specialty Retail Trends in Franchising
 -  Pretzel Franchise Round-up



Make Your Pop-Up
Look Permanent



Play
Sprockets
Spins the
Wheel of Success



Swimming towards wholesale

With wholesaling in mind, in 2004, Sabag returned to look for a factory and a lab that would be able to bring the most innovative high-end line of cosmetics to the market, “he says. His intention was to create cutting-edge Dead Sea cosmetics using the best technology and formulations available. Once his factory was secured, and his line was ready to market, retailers quickly jumped on board. Carts began to sprout up in Florida and spread throughout the East Coast, eventually making their way throughout the entire United States.

By the end of 2004, Deep Sea had approximately 60 carts along the East Coast retailing their products. By the second year, that number jumped to 150. And today, during the bustling holiday season, Deep Sea carts number 450. The product line has also grown, from 12 products to approximately 60 by Deep Sea Cosmetics Laboratories. Retailers carry an average of 40 different products on their units.

But Deep Sea doesn't swim alone. In fact, Sabag estimates there are about 15 competing companies selling Dead Sea products through specialty retail venues today. “What has kept us so unique, different and powerful is the service and honesty we give to our customers,” says Sabag adding that he supports retailers through good times and bad in every aspect of the business. “Everyone that works with us stays with us,” he adds.

Deep Sea prides itself on an extensive training program. The company sends two trainers to each retail location so retailers can learn all aspects of the business. They educate retailers about the benefits of the products and sales techniques based on a polite

demonstration approach. This gives the customer a joyful purchasing experience. "It's another reason for our long-term business stability in malls," says Sabag. Training takes an average of five weekdays. "We go to each location if a retailer is in different malls. We tailor our approach to the type of mall in order to create the winning outcome which is repeat customers," he says. Deep Sea Cosmetics has a very high percentage of repeat customers which point to the quality of the products and its superior customer service.



The complete treatment equals multiple sales

Deep Sea products have instant beneficial results, which can make a significant effect on overall purchases. "We demo one product, and thereafter introduce other products, giving the customer the best professional advice for best complete treatment results," says Sabag. "It's our obligation as a cosmetics distributor to provide the customer with the best professional advice. It's often happened that Deep Sea representatives give a professional consultation even with out making a sale," says Sabag.

Promotional incentives (such as discounts and free gifts) are offered to attract repeat customers to the malls in order to make fast sales without the need to demonstrate the products. Deep Sea retail locations stock many product categories including: Body Care, Facial Care, Nail Care and Age Perfection. Many mall customers are already familiar with the Deep Sea Cosmetics brand and visit the retail locations on their own. Sales representatives invite passersby to try a product, or they generously hand out free samples in the hopes of encouraging future sales. A DVD showing Deep Sea's products in action plays at the cart to entice customers to give the products a try.

Packaging is also designed to attract customers' attention. The

key concepts are "clean, upscale and contemporary," says Sabag.

New packaging is introduced every three years to remain contemporary and eye-catching.

A natural solution

Deep Sea's products use natural ingredients to heal and rejuvenate all types of skin. "The big advantage is we are not using chemicals. The sale of natural products gets bigger and bigger. We are the only company that sells paraben-free, alcohol-free, and mostly fragrance-free products," says Sabag.

The star attractions are, of course, the ingredients from the Dead Sea. The Dead Sea is a landlocked salt lake with waters nearly ten times as salty as the world's oceans. It is renowned not only for its salty seawater, with high concentrations of minerals, but for its therapeutic black mud. Its restorative waters have been known to heal skin problems, such as acne, psoriasis, eczema, and skin allergies. It is also said to fight the signs of aging and decrease muscle tension.

The Dead Sea draws tens of thousands of people each year from around the world. But for the thousands who have neither the time nor the budget to visit, Deep Sea Cosmetics brings the Dead Sea's healing powers into homes across the country at an affordable price.

In addition to Dead Sea minerals, many other natural ingredients can be found in the Deep Sea product line: sweet almond oil, citrus oil, beeswax, apricots, the list goes on.

As for what products sell the best, Deep Sea has many bestsellers, with some products remaining in the top ten year after year. These include the Body Salt Scrub, Body Butter, Facial Peeling Gel and the Nail Kit. Black Diamond Magnetism Mud Mask from the Age Perfection Series, a product used as an anti-wrinkle and anti-expression line treatment, was recently added to the list.



A new series

The Age Perfection Series made its debut in the fourth quarter of 2009, and encompasses a total of 16 products that blend Dead Sea minerals, peptides (an alternative to Botox), anti-oxidants, vitamins and herbal extracts to enhance health and beauty and slow the signs of aging, says Sabag. As we age, collagen production slows. But if the skin is hydrated and collagen structure is preserved, youthful and vibrant skin can be found on women of all ages. The ingredients in the Age Perfection Series are designed to turn back the hands of time.

Hexalin is one of the key ingredients in the line. It is a combination of six peptides, proteins and natural plant amino acids that help reduce facial expression lines and increase skin tightening, says Sabag. Especially suited for mature skin, Hexalin works by stimulating and preserving collagen production. Products with Hexalin include Elasto Lift Thermal Mask, Expression Corrective Cream SPF-15, and Intensive Revival Facial Serum.

Another product in the Series, Multi Vital Night Anti Wrinkle Cream, uses Helioguard as an ingredient, made from nourishing red algae. Along with Dead Sea minerals, vitamins and peptide complex, this cream is intended to accelerate skin renewal, promoting a soft, smooth, younger appearance.

There is even a cream to help with age spots: White Angel—Pigment Whitening Cream. Featuring an exclusive whitening complex called Nano White and infused with peptide complex, vitamins, Omega-3 and Dead Sea minerals, this cream helps reduce the appearance of age spots and evens out skin tones.

And last, but definitely not least, the series includes Adore Skin Tightening Instant Face Lift. Through a unique peptide complex of

natural amino acids that acts as an anti-wrinkle agent, this product promises fine lines and wrinkles will disappear for a total of eight hours after only a 60-second application.

Because of the special ingredients in the Age Perfection Series, and the much-sought-after effects they produce, age defying products carry a higher average retail than the rest of the line: \$160 – \$350 a product.

What men want

Men are another important demographic Deep Sea serves. While they don't purchase as much as women, their interest is increasing, "recently men are really into cosmetics," says Sabag. Products for men include scrubs, lotions, sensitive cleansers, aftershave, and body butter, all with a "unique men's fragrance," Sabag says. There are also unisex products in the Deep Sea line, such as Body Salt Scrub and Body Butter.

The magic word in the sale of every Deep Sea product is "treatment." Because of the many beneficial and active ingredients contained within the products, they are much more than cosmetics, they are like "shelf drugs," says Sabag.

"We introduce new products every couple of months. We always work in sync with our retailers. Our customers will come with a demand. They ask for it—we develop it," says Sabag.

Swimming in the Deep Sea

Training is but one of the many tools Deep Sea offers its retailers. Deep Sea helps retailers find locations and employees, as well as outfits their units with eye-catching displays.

Start-up packages range from \$5,000 to \$10,000. "We also have a lot of independent retailers that do everything themselves," says Sabag.

When it comes to establishing a location, Deep Sea excels. As of 2008, Deep Sea has had an exclusivity deal with Simon Property Group. In other words, Deep Sea is the largest Dead Sea specialty retailer in Simon malls. "In 2010, we were the biggest specialty retailer in the Simon Property Group for the third year in a row. Deep Sea has 150 locations in Simon shopping centers," says Sabag.

Deep Sea also works with other developers: General Growth

Inc. to name a few. “We have a good relationship with all the big guys, but the major exclusivity agreement is with the Simon Group (which included the Mills),” says Sabag.

Relationships are important at Deep Sea, not only with developers, but with every fellow employee, both out in the field and in the corporate office. Sabag supports his corporate staff as strongly as he supports his retailers, emphasizing he has not climbed the specialty retail corporate ladder on his own. Their success is his success, he says.

But perhaps the best part of joining the Deep Sea team is its longevity in the specialty retail world. Retailers can take a bite out of something they can hold onto. Women have been using and replenishing Deep Sea cosmetics for years. And new customers desiring natural products continue to come forward, especially in search of ways to retain a youthful appearance. With Deep Sea cosmetics, beauty is not only skin deep—it’s quite profitable.



Success with Strong Staff

Deep Sea Cosmetics has locations in top malls across the United States and continues to grow with the help and dedication of its vice president, Tziyona Cohen. Cohen was introduced to Deep Sea Cosmetics as a customer, joined as an employee and worked her way up through hard work, focus and devotion.

Cohen, who has been vice president since 2007, manages all customer needs. She helps in matching customers to the right lease agreement and retail location. By placing customers in the best retail locations, Deep Sea Cosmetics contributes to the stability of the Dead Sea cosmetics concept.



Cohen believes in Deep Sea Cosmetics, and can see the potential of the company, which continues to grow above and beyond expectations. These accomplishments would not have been possible without the customer satisfaction that Deep Sea Cosmetics provides to their clientele, Cohen says. Each individual leaseholder gets the full personal attention necessary and is always given the feeling that they are part of the Deep Sea family. This is one aspect that definitely makes Deep Sea Cosmetics stand out from the rest, Cohen adds.

Emily Lambert

Lambert, a senior writer for SRR, resides in Philadelphia. She can be reached at emily.lambert@comcast.net
[View articles by Emily Lambert →](#)

RELATED



Organic Innovation: Lifting the Face of Specialty Retail

M•A•C Cosmetics Brings Upscale Makeup to Travelers at...

Holyoke Mall Black Friday Sales Attract Thousands With Deep...



Sweet Dreams Are Made of This

Taubman: 'His loss leaves a huge hole in our...

Phone: 781.709.2420

Fax: 781.829.1042

© 2000-2016 International Council of Shopping Centers

DRIVE business.

Make MONEY.

Find UNIQUE concepts.
DISCOVER hot products.

For only \$29.95 you can have the
industry's #1 resource.



Subscribe today and save!

EXHIBIT 10

Generated on: This page was generated by TSDR on 2016 08 22 15:19:47 EDT

Mark: ADORE ORGAN C NNOVAT ON



US Serial Number: 85765621

Application Filing Date: Oct 29 2012

US Registration Number: 4453496

Registration Date: Dec 24 2013

Filed as TEAS Plus: Yes

Currently TEAS Plus: Yes

Register: Principal

Mark Type: Trademark

TM5 Common Status Descriptor:



LIVE/REG STRAT ON/ issued and Active

The trademark application has been registered with the Office

Status: Registered The registration date is used to determine when post registration maintenance documents are due

Status Date: Dec 24 2013

Publication Date: Apr 23 2013

Mark Information

Mark Literal Elements: ADORE ORGAN C NNOVAT ON

Standard Character Claim: No

Mark Drawing Type: 5 AN ILLUSTRATION DRAWING WITH WORD(S)/LETTER(S)/NUMBER(S) IN STYLED FORM

Description of Mark: The mark consists of the word "Adore" and below this the words "Organic" and "innovation"

Color(s) Claimed: Color is not claimed as a feature of the mark

Disclaimer: "ORGAN C"

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

- Brackets [] indicate deleted goods/services;
- Double parenthesis (()) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and
- Asterisks * * identify additional (new) wording in the goods/services

For: Organic cosmetics and organic cosmetic preparations

International Class(es): 003 Primary Class

U.S Class(es): 001 004 006 050 051 052

Class Status: ACTIVE

Basis: 1(a)

First Use: Jun 28 2012

Use in Commerce: Jun 28 2012

Basis Information (Case Level)

Filed Use: Yes

Currently Use: Yes

Amended Use: No

Filed ITU: No

Currently ITU: No

Amended ITU: No

Filed 44D: No

Currently 44D: No

Amended 44D: No

Dec 07 2012	NON F NAL ACT ON WR TTEN	82421
Nov 29 2012	ASS GNED TO EXAM NER	82421
Nov 02 2012	NEW APPL CAT ON OFF CE SUPPL ED DATA ENTERED N TRAM	
Nov 01 2012	NEW APPL CAT ON ENTERED N TRAM	

TM Staff and Location Information

TM Staff Information None

File Location

Current Location: PUBL CAT ON AND SSUE SECT ON Date in Location: Dec 24 2013

Proceedings

Summary

Number of Proceedings: 1

Type of Proceeding: Opposition

Proceeding Number: [91210372](#) Filing Date: Apr 24 2013
 Status: Terminated Status Date: Nov 18 2013
 Interlocutory Attorney: CHERYL S GOODMAN

Defendant

Name: Universal Handicraft nc
 Correspondent Address: SAMUEL A LEW S
 FELDMAN GALE PA
 ONE B SCAYNE TOWER 30TH FLOOR 2 SOUTH B SCAYNE BLVD
 M AM FL UN TED STATES 33131 4332
 Correspondent e mail: RWeaver@FeldmanGale.com Trademarks@FeldmanGale.com JFeldman@FeldmanGale.com SLewis@FeldmanGale.com RWeaver@FeldmanGale.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
ADORE ORGAN C NNOVAT ON	Registered	85765621	4453496

Plaintiff(s)

Name: Parfums Christian Dior S A
 Correspondent Address: LAURA POPP ROSENBERG
 FROSS ZELN CK LEHRMAN & Z SSU PC
 866 UN TED NAT ONS PLAZA
 NEW YORK NY UN TED STATES 10017
 Correspondent e mail: lpopp_rosenberg@fzlz.com ykarzoan@frosszelnick.com jinsley_pruitt@frosszelnick.com

Associated marks

Mark	Application Status	Serial Number	Registration Number
JADORE	Renewed	75667022	2696047
JADORE	Renewed	75378164	2455674

Prosecution History

Entry Number	History Text	Date	Due Date
1	F LED AND FEE	Apr 24 2013	
2	NOT CE AND TR AL DATES SENT; ANSWER DUE:	Apr 24 2013	Jun 03 2013
3	PEND NG NST TUTED	Apr 24 2013	
4	MOT TO AMEND APPL CAT ON	May 29 2013	
5	ST P TO SUSPEND PEND D SP C V ACT ON	May 29 2013	
6	SUSPENDED	May 29 2013	
7	W/DRAW OF OPPOS T ON	Oct 01 2013	
8	RESPONSE DUE 30 DAYS (DUE DATE)	Oct 03 2013	Nov 02 2013
9	MOT TO AMEND APPL CAT ON	Nov 01 2013	

10	RESPONSE DUE 30 DAYS (DUE DATE)	Nov 06 2013	Dec 06 2013
11	MOT TO AMEND APPL CAT ON	Nov 07 2013	
12	BD DEC S ON: D SM SSED W/O PREJ	Nov 18 2013	
13	TERM NATED	Nov 18 2013	

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO Form 2100 (Rev 09/2005)

OMB No. 0951-0060 (Exp 09/30/2017)

Revocation of Attorney/Domestic Representative and/or Appointment of Attorney/Domestic Representative

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85765621
REGISTRATION NUMBER	4453496
LAW OFFICE ASSIGNED	LAW OFFICE 114
MARK SECTION	
MARK	ADORE ORGANIC INNOVATION (stylized and/or with design)
ATTORNEY SECTION	
ORIGINAL ADDRESS	SAMUEL A LEWIS Adore Organi 1005 Park Centre Blvd 1005 Park Centre B 2 SOUTH BISCAYNE BLVD MIAMI Florida 33169 US 3056279370 3056279371 francisco@adorecosmetics.com;francisco@adorecosmetics.com
NEW ATTORNEY ADDRESS	
STATEMENT TEXT	By submission of this request, the undersigned REVOKES the power of attorney currently of record, as listed above, and hereby APPOINTS the following new attorney:
NAME	ASHLEY G. KESSLER
FIRM NAME	COZEN O'CONNOR
INTERNAL ADDRESS	2 SOUTH BISCAYNE BOULEVARD
STREET	ONE BISCAYNE TOWER, 30TH FLOOR
CITY	Miami
STATE	Florida
COUNTRY	United States
POSTAL/ZIP CODE	33131
PHONE	305-358-5001
FAX	305-358-3309
EMAIL	akessler@cozen.com
ATTORNEY AUTHORIZED TO COMMUNICATE VIA E-MAIL	YES
NEW CORRESPONDENCE ADDRESS	
NAME	ASHLEY G. KESSLER

FIRM NAME	COZEN O'CONNOR
INTERNAL ADDRESS	2 SOUTH BISCAYNE BOULEVARD
STREET	ONE BISCAYNE TOWER, 30TH FLOOR
CITY	Miami
STATE	Florida
COUNTRY	United States
POSTAL/ZIP CODE	33131
PHONE	305-358-5001
FAX	305-358-3309
EMAIL	akessler@cozen.com;phipdocketing@cozen.com;mlima@cozen.com; breyes@cozen.com
AUTHORIZED TO COMMUNICATE VIA E-MAIL	YES
INDIVIDUAL ATTORNEY DOCKET/REFERENCE NUMBER	
SIGNATURE SECTION	
SIGNATURE	/Ashley G. Kessler/
SIGNATORY NAME	Ashley G. Kessler
SIGNATORY DATE	07/02/2016
SIGNATORY POSITION	Attorney of Record, Member of the New York and New Jersey Bar
FILING INFORMATION SECTION	
SUBMIT DATE	Tue Jul 05 09:03:52 EDT 2016
TEAS STAMP	USPTO/RAA-XX.XXX.XX.XXX-2 0160705090352526562-77536 781-550f6a8c1b52764d20922 cf9e9868b6c4cbf169a36fbee 561ff926ad5c51e2825-N/A-N /A-20160701151553259642

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO Form 2196 (Rev 09/2005)

OMB No. 0651-0056 (Exp 09/30/2017)

Revocation of Attorney/Domestic Representative and/or Appointment of Attorney/Domestic Representative

To the Commissioner for Trademarks:

MARK: ADORE ORGANIC INNOVATION (stylized and/or with design)

SERIAL NUMBER: 85765621

REGISTRATION NUMBER: 4453496

The original attorney

SAMUEL A LEWIS

Adore Organi

1005 Park Centre Blvd 1005 Park Centre B

2 SOUTH BISCAYNE BLVD

MIAMI Florida 33169

US

3056279370

3056279371

francisco@adorecosmetics.com;francisco@adorecosmetics.com

Original Correspondence Address :

SAMUEL A LEWIS

FELDMAN GALE PA

1005 Park Centre Blvd 1005 Park Centre B

2 SOUTH BISCAYNE BLVD

MIAMI Florida 33169

US

3056279370

3056279371

francisco@adorecosmetics.com;francisco@adorecosmetics.com

By submission of this request, the undersigned REVOKES the power of attorney currently of record, as listed above, and hereby APPOINTS the following new attorney:

Newly Appointed Attorney:

ASHLEY G. KESSLER

COZEN O'CONNOR

2 SOUTH BISCAYNE BOULEVARD

ONE BISCAYNE TOWER, 30TH FLOOR

Miami, Florida 33131

United States

305-358-5001

305-358-3309

akessler@cozen.com

The following is to be used as the correspondence address:

ASHLEY G. KESSLER

COZEN O'CONNOR

2 SOUTH BISCAYNE BOULEVARD

ONE BISCAYNE TOWER, 30TH FLOOR

Miami, Florida 33131

United States

305-358-5001

305-358-3309

akessler@cozen.com;phipdocketing@cozen.com;mlima@cozen.com;breyes@cozen.com

Signature: /Ashley G. Kessler/ Date: 07/02/2016

Signatory's Name: Ashley G. Kessler

Signatory's Position: Attorney of Record, Member of the New York and New Jersey Bar

Serial Number: 85765621

Internet Transmission Date: Tue Jul 05 09:03:52 EDT 2016

TEAS Stamp: USPTO/RAA-XX.XXX.XX.XXX-2016070509035252

6562-77536781-550f6a8c1b52764d20922cf9e9

868b6c4cbf169a36fbee561ff926ad5c51e2825-

N/A-N/A-20160701151553259642



Please note that U.S. Customs & Border Protection (CBP), a bureau of the Department of Homeland Security, maintains a trademark recordation system for marks registered at the United States Patent and Trademark Office. Parties who register their marks on the Principal Register may record these marks with CBP, to assist CBP in its efforts to prevent the importation of goods that infringe registered marks. The recordation database includes information regarding all recorded marks, including images of these marks. CBP officers monitor imports to prevent the importation of goods bearing infringing marks, and can access the recordation database at each of the 317 ports of entry.

CBP's Intellectual Property Rights e-Recordation (IPRR) system, located at <https://apps.cbp.gov/e-recordations/>, allows right holders to electronically file IPR recordation applications, thus significantly reducing the amount of time normally required to process paper applications. Some additional benefits of the system include:

- Elimination of paper applications and supporting documents.
- Copies of the certificate issued by the registering agency (U.S. Patent and Trademark Office or the Copyright Office) are retained by the right holder, not submitted to CBP.
- Payment by credit card (preferred), check or money order.
- Ability to upload images of the protected work or trademark, thus obviating the need to send samples to CBP.
- Reduced time from filing of the application to enforcement by field personnel.

Information about how to obtain a recordation, and about CBP's Intellectual Property Rights border enforcement program, is available at CBP's web site, www.cbp.gov.



United States of America

United States Patent and Trademark Office

Adore
Organic Innovation

Reg. No. 4,453,496

Registered Dec. 24, 2013

Int. Cl.: 3

TRADEMARK

PRINCIPAL REGISTER

UNIVERSAL HANDICRAFT, INC. (FLORIDA CORPORATION), DBA DEEP SEA COSMETICS
1005 PARK CENTRE BLVD
MIAMI, FL 33169

FOR: ORGANIC COSMETICS AND ORGANIC COSMETIC PREPARATIONS, IN CLASS 3
(U.S. CLS. 1, 4, 6, 50, 51 AND 52).

FIRST USE 6-28-2012; IN COMMERCE 6-28-2012.

NO CLAIM IS MADE TO THE EXCLUSIVE RIGHT TO USE "ORGANIC", APART FROM
THE MARK AS SHOWN.

THE MARK CONSISTS OF THE WORD "ADORE" AND BELOW THIS THE WORDS "OR-
GANIC" AND "INNOVATION".

SER. NO. 85-765,621, FILED 10-29-2012.

SHAILA LEWIS, EXAMINING ATTORNEY



Deborah S. Cohn

Commissioner for Trademarks of the
United States Patent and Trademark Office

**REQUIREMENTS TO MAINTAIN YOUR FEDERAL
TRADEMARK REGISTRATION**

**WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE
DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.**

Requirements in the First Ten Years*

What and When to File:

- **First Filing Deadline:** You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. *See* 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.
- **Second Filing Deadline:** You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* *See* 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*

What and When to File:

- You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

**The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or
reminder of these filing requirements.**

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. *See* 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. *See* 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see <http://www.wipo.int/madrid/en/>.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at <http://www.uspto.gov>.

**WARNING FROM THE USPTO
CONCERNING UNOFFICIAL TRADEMARK SOLICITATIONS**

Please be aware that private companies not associated with the United States Patent and Trademark Office (USPTO) often use trademark application and registration information from the USPTO's databases to mail or e-mail trademark-related solicitations. These may include offers: (1) for legal services; (2) for trademark monitoring services; (3) to record trademarks with U.S. Customs and Border Protection; and (4) to "register" trademarks in a private registry.

These companies may use names that resemble the USPTO name, including, for example, one or more of the terms "United States," "U.S.," "Trademark," "Patent," "Registration," "Office," or "Agency." Increasingly, some companies attempt to make their solicitations mimic the look of official government documents rather than the look of a typical commercial or legal solicitation by emphasizing official government data like the USPTO application serial number, the registration number, the International Class(es), filing dates, and other information that is publicly available from USPTO records. Many refer to other government agencies and sections of the U.S. Code. Most require "fees" to be paid.

Some applicants and registrants have reported paying fees to these private companies, mistakenly thinking that they were paying required fees to the USPTO. So, be sure to read trademark-related communications carefully before making a decision about whether to respond. **All official correspondence will be from the "United States Patent and Trademark Office" in Alexandria, VA, and if by e-mail, specifically from the domain "@uspto.gov."**

If you receive a trademark-related solicitation that you believe is deceptive, you may file an on-line consumer complaint with the Federal Trade Commission ("FTC"), at www.FTC.gov. Although the FTC does not resolve individual consumer complaints, it may institute, as the nation's consumer protection agency, investigations and prosecutions based on widespread complaints about particular companies or business practices. In addition, the USPTO encourages recipients of deceptive trademark-related solicitations to contact their states' consumer protection authorities. Many, if not all, states have the authority to issue investigative subpoenas and file complaints against companies engaged in deceptive practices directed toward state residents.

For further information about, as well as several examples of, these non-USPTO solicitations, please visit the page on the www.USPTO.gov website entitled "**WARNING: Non-USPTO Solicitations That May Resemble Official USPTO Communications.**"

United States Patent and Trademark Office
Commissioner for Trademarks
P.O. Box 1451
Alexandria, VA 22313-1451
If Undeliverable Return in Ten Day

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, \$300

AN EQUAL OPPORTUNITY EMPLOYER



unc

4453496 85765621 12/24/13
SAMUEL A LEWIS
FELDMAN GALE PA
ONE BISCAYNE TOWER, 30TH FLOOR 2 SOUTH B
ISCAYNE BLVD
MIAMI, FL 33131-4332

NIXIE 331311503-1N 01/04/14
RETURN TO SENDER
ATTEMPTED - NOT KNOWN
UNABLE TO FORWARD
RETURN TO SENDER

|||||

United States of America
United States Patent and Trademark Office

Adore
Organic Innovation

Reg. No. 4,453,496

Registered Dec. 24, 2013

Int. Cl.: 3

TRADEMARK

PRINCIPAL REGISTER

UNIVERSAL HANDICRAFT, INC. (FLORIDA CORPORATION), DBA DEEP SEA COSMETICS
1005 PARK CENTRE BLVD
MIAMI, FL 33169

FOR: ORGANIC COSMETICS AND ORGANIC COSMETIC PREPARATIONS, IN CLASS 3
(U.S. CLS. 1, 4, 6, 50, 51 AND 52).

FIRST USE 6-28-2012; IN COMMERCE 6-28-2012.

NO CLAIM IS MADE TO THE EXCLUSIVE RIGHT TO USE "ORGANIC", APART FROM
THE MARK AS SHOWN.

THE MARK CONSISTS OF THE WORD "ADORE" AND BELOW THIS THE WORDS "OR-
GANIC" AND "INNOVATION".

SER. NO. 85-765,621, FILED 10-29-2012.

SHAILA LEWIS, EXAMINING ATTORNEY



Deborah S. Cohn

Commissioner for Trademarks of the
United States Patent and Trademark Office

**REQUIREMENTS TO MAINTAIN YOUR FEDERAL
TRADEMARK REGISTRATION**

**WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE
DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.**

Requirements in the First Ten Years*

What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods*

What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

***ATTENTION MADRID PROTOCOL REGISTRANTS:** The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see <http://www.wipo.int/madrid/en/>.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at <http://www.uspto.gov>.

UNITED STATES PATENT AND TRADEMARK OFFICE
Trademark Trial and Appeal Board
P.O. Box 1451
Alexandria, VA 22313-1451

csg/nmt

Mailed: November 18, 2013

Opposition No. 91210372

Parfums Christian Dior, S.A.

v.

Universal Handicraft, Inc.

On November 7, 2013, the parties filed a renewed proposed amendment to application Serial No. 85765621, with opposer's consent, and opposer's withdrawal without prejudice of the opposition without prejudice, contingent upon entry of the amendment.

By the proposed amendment applicant seeks to change the identification of goods in International Class 3 as follows:

from

"Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general, including organic perfumes"

to

"Organic cosmetics and organic cosmetic preparations."

Inasmuch as the amendment is clearly limiting in nature as required by Trademark Rule 2.71(a), and because opposer consents thereto, it is approved and entered. See Trademark Rule 2.133(a).

Opposition No. 91210372

The contingency in opposer's withdrawal having now been met, the opposition is dismissed without prejudice.

*By the Trademark Trial
and Appeal Board*

Change Of Correspondence Address

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85765621
LAW OFFICE ASSIGNED	LAW OFFICE 114
MARK SECTION	
MARK	ADORE ORGANIC INNOVATION (stylized and/or with design)
NEW CORRESPONDENCE ADDRESS	
NEW ADDRESS	
AUTHORIZED TO COMMUNICATE VIA E-MAIL	YES
SIGNATURE SECTION	
SIGNATURE	/Shay/Segev/
SIGNATORY NAME	Shay Segev
SIGNATORY DATE	11/12/2013
SIGNATORY POSITION	Owner
SIGNATORY PHONE NUMBER	3056279370
AUTHORIZED SIGNATORY	YES
FILING INFORMATION SECTION	
SUBMIT DATE	Tue Nov 12 12:58:16 EST 2013
TEAS STAMP	USPTO/PRA-XX.XX.XX.XXX-20 131112125816454401-857656 21-5008d6252b157739244236 f7c127a4ed0e58672665cf6c1 01c579940dadb5761d-N/A-N/ A-20131112123917447246

PTO Form 1866 (Rev 9/2006)
 DMB No. 0851 0050 (Exp. 07/31/2017)

Voluntary Amendment

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85765621
LAW OFFICE ASSIGNED	LAW OFFICE 114
MARK SECTION	
MARK FILE NAME	http://tess2.uspto.gov/ImageAgent/ImageAgentProxy?getImage=85765621
LITERAL ELEMENT	ADORE ORGANIC INNOVATION
STANDARD CHARACTERS	NO
USPTO-GENERATED IMAGE	NO
OWNER SECTION (current)	
NAME	Universal Handicraft, Inc.
DBA/AKA/TA/Formerly	DBA Deep Sea Cosmetics
STREET	1005 Park Centre Blvd
CITY	Miami
STATE	Florida
ZIP/POSTAL CODE	33169
COUNTRY	United States
PHONE	3056279370
EMAIL	shayxr@hotmail.com
OWNER SECTION (proposed)	
NAME	Universal Handicraft, Inc.
DBA/AKA/TA/Formerly	DBA Adore Organic Innovation
STREET	1005 Park Centre Blvd
CITY	Miami
STATE	Florida
ZIP/POSTAL CODE	33169
COUNTRY	United States
PHONE	3056279370
EMAIL	shayxr@hotmail.com
LEGAL ENTITY SECTION (current)	
TYPE	corporation
STATE/COUNTRY OF INCORPORATION	Florida
LEGAL ENTITY SECTION (proposed)	

TYPE	corporation
STATE/COUNTRY OF INCORPORATION	Florida
GOODS AND/OR SERVICES SECTION (current)	
INTERNATIONAL CLASS	003
DESCRIPTION	
Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general, including organic perfumes	
FILING BASIS	Section 1(a)
FIRST USE ANYWHERE DATE	At least as early as 06/28/2012
FIRST USE IN COMMERCE DATE	At least as early as 06/28/2012
GOODS AND/OR SERVICES SECTION (proposed)	
INTERNATIONAL CLASS	003
TRACKED TEXT DESCRIPTION	
Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general, including organic perfumes; Organic cosmetics in general.	
FINAL DESCRIPTION	
Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general.	
FILING BASIS	Section 1(a)
FIRST USE ANYWHERE DATE	At least as early as 06/28/2012
FIRST USE IN COMMERCE DATE	At least as early as 06/28/2012
CORRESPONDENCE SECTION	
ORIGINAL ADDRESS	SAMUEL A LEWIS FELDMAN GALE PA ONE BISCAYNE TOWER, 30TH FLOOR 2 SOUTH BISCAYNE BLVD MIAMI Florida (FL) US 33131-4332
NEW CORRESPONDENCE SECTION	
NAME	SAMUEL A LEWIS
FIRM NAME	Shay Segev
DOCKET/REFERENCE NUMBER	Adore Organi
INTERNAL ADDRESS	1005 Park Centre Blvd
STREET	1005 Park Centre Blvd
CITY	MIAMI
STATE	Florida
ZIP/POSTAL CODE	33169
COUNTRY	United States
PHONE	3056279370
FAX	3056279371
EMAIL	francisco@adorecosmetics.com;francisco@adorecosmetics.com

AUTHORIZED EMAIL COMMUNICATION	Yes
SIGNATURE SECTION	
RESPONSE SIGNATURE	/Shay/Segev/
SIGNATORY'S NAME	Shay Segev
SIGNATORY'S POSITION	Owner
SIGNATORY'S PHONE NUMBER	3056279370
DATE SIGNED	11/12/2013
AUTHORIZED SIGNATORY	YES
FILING INFORMATION SECTION	
SUBMIT DATE	Tue Nov 12 12:58:16 EST 2013
TEAS STAMP	USPTO/PRA-XX.XX.XX.XXX-20 131112125816454401-857656 21-5008d6252b157739244236 f7c127a4ed0e58672665cf6c1 01c579940dadb5761d-N/A-N/ A-20131112123917447246

PTO Form 1996 (Rev 5/2008)
CMB No. 0651 0060 (Exp 07/31/2017)

Voluntary Amendment

To the Commissioner for Trademarks:

Application serial no. **85765621** ADORE ORGANIC INNOVATION (Stylized and/or with Design, see <http://tess2.uspto.gov/ImageAgent/ImageAgentProxy?getImage=85765621>) has been amended as follows:

CLASSIFICATION AND LISTING OF GOODS/SERVICES

Applicant proposes to amend the following class of goods/services in the application:

Current: Class 003 for Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general, including organic perfumes

Original Filing Basis:

Filing Basis: Section 1(a), Use in Commerce: The applicant is using the mark in commerce, or the applicant's related company or licensee is using the mark in commerce, on or in connection with the identified goods and/or services. 15 U.S.C. Section 1051(a), as amended. The mark was first used at least as early as 06/28/2012 and first used in commerce at least as early as 06/28/2012, and is now in use in such commerce.

Proposed:

Tracked Text Description: Organic cosmetics; Organic cosmetics and organic cosmetic preparations; ~~Organic cosmetics in general, including organic perfumes;~~ Organic cosmetics in general.

Class 003 for Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general.

Filing Basis: Section 1(a), Use in Commerce: The applicant is using the mark in commerce, or the applicant's related company or licensee is using the mark in commerce, on or in connection with the identified goods and/or services. 15 U.S.C. Section 1051(a), as amended. The mark was first used at least as early as 06/28/2012 and first used in commerce at least as early as 06/28/2012, and is now in use in such commerce.

APPLICANT AND/OR ENTITY INFORMATION

Applicant proposes to amend the following:

Current: Universal Handicraft, Inc., DBA Deep Sea Cosmetics, a corporation of Florida, having an address of
1005 Park Centre Blvd
Miami, Florida 33169
United States

shayxr@hotmail.com

3056279370

Proposed: Universal Handicraft, Inc., DBA Adore Organic Innovation, a corporation of Florida, having an address of
1005 Park Centre Blvd
Miami, Florida 33169
United States
shayxr@hotmail.com
3056279370

CORRESPONDENCE ADDRESS CHANGE

Applicant proposes to amend the following:

Current:

SAMUEL A LEWIS
FELDMAN GALE PA
ONE BISCAYNE TOWER, 30TH FLOOR
2 SOUTH BISCAYNE BLVD
MIAMI
Florida (FL)
US
33131-4332

Proposed:

SAMUEL A LEWIS of Shay Segev, having an address of
1005 Park Centre Blvd 1005 Park Centre Blvd MIAMI, Florida 33169
United States
francisco@adorecosmetics.com;francisco@adorecosmetics.com
3056279370
3056279371
The docket/reference number is Adore Organi .

SIGNATURE(S)

Voluntary Amendment Signature

Signature: /Shay/Segev/ Date: 11/12/2013
Signatory's Name: Shay Segev
Signatory's Position: Owner

Signatory's Phone Number: 3056279370

The signatory has confirmed that he/she is not represented by either an authorized attorney or Canadian attorney/agent, and that he/she is either (1) the applicant or (2) a person(s) with legal authority to bind the applicant; and if an authorized U.S. attorney or Canadian attorney/agent previously represented him/her in this matter, either he/she has filed a signed revocation of power of attorney with the USPTO or the USPTO has granted the request of his/her prior representative to withdraw.

Mailing Address: SAMUEL A LEWIS
Shay Segev
1005 Park Centre Blvd
1005 Park Centre Blvd
MIAMI, Florida 33169

Serial Number: 85765621
Internet Transmission Date: Tue Nov 12 12:58:16 EST 2013
TEAS Stamp: USPTO/PRA-XX.XX.XX.XXX-20131112125816454
401-85765621-5008d6252b157739244236f7c12
7a4ed0e58672665cf6c101c579940dad5761d-N
/A-N/A-20131112123917447246

From: TMOfficialNotices@USPTO.GOV
Sent: Tuesday, April 23, 2013, 00:32 AM
To: lisa@acplegal.com
Subject: Adore Organi Official USPTO Notification TMOG Publication Confirmation for Serial Number 85765621

TRADEMARK OFFICIAL GAZETTE PUBLICATION CONFIRMATION

U.S. Serial Number: 85 765 621
Mark: ADORE ORGAN C INNOVATION (STYLIZED/DESIGN)
International Class(es): 003
Applicant: Universal Handicraft, Inc.
Docket/Reference Number: Adore Organi

The mark identified above has been published in the Trademark Official Gazette (TMOG) on April 23, 2013.

To View the Mark in the TMOG:

1. Click on the following link or paste the URL into an internet browser: http://www.uspto.gov/web/trademarks/tmog/20130423_OG.pdf#page=00000451
2. Locate your mark on the displayed page.

If the TMOG PDF file does not open to the page containing your mark (you must have an Adobe Reader installed on your workstation), click on the following link or paste the URL into an internet browser to review the Frequently Asked Questions about the Trademark Official Gazette: http://www.uspto.gov/trademarks/resources/tmog_faqs.jsp

On the publication date or shortly thereafter, the applicant should carefully review the information that appears in the TMOG for accuracy. If any information is incorrect due to USPTO error, the applicant should immediately email the requested correction to TMPostPubQuery@uspto.gov. For applicant corrections or amendments after publication, please file a post-publication amendment using the form available at <http://teasroa.uspto.gov/ppa/>. For general information about this notice, please contact the Trademark Assistance Center at 1-800-786-9199.

Significance of Publication for Opposition:

Any party who believes it will be damaged by the registration of the mark may file a notice of opposition (or extension of time therefor) with the Trademark Trial and Appeal Board. If no party files an opposition or extension request within thirty (30) days after the publication date, then eleven (11) weeks after the publication date, a certificate of registration should issue.

To view this notice and other documents for this application online, go to Trademark Status and Document Retrieval at <http://tsdr.uspto.gov/>, enter the United States application serial number and select the button labeled "Documents." NOTE: This notice will only be available online the next business day after receipt of this e-mail.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Trademarks
P O Box 1451
Alexandria VA 22313-1451
www.uspto.gov

Apr 3, 2013

NOTICE OF PUBLICATION

- | | | | |
|---|---------------------------------|---|--|
| 1 | Serial No
85 765 621 | 2 | Mark
ADORE ORGAN C NNOVAT ON
(STYL ZED/DES GN) |
| 3 | International Class(es)
3 | 5 | Applicant
Universal Handcraft nc |
| 4 | Publication Date
Apr 23 2013 | | |

The mark of the application identified appears to be entitled to registration. The mark will, in accordance with Section 12(a) of the Trademark Act of 1946, as amended, be published in the *Official Gazette* on the date indicated above for the purpose of opposition by any person who believes he will be damaged by the registration of the mark. If no opposition is filed within the time specified by Section 13(a) of the Statute or by rules 2.101 or 2.102 of the Trademark Rules, the Commissioner of Patents and Trademarks may issue a certificate of registration.

Copies of the trademark portion of the *Official Gazette* containing the publication of the mark may be obtained from:
The Superintendent of Documents
U S Government Printing Office
PO Box 371954
Pittsburgh PA 15250 7954
Phone 202 512 1800

By direction of the Commissioner

Email Address(es):

lisa@acplegal.com

From: TMOfficialNotices@USPTO.GOV
Sent: Wednesday, April 3, 2013, 03:27 AM
To: lisa@acplegal.com
Subject: Adore Organi Official USPTO Notification - Issuance of Notice of Publication for Serial Number 85765621

NOTIFICATION OF "NOTICE OF PUBLICATION"

Your trademark application (Serial No. 85765621) is scheduled to publish in the *Official Gazette* on Apr 23, 2013. To preview the Notice of Publication, go to <http://tdr.uspto.gov/search/action?sn=85765621>. If you have difficulty accessing the Notice of Publication, contact TDR@uspto.gov.

PLEASE NOTE:

1. The Notice of Publication may not be immediately available but will be viewable within 24 hours of this e-mail notification.
2. You will receive a second e-mail on the actual "Publication Date," which will include a link to the issue of the *Official Gazette* in which the mark has published.

Do NOT hit "Reply" to this e-mail notification. If you have any questions about the content of the Notice of Publication, contact TMPostPubQuery@uspto.gov.

Trademark Snap Shot Publication & Issue Review Stylesheet
(Table presents the data on Publication & Issue Review Complete)

OVERVIEW

SERIAL NUMBER	85765621	FILING DATE	10/29/2012
REG NUMBER	0000000	REG DATE	N/A
REGISTER	PRINCIPAL	MARK TYPE	TRADEMARK
NTL REG #	N/A	NTL REG DATE	N/A
TM ATTORNEY	LEWIS SHA LA E	LO ASSIGNED	114

PUB INFORMATION

RUN DATE	03/19/2013
PUB DATE	04/23/2013
STATUS	681 PUBLICATION/ISSUE REVIEW COMPLETE
STATUS DATE	03/18/2013
LITERAL MARK ELEMENT	ADORE ORGANIC INNOVATION

DATE ABANDONED	N/A	DATE CANCELLED	N/A
SECTION 2F	NO	SECTION 2F IN PART	NO
SECTION 8	NO	SECTION 8 IN PART	NO
SECTION 15	NO	REPUBLIC 12C	N/A
RENEWAL FILED	NO	RENEWAL DATE	N/A
DATE AMEND REG	N/A		

FILING BASIS

FILED BASIS		CURRENT BASIS		AMENDED BASIS	
1 (a)	YES	1 (a)	YES	1 (a)	NO
1 (b)	NO	1 (b)	NO	1 (b)	NO
44D	NO	44D	NO	44D	NO
44E	NO	44E	NO	44E	NO
66A	NO	66A	NO		
NO BASIS	NO	NO BASIS	NO		

MARK DATA

STANDARD CHARACTER MARK	NO
LITERAL MARK ELEMENT	ADORE ORGANIC INNOVATION
MARK DRAWING CODE	5 AN ILLUSTRATION DRAWING WITH WORD(S)/LETTER(S)/NUMBER(S) IN STYLED FORM
COLOR DRAWING FLAG	NO

CURRENT OWNER INFORMATION

PARTY TYPE	10 ORIGINAL APPLICANT
NAME	Universal Handicraft Inc
ADDRESS	1005 Park Centre Blvd Miami FL 33169
ENTITY	03 CORPORATION

C T ZENSH P	Florida
DBA/AKA	DBA Deep Sea Cosmetics
GOODS AND SERVICES	
INTERNAT ONAL CLASS	003
DESCR PT ON TEXT	Organic cosmetics Organic cosmetics and organic cosmetic preparations Organic cosmetics in general including organic perfumes

GOODS AND SERVICES CLASSIFICATION							
INTERNAT ONAL CLASS	003	F RST USE DATE	06/28/2012	F RST USE N COMMERCE DATE	06/28/2012	CLASS STATUS	6 ACT VE

MISCELLANEOUS INFORMATION/STATEMENTS	
CHANGE N REG STRAT ON	NO
COLORS CLA MED STATEMENT	Color is not claimed as a feature of the mark
D SCLA MER W/PREDETER TXT	"ORGAN C"
DESCR PT ON OF MARK	The mark consists of the word "Adore" and below this the words "Organic and nnovation"

PROSECUTION HISTORY				
DATE	ENT CD	ENT TYPE	DESCR PT ON	ENT NUM
03/18/2013	PREV	O	LAW OFF CE PUBL CAT ON REV EW COMPLETED	013
03/18/2013	AL E	A	ASS GNED TO L E	012
03/05/2013	CNSA	O	APPROVED FOR PUB PR NC PAL REG STER	011
03/05/2013	XAEC		EXAM NERS AMENDMENT ENTERED	010
03/05/2013	GNEN	O	NOT F CAT ON OF EXAM NERS AMENDMENT E MA LED	009
03/05/2013	GNEA	O	EXAM NERS AMENDMENT E MA LED	008
03/05/2013	CNEA	R	EXAM NERS AMENDMENT WR TTEN	007
12/07/2012	GNRN	O	NOT F CAT ON OF NON F NAL ACT ON E MA LED	006
12/07/2012	GNRT	F	NON F NAL ACT ON E MA LED	005
12/07/2012	CNRT	R	NON F NAL ACT ON WR TTEN	004
11/29/2012	DOCK	D	ASS GNED TO EXAM NER	003
11/02/2012	NWOS		NEW APPL CAT ON OFF CE SUPPL ED DATA ENTERED N TRAM	002
11/01/2012	NWAP		NEW APPL CAT ON ENTERED N TRAM	001

CURRENT CORRESPONDENCE INFORMATION	
ATTORNEY	Lisa Capote
CORRESPONDENCE ADDRESS	L SA CAPOTE ARRAST A & CAPOTE 80 SW 8TH ST STE 2310 M AM FL 33130 3058
DOMEST C REPRESENTAT VE	NONE

Adore

Organic Innovation

Trademark Snap Shot Publication Stylesheet
 (Table presents the data on Publication Approval)

OVERVIEW

SERIAL NUMBER	85765621	FILING DATE	10/29/2012
REG NUMBER	0000000	REG DATE	N/A
REGISTER	PRINCIPAL	MARK TYPE	TRADEMARK
NTL REG #	N/A	NTL REG DATE	N/A
TM ATTORNEY	LEWIS SHALE	LO ASSIGNED	114

PUB INFORMATION

RUN DATE	03/06/2013
PUB DATE	N/A
STATUS	680 APPROVED FOR PUBLICATION
STATUS DATE	03/05/2013
LITERAL MARK ELEMENT	ADORE ORGANIC INNOVATION

DATE ABANDONED	N/A	DATE CANCELLED	N/A
SECTION 2F	NO	SECTION 2F IN PART	NO
SECTION 8	NO	SECTION 8 IN PART	NO
SECTION 15	NO	REPUB 12C	N/A
RENEWAL FILED	NO	RENEWAL DATE	N/A
DATE AMEND REG	N/A		

FILING BASIS

FILED BASIS		CURRENT BASIS		AMENDED BASIS	
1 (a)	YES	1 (a)	YES	1 (a)	NO
1 (b)	NO	1 (b)	NO	1 (b)	NO
44D	NO	44D	NO	44D	NO
44E	NO	44E	NO	44E	NO
66A	NO	66A	NO		
NO BASIS	NO	NO BASIS	NO		

MARK DATA

STANDARD CHARACTER MARK	NO
LITERAL MARK ELEMENT	ADORE ORGANIC INNOVATION
MARK DRAWING CODE	5 AN ILLUSTRATION DRAWING WITH WORD(S)/LETTER(S)/NUMBER(S) IN STYLED FORM
COLOR DRAWING FLAG	NO

CURRENT OWNER INFORMATION

PARTY TYPE	10 ORIGINAL APPLICANT
NAME	Universal Handicraft Inc
ADDRESS	1005 Park Centre Blvd Miami FL 33169
ENTITY	03 CORPORATION

C T ZENSH P	Florida
DBA/AKA	DBA Deep Sea Cosmetics
GOODS AND SERVICES	
INTERNAT ONAL CLASS	003
DESCR PT ON TEXT	Organic cosmetics Organic cosmetics and organic cosmetic preparations Organic cosmetics in general including organic perfumes

GOODS AND SERVICES CLASSIFICATION							
INTERNAT ONAL CLASS	003	F RST USE DATE	06/28/2012	F RST USE N COMMERCE DATE	06/28/2012	CLASS STATUS	6 ACT VE

MISCELLANEOUS INFORMATION/STATEMENTS	
CHANGE N REG STRAT ON	NO
COLORS CLA MED STATEMENT	Color is not claimed as a feature of the mark
D SCLA MER W/PREDETER TXT	"ORGAN C"
DESCR PT ON OF MARK	The mark consists of the word Adore and below this the words Organic and nnovation

PROSECUTION HISTORY				
DATE	ENT CD	ENT TYPE	DESCR PT ON	ENT NUM
03/05/2013	CNSA	O	APPROVED FOR PUB PR NC PAL REG STER	011
03/05/2013	XAEC		EXAM NERS AMENDMENT ENTERED	010
03/05/2013	GNEN	O	NOT F CAT ON OF EXAM NERS AMENDMENT E MA LED	009
03/05/2013	GNEA	O	EXAM NERS AMENDMENT E MA LED	008
03/05/2013	CNEA	R	EXAM NERS AMENDMENT WR TTEN	007
12/07/2012	GNRN	O	NOT F CAT ON OF NON F NAL ACT ON E MA LED	006
12/07/2012	GNRT	F	NON F NAL ACT ON E MA LED	005
12/07/2012	CNRT	R	NON F NAL ACT ON WR TTEN	004
11/29/2012	DOCK	D	ASS GNED TO EXAM NER	003
11/02/2012	NWOS		NEW APPL CAT ON OFF CE SUPPL ED DATA ENTERED N TRAM	002
11/01/2012	NWAP		NEW APPL CAT ON ENTERED N TRAM	001

CURRENT CORRESPONDENCE INFORMATION	
ATTORNEY	Lisa Capote
CORRESPONDENCE ADDRESS	L SA CAPOTE ARRAST A & CAPOTE 80 SW 8TH ST STE 2310 M AM FL 33130 3058
DOMEST C REPRESENTAT VE	NONE

Adore

Organic Innovation

Trademark Snap Shot Amendment & Mail Processing Stylesheet
 (Table presents the data on Amendment & Mail Processing Complete)

OVERVIEW

SERIAL NUMBER	85765621	FILING DATE	10/29/2012
REG NUMBER	0000000	REG DATE	N/A
REGISTER	PRINCIPAL	MARK TYPE	TRADEMARK
NTL REG #	N/A	NTL REG DATE	N/A
TM ATTORNEY	LEWIS SHALE	LO ASSIGNED	114

PUB INFORMATION

RUN DATE	03/06/2013
PUB DATE	N/A
STATUS	680 APPROVED FOR PUBLICATION
STATUS DATE	03/05/2013
LITERAL MARK ELEMENT	ADORE ORGANIC INNOVATION

DATE ABANDONED	N/A	DATE CANCELLED	N/A
SECTION 2F	NO	SECTION 2F IN PART	NO
SECTION 8	NO	SECTION 8 IN PART	NO
SECTION 15	NO	REPUBLIC 12C	N/A
RENEWAL FILED	NO	RENEWAL DATE	N/A
DATE AMEND REG	N/A		

FILING BASIS

FILED BASIS		CURRENT BASIS		AMENDED BASIS	
1 (a)	YES	1 (a)	YES	1 (a)	NO
1 (b)	NO	1 (b)	NO	1 (b)	NO
44D	NO	44D	NO	44D	NO
44E	NO	44E	NO	44E	NO
66A	NO	66A	NO		
NO BASIS	NO	NO BASIS	NO		

MARK DATA

STANDARD CHARACTER MARK	NO
LITERAL MARK ELEMENT	ADORE ORGANIC INNOVATION
MARK DRAWING CODE	5 AN ILLUSTRATION DRAWING WITH WORD(S)/LETTER(S)/NUMBER(S) IN STYLED FORM
COLOR DRAWING FLAG	NO

CURRENT OWNER INFORMATION

PARTY TYPE	10 ORIGINAL APPLICANT
NAME	Universal Handicraft Inc
ADDRESS	1005 Park Centre Blvd Miami FL 33169
ENTITY	03 CORPORATION

C T ZENSH P	Florida
DBA/AKA	DBA Deep Sea Cosmetics
GOODS AND SERVICES	
INTERNAT ONAL CLASS	003
DESCR PT ON TEXT	Organic cosmetics Organic cosmetics and organic cosmetic preparations Organic cosmetics in general including organic perfumes

GOODS AND SERVICES CLASSIFICATION							
INTERNAT ONAL CLASS	003	F RST USE DATE	06/28/2012	F RST USE N COMMERCE DATE	06/28/2012	CLASS STATUS	6 ACT VE

MISCELLANEOUS INFORMATION/STATEMENTS	
CHANGE N REG STRAT ON	NO
COLORS CLA MED STATEMENT	Color is not claimed as a feature of the mark
D SCLA MER W/PREDETER TXT	"ORGAN C"
DESCR PT ON OF MARK	The mark consists of the word Adore and below this the words Organic and nnovation

PROSECUTION HISTORY				
DATE	ENT CD	ENT TYPE	DESCR PT ON	ENT NUM
03/05/2013	CNSA	O	APPROVED FOR PUB PR NC PAL REG STER	011
03/05/2013	XAEC		EXAM NERS AMENDMENT ENTERED	010
03/05/2013	GNEN	O	NOT F CAT ON OF EXAM NERS AMENDMENT E MA LED	009
03/05/2013	GNEA	O	EXAM NERS AMENDMENT E MA LED	008
03/05/2013	CNEA	R	EXAM NERS AMENDMENT WR TTEN	007
12/07/2012	GNRN	O	NOT F CAT ON OF NON F NAL ACT ON E MA LED	006
12/07/2012	GNRT	F	NON F NAL ACT ON E MA LED	005
12/07/2012	CNRT	R	NON F NAL ACT ON WR TTEN	004
11/29/2012	DOCK	D	ASS GNED TO EXAM NER	003
11/02/2012	NWOS		NEW APPL CAT ON OFF CE SUPPL ED DATA ENTERED N TRAM	002
11/01/2012	NWAP		NEW APPL CAT ON ENTERED N TRAM	001

CURRENT CORRESPONDENCE INFORMATION	
ATTORNEY	Lisa Capote
CORRESPONDENCE ADDRESS	L SA CAPOTE ARRAST A & CAPOTE 80 SW 8TH ST STE 2310 M AM FL 33130 3058
DOMEST C REPRESENTAT VE	NONE

Adore

Organic Innovation

To: Universal Handicraft, Inc. (lisa@acplegal.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85765621 - ADORE ORGANIC INNOVATION - Adore Organi
Sent: 3/5/2013 1:32:03 PM
Sent As: ECOM114@USPTO.GOV
Attachments:

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

U.S. APPLICATION SERIAL NO. 85765621

MARK: ADORE ORGANIC INNOVATION

85765621

CORRESPONDENT ADDRESS:

LISA CAPOTE
ARRASTIA & CAPOTE
80 SW 8TH ST STE 2310
MIAMI, FL 33130-3058

GENERAL TRADEMARK INFORMATION:

<http://www.uspto.gov/trademarks/index.jsp>

APPLICANT: Universal Handicraft, Inc.

CORRESPONDENT'S REFERENCE/DOCKET NO :

Adore Organi

CORRESPONDENT E-MAIL ADDRESS:

lisa@acplegal.com

EXAMINER'S AMENDMENT

ISSUE/MAILING DATE: 3/5/2013

DATABASE SEARCH: The trademark examining attorney has searched the USPTO's database of registered and pending marks and has found no conflicting marks that would bar registration under Trademark Act Section 2(d). TMEP §704.02; *see* 15 U.S.C. §1052(d).

APPLICATION HAS BEEN AMENDED: In accordance with the authorization granted by Lisa Capote on March 5, 2013, the trademark examining attorney has amended the application as indicated below. Please advise the undersigned immediately of any objections. Otherwise, no response is necessary. TMEP §707. Any amendments to the identification of goods and/or services may clarify or limit the goods and/or services, but may not add to or broaden the scope of the goods and/or services. 37 C.F.R. §2.71(a); *see* TMEP §§1402.06 *et seq.*

AMENDMENT TO IDENTIFICATION OF GOODS

The identification of goods is amended to read as follows: "Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general, including organic perfumes".

DISCLAIMER ENTERED

The following disclaimer statement is added to the record: No claim is made to the exclusive right to use "ORGANIC" apart from the mark as shown.

/Shaile E. Lewis/
Trademark Examining Attorney
Law Office 114

(571) 270-1527 (t)
(571) 270-2527 (f)
shaila.lewis@uspto.gov

PERIODICALLY CHECK THE STATUS OF THE APPLICATION: To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using the Trademark Status and Document Retrieval (TSDR) system at <http://tsdr.uspto.gov/>. Please keep a copy of the TSDR status screen. If the status shows no change for more than six months, contact the Trademark Assistance Center by e-mail at TrademarkAssistanceCenter@uspto.gov or call 1-800-786-9199. For more information on checking status, see <http://www.uspto.gov/trademarks/process/status/>.

TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS: Use the Trademark Electronic Application System (TEAS) form at <http://www.uspto.gov/trademarks/teas/correspondence.jsp>.

To: Universal Handicraft, Inc. (lisa@acplegal.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85765621 - ADORE ORGANIC INNOVATION - Adore Organi
Sent: 3/5/2013 1:32:03 PM
Sent As: ECOM114@USPTO.GOV
Attachments:

UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)

**IMPORTANT NOTICE REGARDING YOUR
U.S. TRADEMARK APPLICATION**

USPTO OFFICE ACTION (OFFICIAL LETTER) HAS ISSUED
ON **3/5/2013** FOR U.S. APPLICATION SERIAL NO.85765621

Please follow the instructions below:

(1) TO READ THE LETTER: Click on this [link](#) or go to <http://tsdr.uspto.gov/>, enter the U.S. application serial number, and click on "Documents."

The Office action may not be immediately viewable, to allow for necessary system updates of the application, but will be available within 24 hours of this e-mail notification.

(2) QUESTIONS: For questions about the contents of the Office action itself, please contact the assigned trademark examining attorney. For *technical* assistance in accessing or viewing the Office action in the Trademark Status and Document Retrieval (TSDR) system, please e-mail TSDR@uspto.gov.

WARNING

PRIVATE COMPANY SOLICITATIONS REGARDING YOUR APPLICATION: Private companies **not** associated with the USPTO are using information provided in trademark applications to mail or e-mail trademark-related solicitations. These companies often use names that closely resemble the USPTO and their solicitations may look like an official government document. Many solicitations require that you pay "fees."

Please carefully review all correspondence you receive regarding this application to make sure that you are responding to an official document from the USPTO rather than a private company solicitation. All official USPTO correspondence will be mailed only from the "United States Patent and Trademark Office" in Alexandria, VA; or sent by e-mail from the domain "@uspto.gov." For more information on how to handle private company solicitations, see http://www.uspto.gov/trademarks/solicitation_warnings.jsp.

NOTE TO THE FILE

SERIAL NUMBER: 85765621
DATE: 03/05/2013
NAME: ssettles

NOTE:

Searched:

- Google
- Lexis/Nexis
- OneLook
- Wikipedia
- Acronym Finder
- Other:

Discussed ID with:

- Senior Atty
- Managing Atty

- Protest evidence reviewed

Checked:

- Geographic significance
- Surname
- Translation
- ID with ID/CLASS mailbox

Discussed Geo. Sig. with:

- Senior Atty
- Managing Atty

Checked list of approved Canadian attorneys and agents

Discussed file with

Attorney/Applicant via:

- phone
- email

- Left message with Attorney/Applicant

- Issued Examiner's Amendment and entered changes in TRADEUPS

- Added design code in TRADEUPS

- Re-imaged standard character drawing

- Contacted TM MADRID ID/CLASS about misclassified definite ID

Requested Law Library search for:

- PRINT** **DO NOT PRINT**
- Description of the mark
- Translation statement

- Negative translation statement
- Consent of living individual

Changed TRADEUPS to:

OTHER:

From: Lewis Sha a E
Sent: Tuesday March 05 2013 12:28 PM
To: Lisa Capote
Subject: RE: Applicant on 85765621

Ms. Capote,

In order to enter an examiner's amendment, all issues in the Office action must be resolved at the time of entering the amendment. There is also a requirement to amend the identification so that it clearly states that the goods are "organic". I'm happy to enter the identification amendment that I suggested in the Office action along with the disclaimer of the word "organic".

Sha a E Lewis
Trademark Examining Attorney

Law Office 114
United States Patent and Trademark Office
600 Duany Street
Alexandra Vrgina 22314
571 270 1527 (Tel)
571 270 2527 (Fax)

From: Lisa Capote [[mailto: lisa@acplegal.com](mailto:lisa@acplegal.com)]
Sent: Tuesday, March 05, 2013 10:53 AM
To: Lewis, Shauna E
Subject: Application 85765621

Dear Attorney Lewis,

I am writing to request an examiner's amendment on the above referenced trademark for the required disclaimer for "organic." Please advise if you need additional information or action on my part. Thank you and I look forward to your response.

Lisa

LISA CAPOTE
T 786 871 5680
D 786 871 5683
F 786 866 6358
E lisa@acplegal.com

80 SW 8 Street / Suite 2310 / Miami, Florida 33130

Connect with us: [Website](#) / [Facebook](#) / [Twitter](#) / [LinkedIn](#)

P Please consider the environment before printing this e-mail.

IMPORTANT: This e-mail is subject to the Electronics Communications Privacy Act, 18 U.S.C. §§2510-2521, and contains information which is or may be confidential and/or privileged. The information contained in this e-mail message, together with any attachments or links, is strictly confidential and intended only for the use of the recipient named above. If the reader of this email is not the intended recipient, you are notified that any use, distribution, or copying of this communication

To: Universal Handicraft, Inc. (lisa@acplegal.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85765621 - ADORE ORGANIC INNOVATION - Adore Organi
Sent: 12/7/2012 5:31:58 PM
Sent As: ECOM114@USPTO.GOV
Attachments: [Attachment - 1](#)
[Attachment - 2](#)
[Attachment - 3](#)

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

APPLICATION SERIAL NO. 85765621

MARK: ADORE ORGANIC INNOVATION

85765621

CORRESPONDENT ADDRESS:

LISA CAPOTE
ARRASTIA & CAPOTE
80 SW 8TH ST STE 2310
MIAMI, FL 33130-3058

CLICK HERE TO RESPOND TO THIS LETTER:
http://www.uspto.gov/trademarks/teas/response_forms.jsp

APPLICANT: Universal Handicraft, Inc.

CORRESPONDENT'S REFERENCE/DOCKET NO :

Adore Organi

CORRESPONDENT E-MAIL ADDRESS:

lisa@acplegal.com

OFFICE ACTION

STRICT DEADLINE TO RESPOND TO THIS LETTER

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER **WITHIN 6 MONTHS** OF THE ISSUE/MAILING DATE BELOW.

ISSUE/MAILING DATE: 12/7/2012

The referenced application has been reviewed by the assigned trademark examining attorney. Applicant must respond timely and completely to the issue(s) below. 15 U.S.C. §1062(b); 37 C.F.R. §§2.62(a), 2.65(a); TMEP §§711, 718.03.

DISCLAIMER REQUIRED

Applicant must disclaim the descriptive wording "ORGANIC" apart from the mark as shown because it merely describes a feature of the goods and/or an ingredient of the goods. See 15 U.S.C. §1056(a); TMEP §§1213, 1213.03(a).

The word "ORGANIC" means "pertaining to, involving, or grown with fertilizers or pesticides of animal or vegetable origin, as distinguished from manufactured chemicals". See attached dictionary evidence. This term, when used in connection with cosmetics and perfumes, immediately conveys to consumers that the identified cosmetics contain ingredients grown with fertilizers or pesticides of animal or vegetable origin as opposed to manufactured chemicals. The attached evidence from Ecco Bella and Miessence shows organic cosmetics being offered for sale to the public, and the attached evidence from the U.S. Food and Drug Administration discusses the fact that the term "organic" is regulated by the U.S. Department of Agriculture when used in connection with cosmetics. Therefore, the term "organic" is, at minimum, descriptive, and must be disclaimed.

A disclaimer does not physically remove the disclaimed matter from the mark, but rather is a written statement that applicant does not claim exclusive rights to the disclaimed wording and/or design separate and apart from the mark as shown in the drawing. TMEP §§1213, 1213.10.

The Office can require an applicant to disclaim an unregistrable part of a mark consisting of particular wording, symbols, numbers, design elements or combinations thereof. 15 U.S.C. §1056(a). Under Trademark Act Section 2(e), the Office can refuse registration of an entire mark if the entire mark is merely descriptive, deceptively misdescriptive, or primarily geographically descriptive of the goods. 15 U.S.C. §1052(e). Thus, the Office may require an applicant to disclaim a portion of a mark that, when used in connection with the goods or services, is merely descriptive, deceptively misdescriptive, primarily geographically descriptive, or otherwise unregistrable (e.g., generic). *See* TMEP §§1213, 1213.03.

Failure to comply with a disclaimer requirement can result in a refusal to register the entire mark. TMEP §1213.01(b).

The following is the accepted format for a disclaimer:

No claim is made to the exclusive right to use “ORGANIC” apart from the mark as shown.

TMEP §1213.08(a)(i).

AMENDMENT TO IDENTIFICATION REQUIRED

If applicant uses or intends to use the mark on goods other than organic cosmetics, organic cosmetic preparations, and organic perfumes, such use would be deceptive. *See* TMEP §§1203.02, 1209.04, 1402.05 *et seq.* Therefore, applicant must amend the identification by limiting it to “organic cosmetics, organic cosmetics and organic cosmetic preparations, and organic cosmetics in general, including organic perfumes”.

RESPONSE GUIDELINES

TEAS PLUS APPLICANTS MUST SUBMIT DOCUMENTS ELECTRONICALLY OR SUBMIT FEE: Applicants who filed their application online using the reduced-fee TEAS Plus application must continue to submit certain documents online using TEAS, including responses to Office actions. *See* 37 C.F.R. §2.23(a)(1). For a complete list of these documents, see TMEP §819.02(b). In addition, such applicants must accept correspondence from the Office via e-mail throughout the examination process and must maintain a valid e-mail address. 37 C.F.R. §2.23(a)(2); TMEP §§819, 819.02(a). TEAS Plus applicants who do not meet these requirements must submit an additional fee of \$50 per international class of goods and/or services. 37 C.F.R. §2.6(a)(1)(iv); TMEP §819.04. In appropriate situations and where all issues can be resolved by amendment, responding by telephone to authorize an examiner’s amendment will not incur this additional fee.

If there are questions regarding this action or the application in general, the undersigned examining attorney can be contacted at the telephone number below.

/Shaila E. Lewis/
Trademark Examining Attorney
Law Office 114
(571) 270-1527 (t)
(571) 270-2527 (f)
shaila.lewis@uspto.gov

TO RESPOND TO THIS LETTER: Go to http://www.uspto.gov/trademarks/teas/response_forms.jsp. Please wait 48-72 hours from the issue/ mailing date before using TEAS, to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail TEAS@uspto.gov. For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

All informal e-mail communications relevant to this application will be placed in the official application record.

WHO MUST SIGN THE RESPONSE: It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

PERIODICALLY CHECK THE STATUS OF THE APPLICATION: To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using Trademark Applications and Registrations Retrieval (TARR) at <http://tarr.uspto.gov/>. Please keep a copy of the complete TARR screen. If TARR shows no change for more than six months, call

1-800-786-9199. For more information on checking status, see <http://www.uspto.gov/trademarks/process/status/>.

TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS: Use the TEAS form at <http://www.uspto.gov/teas/eTEASpageE.htm>.



This is Google's cache of <http://www.eccobella.com/>. It is a snapshot of the page as it appeared on Dec 1, 2012 22:48:06 GMT. The [current page](#) could have changed in the meantime. [Learn more](#)

Tip: To quickly find your search term on this page, press **Ctrl+F** or **⌘-F** (Mac) and use the find bar.

These search terms are highlighted: **organic cosmetics**

[Text-only version](#)

ECCO BELLA


Your Home for Natural and **Organic** Intelligent Beauty

877 696 2220

[Log In](#)



Body Care **Cosmetics** Hair Care Fragrance Skin Care Room Mists Gifts Vegan Specials



It's both in one.
Anti-Aging
Anti-Blemish
Skin Care with
VitaminCells.



1 2 3 4 5 6 7 8 9 < || >

Ecco Bella was started to provide cruelty-free **organic cosmetics** and natural skin care products. The effort grew to include products derived from organics and vitamins. We are so glad you have joined us in this mission. Indulge yourself in **organic cosmetics** and natural skin care products that offer a pure and beautiful experience, while helping to conserve our planet and protect its animals.

WHAT'S NEW

Now you can try our **Organic** Anti-Aging, Anti-Blemish Skin Care Foursome! See more.



BEST SELLERS

Luxurious **Organic** & Water-Free Herbal Body Lotions



Search Products

Like 7,142 people like this. Sign Up to see what your friends like.



Instant \$10 for your Invincible Spirit Signup



Free Beauty Consultation & Live Chat

Find us on Facebook

[Sign Up](#) Create an account or [Log In](#) to see what your friends like.



Ecco Bella

Like



Ecco Bella added a new photo.



7,142 people like Ecco Bella.

Facebook social plugin

To: Universal Handicraft, Inc. (lisa@acplegal.com)
Subject: U.S. TRADEMARK APPLICATION NO. 85765621 - ADORE ORGANIC INNOVATION - Adore Organi
Sent: 12/7/2012 5:31:59 PM
Sent As: ECOM114@USPTO.GOV
Attachments:

UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)

**IMPORTANT NOTICE REGARDING YOUR
U.S. TRADEMARK APPLICATION**

USPTO OFFICE ACTION (OFFICIAL LETTER) HAS ISSUED
ON **12/7/2012** FOR U.S. APPLICATION SERIAL NO. 85765621

Please follow the instructions below:

(1) **TO READ THE LETTER:** Click on this [link](#) or go to <http://tsdr.uspto.gov>, enter the U.S. application serial number, and click on "Documents."

The Office action may not be immediately viewable, to allow for necessary system updates of the application, but will be available within 24 hours of this e-mail notification.

(2) **TIMELY RESPONSE IS REQUIRED:** Please carefully review the Office action to determine (1) how to respond, and (2) the applicable response time period. Your response deadline will be calculated from **12/7/2012** (or sooner if specified in the Office action). For information regarding response time periods, see <http://www.uspto.gov/trademarks/process/status/responsetime.jsp>.

Do NOT hit "Reply" to this e-mail notification, or otherwise e-mail your response because the USPTO does NOT accept e-mails as responses to Office actions. Instead, the USPTO recommends that you respond online using the Trademark Electronic Application System (TEAS) response form located at http://www.uspto.gov/trademarks/teas/response_forms.jsp.

(3) **QUESTIONS:** For questions about the contents of the Office action itself, please contact the assigned trademark examining attorney. For technical assistance in accessing or viewing the Office action in the Trademark Status and Document Retrieval (TSDR) system, please e-mail TSDR@uspto.gov.

WARNING

Failure to file the required response by the applicable response deadline will result in the ABANDONMENT of your application. For more information regarding abandonment, see <http://www.uspto.gov/trademarks/basics/abandon.jsp>.

PRIVATE COMPANY SOLICITATIONS REGARDING YOUR APPLICATION: Private companies **not** associated with the USPTO are using information provided in trademark applications to mail or e-mail trademark-related solicitations. These companies often use names that closely resemble the USPTO and their solicitations may look like an official government document. Many solicitations require that you pay "fees."

Please carefully review all correspondence you receive regarding this application to make sure that you are responding to an official document from the USPTO rather than a private company solicitation. All official USPTO correspondence will be mailed only from the "United States Patent and Trademark Office" in Alexandria, VA; or sent by e-mail from the domain "@uspto.gov." For more information on how to handle private company solicitations, see http://www.uspto.gov/trademarks/solicitation_warnings.jsp.

*** User:ssettles ***

#	Total Marks	Dead Marks	Live Viewed Docs	Live Viewed Images	Status/ Search Duration	Search
01	1079	N/A	0	0	0:03	*ador*[bi,ti] and live[lid]
02	278	0	278	245	0:02	1 and 003 [cc]
03	2490	N/A	0	0	0:01	*organ{ iey }{ ckqx }*[bi,ti] and live[lid]
04	2651	N/A	0	0	0:03	*novation*[bi,ti] and live[lid]
05	3	0	3	3	0:01	3 and 4

Session started 11/29/2012 1:20:07 PM
 Session finished 11/29/2012 1:56:45 PM
 Total search duration 0 minutes 10 seconds
 Session duration 36 minutes 38 seconds
 Default NEAR limit=1ADJ limit=1

Sent to TICRS as Serial Number: 85765621

Adore

Organic Innovation

EXHIBIT 11

JUL 01, 2016, 16:48 ET

News provided by

Adore Cosmetics → (<http://www.prnewswire.com/news/adore+cosmetics>)

f t g+ in @ ✉

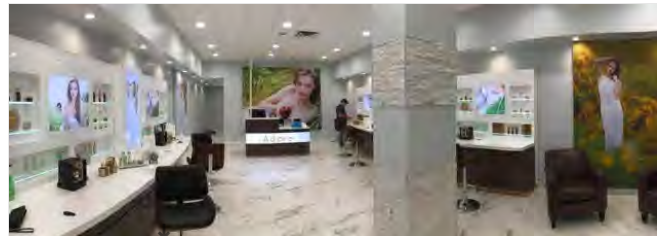
Adore Cosmetics Opens New Store in Boston/Cambridge Area

MIAMI, July 1, 2016 /PRNewswire/ -- Adore Cosmetics—a leading purveyor of organic skin care and beauty products—has announced the opening of a new store to serve the Boston area. The new Adore Cosmetics store is located in the Galleria CambridgeSide Mall in Cambridge, Massachusetts. With more than 120 stores, Galleria CambridgeSide Mall is one of the premier urban shopping centers in the Boston area and includes a range of well-known brands, including Armani Exchange, Forever 21 and Swarovski.

Photo - <http://photos.prnewswire.com/prnh/20160701/385765> (<http://photos.prnewswire.com/prnh/20160701/385765>)

"We're very excited to bring the Adore Cosmetics store concept to the Boston area," says Shay Segev, president and CEO of Adore Cosmetics. "The Galleria CambridgeSide Mall offers an excellent opportunity to share the direct experience of using Adore Cosmetics products to a vibrant, growing area while its selection of stores aligns nicely with the upscale brand personality that characterizes our stores."

The Boston store joins a rapidly growing roster of more than 70 Adore Cosmetics stores worldwide, including new locations in Panama, St. Martin, and Austria, as well as 10-15 Adore Cosmetics stores to be opened in Canada in the near future, starting with a store in Ottawa in August. In addition, the brand is looking at a range of other new locations in the United States and Europe.



(<http://photos.prnewswire.com/prnvar/20160701/385765?max=1600>)
(<http://photos.prnewswire.com/prnvar/20160701/385765>)

f () t g+ in @ ✉ max=1600

About Adore Cosmetics

Adore Cosmetics Organic Innovation specializes in organic innovation when it comes to skin care and beauty, using organic ingredients as a base for a range of formulations designed to erase the signs of age and promote vibrant, radiant skin.

<http://www.adoreorganicinnovation.com/> (<http://www.adoreorganicinnovation.com/>)

Press Contact: Abel Delgado, Adore Cosmetics Marketing Manager
adelgado@uhicosmetics.com (<mailto:adelgado@uhicosmetics.com>), 305.627.9370

Related Images

image1.jpg (<https://www.newswire.com/files/51/c0/ff589a694758cc58a31e78edd27c.jpg>)

image2.jpg (<https://www.newswire.com/files/bd/00/a5848748cfeefc5afff2424d2205.jpg>)

This content was issued through the press release distribution service at Newswire.com. For more info visit:
<http://www.newswire.com> (<http://www.newswire.com/>)

SOURCE Adore Cosmetics

Related Links

<http://www.adoreorganicinnovation.com/> (<http://www.adoreorganicinnovation.com/>)

(<http://www.prnewswire.com/news-releases/grand-opening-of-adore-cosmetics-store-in-multiplaza-pacific-mall-in-panama-300295385.html>)
(<http://www.prnewswire.com/news-releases/adore-cosmetics-launches-special-offers-site-300286471.html>)

Also from this source

AUG 16, 2016, 18:09 ET

Adore Cosmetics Featured at the Just Jared Summer Bash (<http://www.prnewswire.com/news-releases/adore-cosmetics-featured-at-the-just-jared-summer-bash-300314344.html>)



(<http://www.prnewswire.com/news-releases/adore-cosmetics-featured-at-the-just-jared-summer-bash-300314344.html>)

AUG 18, 2016, 16:37 ET

Grand Opening of New Adore Cosmetics Store in Ottawa, Canada (<http://www.prnewswire.com/news-releases/grand-opening-of-new-adore-cosmetics-store-in-ottawa-canada-300315578.html>)

Explore

More news releases in similar topics

Cosmetics and Personal Care
(<http://www.prnewswire.com/news-releases/consumer-products-retail-latest-news/cosmetics-and-personal-care-list/>)

Household, Consumer & Cosmetics
(<http://www.prnewswire.com/news-releases/consumer-products-retail-latest-news/household-consumer-cosmetics-list/>)

Retail
(<http://www.prnewswire.com/news-releases/consumer-products-retail-latest-news/retail-list/>)

Corporate Expansion
(<http://www.prnewswire.com/news-releases/general-business-latest-news/corporate-expansion-list/>)

You just read:

Adore Cosmetics Opens New Store in Boston/Cambridge Area

News provided by Adore Cosmetics → (<http://www.prnewswire.com/news/adore+cosmetics>)



<http://www.prnewswire.com/news-releases/adore-cosmetics-opens-new-store-in-bostoncambridge-area-300293426.html>

Contact (</contact-us/>)

888-776-0942
from 8 AM - 10 PM ET
Chat Online with an Expert
Contact Us (</contact-us/>)

Solutions
(</solutions/overview/>)

For Marketers (</solutions/marketing/>)
For Public Relations (</solutions/public-relations/>)

About
(<http://prnewswire.mediaroom.com/index.php>)

About PR Newswire
(<http://prnewswire.mediaroom.com/index.php>)
About Cision (<http://www.cision.com/us/>)

My Services
All News Releases (</news-releases/>)
Online Member Center
(<https://portal.prnewswire.com/Login.aspx>)
ProfNet™ (</profnet/>)

[For IR & Compliance \(/solutions/ir-compliance/\)](/solutions/ir-compliance/)
[For Agency \(/solutions/agency/\)](/solutions/agency/)
[For Small Business \(http //www.smallbusinesspr.com/\)](http://www.smallbusinesspr.com/)
[All Products \(/solutions/products-overview/\)](/solutions/products-overview/)

[utm_medium=website&utm_source=prnewswire&utm_content=cishomepage&utm_campaign=prn](#)
[Become a Publishing Partner \(/contact-us/prnewswire-partners/\)](/contact-us/prnewswire-partners/)
[Become a Channel Partner \(/contact-us/become-a-partner/\)](/contact-us/become-a-partner/)
[Careers \(http://prncareers.mediaroom.com/\)](http://prncareers.mediaroom.com/)

[Global Sites ^ \(\)](#)

[Terms of Use \(/terms-of-use-apply.html\)](/terms-of-use-apply.html) | [Privacy Policy \(/privacy-policy.html\)](/privacy-policy.html) | [Information Security Policy Statement \(/prn-information-security-policy.html\)](/prn-information-security-policy.html) | [Site Map \(/sitemap/\)](/sitemap/) | [RSS Feeds \(/rss/\)](/rss/)

Copyright © 2016 PR Newswire Association LLC. All Rights Reserved. A Cision (http://www.cision.com/us/?utm_medium=website&utm_source=prnewswire&utm_content=cishomepage&utm_campaign=prnewswire) company.

EXHIBIT 12

The screenshot shows a web browser displaying the Adore cosmetics website. The browser's address bar shows 'adorecosmetics.com' and the page title is 'About Adore Organic Innovation'. The website's navigation menu includes: HOME, SKIN CARE, CONCEAEN, COLLECTION, FEATURES, SPECIAL OFFERS, GIVEAWAYS, BLOG, REVIEWS. The main content area features an article titled 'Breakthrough Anti-Aging Skin Care via Organic Stem Cells'. The article text describes Adore's research on stem cells and their benefits for skin health. At the bottom of the page, there are links for 'About the Brand', 'Customer Service', and 'Adore Cosmetics Cellmax Review'.

Home > About Us
About Adore Organic Innovation

adorecosmetics.com
About Us
Select Your Currency US Dollar - USD

HOME SKIN CARE CONCEAEN COLLECTION FEATURES SPECIAL OFFERS GIVEAWAYS BLOG REVIEWS

Breakthrough Anti-Aging Skin Care via Organic Stem Cells

Adore Cosmetic's research teams have discovered that stem cells harvested from organic produce—which is generally richer in nutrients than mass-harvested fruits and vegetables found in most supermarkets—have profound impact on our skin. Using our patented plant stem cell formula, Adore Cosmetics products take advantage of the epigenetic factors of resilient plant stem cells. In turn, this enables your skin's own stem cells to self-renew while slowing down the aging process. Stem cells have shown great potential to treat critical conditions like Alzheimer's and Parkinson's disease. Adore Cosmetics uses the same type of technology for beauty—using stem cells found in organic fruits and vegetables.

The Power of Plants for Better Beauty

Adore Cosmetics' research team kicked off their skin studies by knowing that stem cells account for just 2% to 7% of your skin's total cells...yet they're responsible for ALL of your skin's ability to heal itself. As time passes and environmental damage mounts, these stem cells lose effectiveness—and skin loses its vitality. Scientists from Adore Cosmetics reviewed independent research that pointed out that plants also have stem cells...and that some fruit stem cells act similarly to human stem cells. The team saw the potential of applying these plant stem cells to protect human skin cells.

Innovating an Anti-Aging Organic Solution

Adore Cosmetic's researchers started experimenting by applying an extract of these organic plant cells to ethically collected human skin stem cells and then exposing them to UV light. They noticed that the skin cells experienced only a small loss of vitality—while half of those with no extract died. Adore Cosmetics' scientists also tested human skin cells for premature aging due to cellular DNA damage. While the cells incubated with the extract experienced a neutralization of the negative effects and increased their growth rate, the cells that weren't treated with the extract experienced a decrease in cellular growth.

Adore Cosmetics researchers later observed the same protective effect when they applied a cream containing the extract to the crow's feet area of clinical trial volunteers. Four weeks later, wrinkle depth was reduced by as much as 15%.

Now Adore Cosmetics brings the anti-aging properties of this breakthrough to you in a luxurious line of skin care products.

A few simple steps will help you use Adore Cosmetics to put these plant stem cells to work to defend your skin against the effects of aging and sunlight. Adore Cosmetics products have a specially calibrated concentration of plant stem cell formula available, along with a rich blend of vitamins, essential oils, organic flower extracts and organic vegetable protein. By blending plant cell power with proven nutrients for the skin, the Adore Cosmetics skin care line restores healthy-looking skin by:

- Protecting your skin's own stem cells, the key to its regenerative ability
- Preventing UV stress and environmental damage
- Delaying skin aging processes
- Promoting vitality and longevity of skin stem cells.

Adore Cosmetics represents the most advanced breakthrough in anti-aging found in the beauty industry today—and it's yours exclusively to adore.

Search products... SEARCH

Contact Us
Login

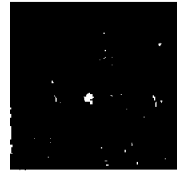
About the Brand
Customer Service

Adore Cosmetics Cellmax Review

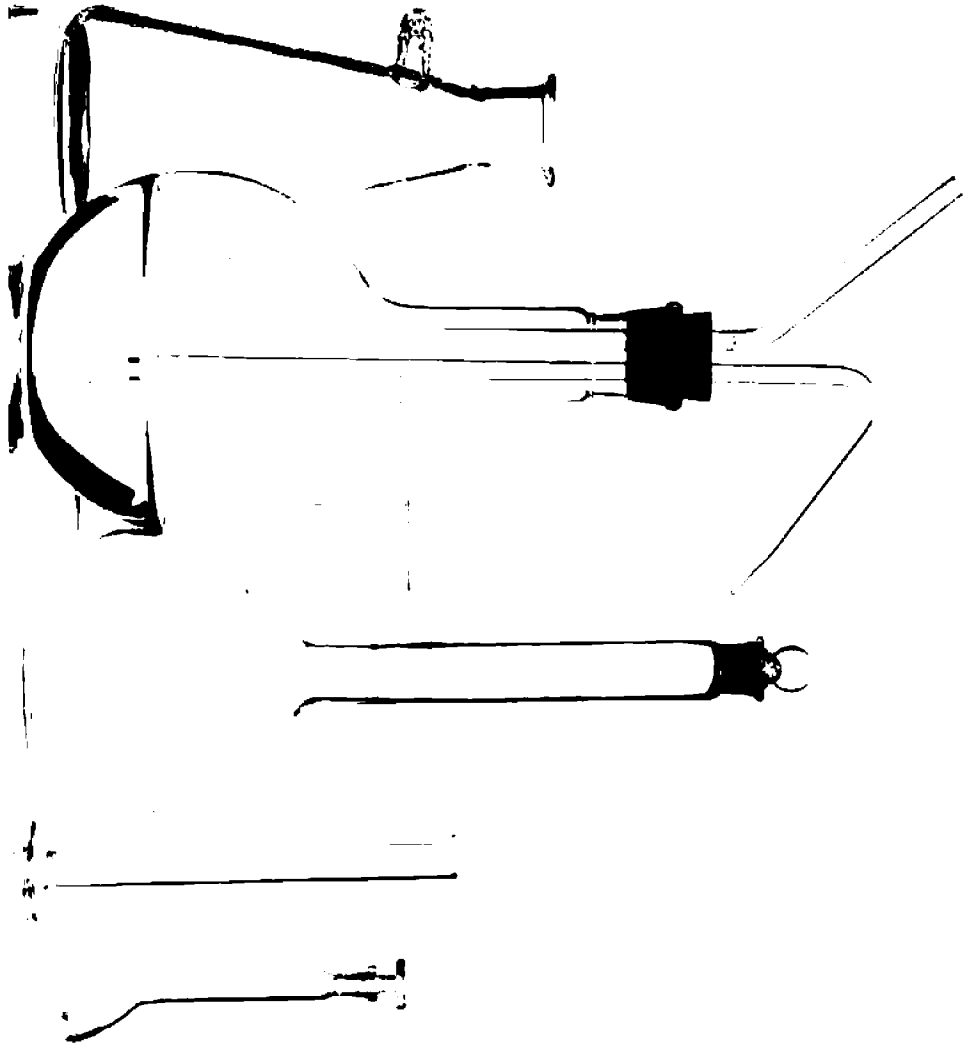
EXHIBIT 13

Adore

Organic Innovation



Science



Science - Stem Cell Technology

Exhibit 13

Page 104 of 143

Adore

Organic Innovation

Science

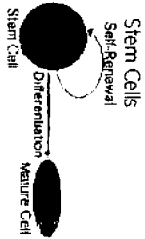
ADORE CATALOG TECHNOLOGY SECTION

Intro: What are Stem Cells?

Stem cells are biological cells found in all multi-cellular organisms. All plants and animals have them.

Two key features set stem cells apart from ordinary cells. They can become a wide range of specialized cells of the same tissue (differentiate) and they have the remarkable ability to replace themselves through cell division throughout a person's life.

In the human body, adult stem cells supply all the necessary cells for renewal and repair of organs and tissue, including skin. This makes stem cells especially valuable and important in regenerative skin care research.



Stem Cells in the Skin – Epidermal Stem Cells

Adult stem cells are present in the outer layer of human skin, the epidermis. These cells are called epidermal stem cells and are found in the innermost layer of the epidermis (basal layer). Every second to seventh cell in this layer is a stem cell. While these wondrous cells can replace themselves, they cannot generate additional epidermal stem cells. Each of us is born with all the skin stem cells we will ever have.

Although their appearance does not differ from that of the other cells in the basal layer, stem cells have a unique function: They constantly renew and rejuvenate the skin by forming new keratinocytes and regenerating damaged tissue.

Stem Cells in Skin



Epidermal stem cells, which reside in the basal layer of the epidermis, are responsible for the continuous renewal of the epidermis. The basal layer is the innermost layer of the epidermis, and the dermis is the layer below it.

Stem Cells and Aging

In young skin, the epidermis fully renews itself approximately every 4 weeks. This process continuously slows as we age. The number of skin stem cells decreases and their vitality diminishes. Excessive UV exposure of the skin and an unhealthy lifestyle (smoking, alcohol) aggravate these effects considerably, resulting in thinner, more deeply wrinkled skin. The hydrolipid film, which continually coats the skin with a water/oil emulsion and ensures the correct balance of skin flora, becomes reduced, leaving skin dryer and less well protected.

As no new epidermal stem cells can develop during a person's life, it is all the more important to maintain the vitality of these valuable cells and their ability to divide as long as possible.

Adore

Organic Innovation

Science

Plant Stem Cells
Like humans, every plant has stem cells. But unlike humans, every plant cell has the potential to turn back into a stem cell and grow into an entirely new plant. If a plant is wounded, it forms what's known as callus tissue, in which normal cells become stem cells, which act to heal the wound. This is common in plants but not possible in humans.

Researchers have long been interested in plants' ability to heal themselves via callus tissue, and even more so, certain plants' remarkable abilities to stay fresh long after being harvested and to protect themselves from prolonged exposure to UV rays that are harmful to living tissue. The question was, could these potent plant stem cells be used to protect human skin stem cells? The answer is yes.



Plant Stem Cells Protect Skin Stem Cells

Every stem cell contains epigenetic factors—meaning, abilities to activate or deactivate certain genes' expression—that preserve its ability to make new, differentiated cells and self-renew. Researchers discovered that plant stem cells contain epigenetic factors similar to those of adult human stem cells. Applied in the right way, plant stem cells have a positive impact on the vitality of skin stem cells and their proper functioning.

By growing callus cells in selected plant tissue under special conditions, researchers have created a new biotechnology that generates plant stem cells that safely help protect human skin stem cells from chronological aging, UV stress and other environmental damage. We call this new biotechnology Plant Stem Cell formula.

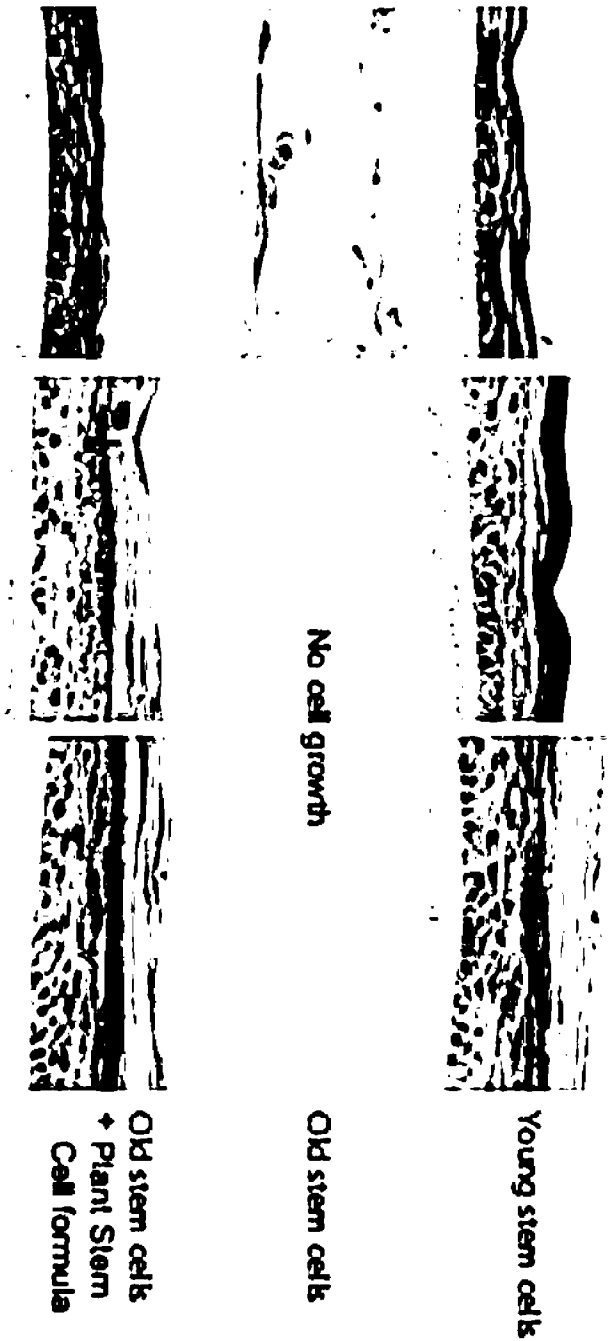


Adore

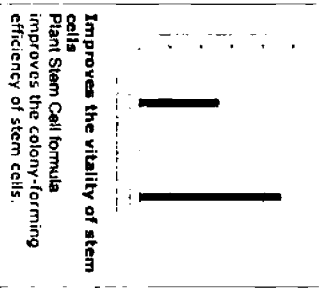
Organic Innovation

Science

Measuring The Vitality Of Epidermal Stem Cells
 The development of a new test method, called 'progenitor cell targeting,' made it possible to isolate stem cells, which look the same as other skin cells, from the human epidermis for test purposes.
 Using this method, these epidermal stem cells are grown in Petri dishes. During this process, each healthy stem cell divides, forming a colony of cells, which is visible to the naked eye and can be counted. Stem cells that have aged and are weakened do not die, but they no longer form colonies. Researchers were thus able to prove that using plant stem cells increases the longevity and the vitality of human skin stem cells.
 Extensive studies have shown that Plant Stem Cell formula increases the vitality and efficiency of all essential skin cells and improves skin's resistance



Plant Stem Cells Improve the Vitality of Skin Stem Cells
 Cultures of epidermal stem cells were treated with different concentrations of Plant Stem Cell formula and their colony-forming efficiency was measured. The research demonstrated that Plant Stem Cell formula clearly has a positive effect on stem cell characteristics.



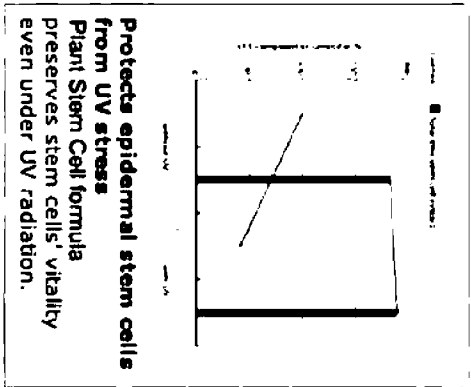
Improves the vitality of stem cells
 Plant Stem Cell formula improves the colony-forming efficiency of stem cells.

Adore

Organic Innovation

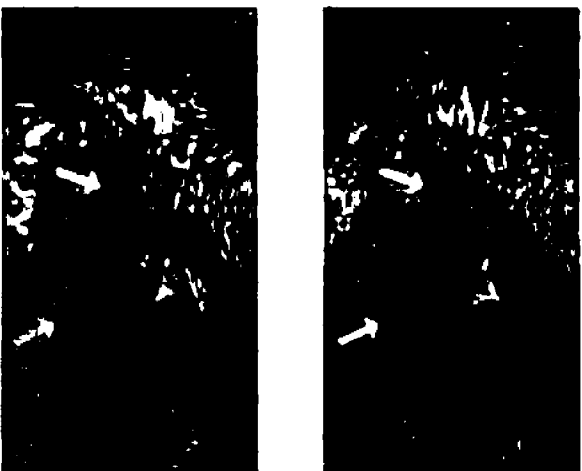
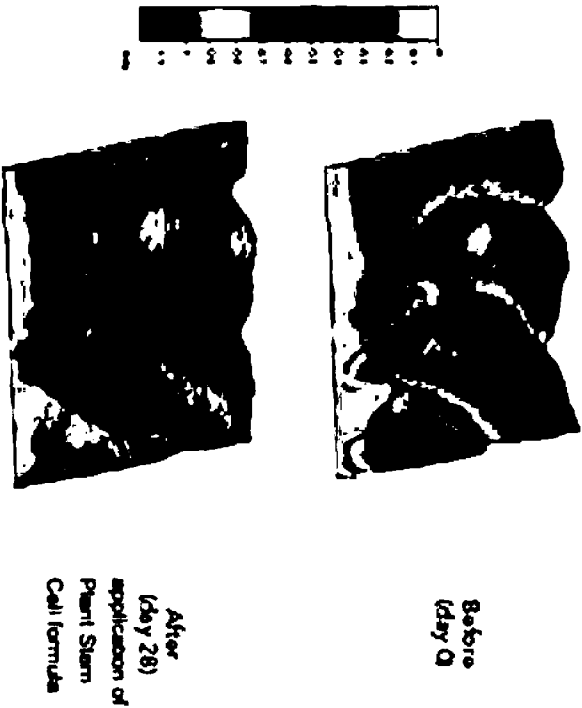
Science

Plant Stem Cells Protect Epidermal Stem Cells From UV Stress
Cultures of epidermal stem cells were treated with Plant Stem Cell formula, while others were left untreated. The cultures were exposed to UVA and UVB rays, and the colony-forming efficiency (CFE) of the stem cells was then measured. The results showed that UV radiation strongly reduced cells' colony-forming efficiency (-58.9%). Treatment with Plant Stem Cell formula improved the colony-forming ability of the stem cells, and the cells' vitality was not impaired even after exposure to UV radiation.



The Anti-Wrinkle Effect

The anti-wrinkle effect of Plant Stem Cell formula was evaluated in a study with 20 volunteers aged from 37 to 64. An emulsion containing 2% of Plant Stem Cell formula was applied twice daily for 28 days to the crow's feet area of the eye. Wrinkle depth was determined by means of PRMDS (phase-shifting rapid in vivo measurement of skin). Results showed a significant and visible decrease in wrinkle depth for 100% of the subjects.



Adore

Organic Innovation

Science

PlantStemCellFormula Effects on Genes

Normal cells express only a limited number of genes (fibroblast: collagen, blood cells: hemoglobin), whereas stem cells have the possibility to express the whole DNA. It's the epigenetic profile that regulates gene expression in stem cells.

In this study, normal human dermal fibroblasts, which are responsible for the growth of collagen in human skin, were 'aged' by immersion in hydrogen peroxide (H2O2). Half of those cells were then treated with 2% PlantStemCellFormula while the other half were not.

Decrease of senescence (aging) markers occurred in the fibroblasts treated with Plant Stem Cell formula, which correlate with its ability to extend longevity of skin cells and delay aging.

PhytoCellTec™ Malus Domestica Gene Profile (Microarray)

↓ Gen, that is down-regulated by senescence induction (see control)



Gen, that is up-regulated or normalized in senescent cells by PhytoCellTec Malus Domestica

Gen	After H ₂ O ₂ Control	After H ₂ O ₂ - 2% Malus Domestica (Plant Cell Extract)
cyclin B1: induces proliferation	73 ↓	↑
cyclin E1: tumor inducer	78 ↓	↑
p53: tumor suppressor gene	63 ↓	↑
Insulin-like growth factor II: cell proliferation enhancer	71 ↓	↑
heme oxygenase 1: antioxidants enzyme	89 ↓	↑

Summary

- Plant stem cells can activate, protect and delay aging of the skin's most important cells, namely the stem cells, thereby:
 - Triggering rejuvenation of the skin
 - Delaying the natural aging process by maintaining skin stem cell activity
 - Reducing wrinkles
 - Protecting against UV damage
 - Maintaining skin stem cells self-renewing capacity, representing a breakthrough in anti-aging
- All of which serves to extend skin cell vitality and the ability to keep skin appearance young and beautiful longer.



Patent # 8,308,100 Method 13

EXHIBIT 14

9/28/2016

- USATODAY.com

USA TODAY | News Subscribe Mobile Google USA TODAY stories, photos and more Join USA TODAY Sign in | Become a member

Home News Travel Money Sports Life Tech Weather

News Communities | Education | Nation | Military | Election 2012 | Religion | Health & Wellness | Washington | World | Opinion

Boomers will be spending billions to counter aging

By David Crary, Associated Press

Updated 8/22/2011 1:29 PM

[Comment](#) [Recommend 243](#) [Tweet](#) [G+1](#) 3

NEW YORK – Baby boomers heading into what used to be called retirement age are providing a 70 million-member strong market for legions of companies, entrepreneurs and cosmetic surgeons eager to capitalize on their "forever young" mindset, whether it's through wrinkle creams, face-lifts or workout regimens.



Jae C. Hong, AP

Photos of Dr. Jeffrey Life, a proponent of hormone therapy, hang in his office in 2008. His "age management" practice is one of the outlets catering to boomers' "forever young" mindset.

It adds up to potential bonanza. The market research firm Global Industry Analysts projects that a boomer-fueled consumer base, "seeking to keep the dreaded signs of aging at bay," will push the U.S. market for anti-aging products from about \$80 billion now to more than \$114 billion by 2015.

The boomers, who grew up in a culture glamorizing youth, face an array of choices as to whether and how to be a part of that market.

Anti-aging enthusiasts contend that life spans can be prolonged through interventions such as hormone replacement therapy and dietary supplements. Critics, including much of the medical establishment, say many anti-aging interventions are ineffective or harmful.

From mainstream organizations such as the [National Institute on Aging](#), the general advice is to be a skeptical consumer on guard for possible scams involving purported anti-aging products.

"Our culture places great value on staying young, but aging is normal," the institute says. "Despite claims about pills or treatments that lead to endless youth, no treatments have been proven to slow or reverse the aging process."

Its advice for aging well is basic: Eat a healthy diet, exercise regularly, don't smoke.

"If someone is promising you today that you can slow, stop or reverse aging, they're likely trying hard to separate you from your money," said S. Jay Olshansky, a professor at the University of Illinois-Chicago's School of Public Health who has written extensively about aging.

"It's always the same message: 'Aging is your fault and we've got the cure,'" Olshansky said. "Invest in yourself, in the simple things we know work. Get a good pair of running or walking shoes and a health club membership, and eat more fruits and vegetables."

But such advice hasn't curtailed the demand for anti-aging products, including many with hefty price tags that aren't covered by health insurance. These include cosmetic surgery procedures at \$10,000 or more, human growth hormone treatment at \$15,000 per year and a skin-care product called Peau Magnifique that costs \$1,500 for a 28-day supply.

Videos you may be interested in



California Homeowners B
FetchaRate Quotes

Sponsored Links by Taboola
[More videos](#)

Most Popular

Stories

- HF Test

Videos

- Ed Baig reviews Kindle Paperwhite
- "Pregnant man" struggles through nasty divorce
- Tennis Channel Court Report 9-30-2012

Photos

- Dramatic weight-loss success stories
- Unrest in Syria
- Editorial Cartoons

Most Popular E-mail Newsletter

Sign up to get:

Top viewed stories, photo galleries and community posts of the day

Most popular right now

HF Test



Sign up for USA TODAY E-mail newsletters

9/28/2016

- USATODAY.com

Another challenge for consumers is that many dietary supplements and cosmetics, unlike prescription drugs and over-the-counter medicines, aren't required to undergo government testing or review before they are marketed. The Food and Drug Administration and the [Federal Trade Commission](#) do crack down at times on egregiously false anti-aging claims, but generally there's little protection for people who don't get hoped-for results.

Mary Engle, director of the FTC's division of advertising practices, said her agency focuses on the cases that could cause serious harm, such as bogus cancer treatments that might prompt an ill person to forgo proper care.

She said the agency lacks the resources to crack down comprehensively on ads with exaggerated claims that exploit customers' hopes for better looks or more energy.

"Often it doesn't rise to the level of fraud," she said. "There are so many problematic ads out there and we really have to pick and choose what we focus on."

In contrast to the caution of mainstream organizations, there are many vocal promoters of anti-aging products and procedures, including the American Academy of Anti-Aging Medicine. It hosts annual conferences in the U.S. and abroad, and claims 22,000 members, mostly physicians.

In its mission statement, the academy says the disabilities associated with normal aging "are caused by physiological dysfunction which in many cases are ameliorable to medical treatment, such that the human life span can be increased."

One of the academy's co-founders is [Robert Goldman](#), a doctor of osteopathic medicine. He contends that much of the resistance to the anti-aging movement comes from sectors of the health and pharmaceutical industries that feel threatened financially — for example by the surging use of over-the-counter nutritional supplements.

"It all has to do with who's controlling the dollars," he said.

Though many anti-aging interventions are expensive, Goldman said people on tight budgets still can take useful steps such as drinking purified water, taking vitamins and using sun screen.

"People should be healthy and strong well into 100 to 120 years of age," Goldman says in a biographical video. "That's what's really exciting — to live in a time period when the impossible is truly possible."

Olshansky, who over the years has been among Goldman's harshest critics, believes there will be scientific breakthroughs eventually, perhaps based on studies of the genes of long-lived people, that will help slow the rate of aging.

In the meantime, Olshansky says, "I understand the need for personal freedom, the freedom to make bad decisions."

A look at some of the major sectors in the anti-aging industry:

Hormone replacement therapy:

Numerous companies and clinics promote hormone replacement drugs, including testosterone for men and custom-mixed "bioidentical" hormones for women, as a way to slow the aging process.

Many consumers have seen ads featuring muscle-bound Dr. Jeffrey Life, now 72. He used testosterone and human growth hormone in his own bodybuilding regimen and recommends hormonal therapy for some of the patients patronizing his age-management practice in [Las Vegas](#).

The [FDA](#) has approved hormone replacement drugs for some specific purposes related to diseases and deficiencies, but not to combat aging.

"Finding a 'fountain of youth' is a captivating story," says the National Institute on Aging.

"The truth is that, to date, no research has shown that hormone replacement drugs add

9/28/2016

- USATODAY.com

years to life or prevent age-related frailty."

Dr. Evan Hadley, director of the institute's Division of Geriatrics, says hormone replacement drugs can have harmful side effects. He said there is a need for more research, such as an institute study of testosterone therapy, to identify the potential risks and benefits.

"There is indeed potential that people can be healthier in old age," Hadley said. "But it still requires evidence about what's going to help and what's not."

Hormone drugs can be expensive. HGH shots can cost more than \$15,000 a year, according to the institute. A hormone-based dietary supplement known as DHEA (dehydroepiandrosterone), a precursor of estrogen and testosterone, is marketed online for \$12.95 per capsule by Utah-based NutraScriptives.

Some proponents say over-the-counter DHEA supplements can improve energy and strength, boost immunity and decrease fat. The institute says there's no conclusive scientific evidence of any such benefits.

Life says he's a staunch advocate of exercise and healthy eating, but insists that hormone replacement therapy, under a doctor's supervision, is a crucial addition for some men, and that includes him.

"There's no way I could look and feel the way I do if all I had done the last 13 years was exercise and eat right," he said. "Even if you do everything right, if you have a deficiency in testosterone, you will lose the fight."

Life acknowledged that the cost of testosterone replacement, probably more than \$5,000 year and not covered by insurance, could be daunting for some. But he contends the investment pays off in more vitality.

"It's hard to put on price on good health," he says.

Cosmetic Surgery:

According to the American Society of Plastic Surgeons, there were 13.1 million cosmetic plastic surgery procedures performed in the U.S. in 2010, a 77 percent increase over a decade.

One notable trend is increased preference for less invasive procedures that enable patients to get back to work and social settings without a long leave of absence.

The most popular of these is treatment with the wrinkle-smoothing drugs Botox or Dysport. They account for 5.4 million procedures, averaging about \$400 per treatment. Other popular noninvasive procedures include soft-tissue facial fillers, chemical peels and microdermabrasion.

More invasive procedures come at a higher price. Face-lifts can run from \$6,000 to \$15,000; the plastic surgeons' academy reported performing 112,000 of them in 2010.

Dr. Peter Schmid, who runs a cosmetic surgery practice in Longmont, Colo., says his field is flourishing because of evolving attitudes among appearance-conscious boomers. A recent Associated Press-LifeGoesStrong.com poll found that 1 in 5 boomers either have had or would consider cosmetic surgery.

"Cosmetic surgery has become table talk at home. There's a lot of satisfaction and acceptance from people who've had it, friend to friend, word of mouth," Schmid said.

While the noninvasive procedures cost less than a face-lift, the effects won't last as long and repeat treatments might be needed several times a year, Schmid said. He advised patients to calculate carefully which type of procedure makes the most sense for them financially.

Schmid, who is on the board of the American Academy of Cosmetic Surgery, cautioned against any rush to try new procedures that get a burst of publicity.

9/28/2016

- USATODAY.com

"There's a certain vulnerability because everybody's looking for that quick fix, that fountain of youth," he said. "Many people will shop emotionally instead of objectively, before something has been tried and tested."

Some critics of the anti-aging industry are supportive of cosmetic surgery, provided the patient can comfortably afford it.

Professor Robert Binstock, an expert on aging at Case Western Reserve University's School of Medicine, told of a recently widowed friend whose spirits lifted after getting the bags under her eyes removed. "If you feel better looking in the mirror in the morning, fine," he said. "I have no objection to people being narcissistic."

Skin care:

One of the industry's booming sectors is anti-aging skin care, featuring wrinkle creams and facial serums. By some estimates, the U.S. market for cosmeceutical products — cosmetics with medicine-based ingredients — is approaching \$20 billion a year.

The FDA, which oversees cosmetic safety and labeling, doesn't require manufacturers to prove the effectiveness of cosmetic products before they go on sale, and many ads make claims which critics say are exaggerated or unverifiable. The American Academy of Dermatology recommends consulting a dermatologist on what skin care products have been proved safe and effective in human studies.

Consumer Reports has ventured into the realm of anti-aging cosmetics several times recently, using high-tech optical devices and other scientific methods to assess the products.

Last year, the magazine tested nine face serums, available at drug stores for prices ranging from \$20 to \$65 and all claiming to reduce wrinkles.

"After six weeks of use, the effectiveness of even the best products was limited and varied from subject to subject," according to the review. "When we did see wrinkle reductions, they were at best slight, and they fell short of the miracles that manufacturers seemed to imply on product labels."

Earlier, the magazine tested wrinkle creams.

"Even the best performers reduced the average depth of wrinkles by less than 10 percent, a magnitude of change that was, alas, barely visible to the naked eye," it said.

Its top-rated product, Olay Regenerist, cost about \$19 at the time of the testing. La Prairie Cellular, the most expensive at \$335, was rated among the least effective.

Similar conclusions were reached in testing 16 over-the-counter eye creams.

"Even among the best-performing products, wrinkle reduction around the eyes was generally pretty subtle," the magazine said. "After six weeks of daily use, none came close to eliminating wrinkles."

It said the most expensive, Perricone MD at \$95 a jar, was no better than cheaper drugstore brands.

One recent development in anti-aging skin care is the use of stem cell technology. ReVive's expensive Peau Magnifique is among the new products, claiming to "recruit adult stem cells into brand new stem cells."

Neither Consumer Reports nor the FDA has conducted any specific assessment of Peau Magnifique's effectiveness. On a Web site called Makeupalley.com, some customer reviews raved about it; others trashed it as a waste of money.

Copyright 2011 The Associated Press. All rights reserved. This material may not be published, broadcast, rewritten or redistributed.

For more information about [reprints & permissions](#), visit our [FAQ](#)s. To report corrections and clarifications, contact Standards Editor Brent Jones. For publication consideration in the newspaper, send comments to letters@usatoday.com. Include name, phone number, city and state for verification. To view our corrections, go to corrections.usatoday.com.

<http://usatoday30.usatoday.com/news/health/story/health/story/2011/08/Anti-aging-industry-grows-with-boomer-demand/50087672/1>

9/28/2016

- USATODAY.com

Posted 8/22/2011 11:10 AM | Updated 8/22/2011 1:29 PM



More from USATODAY

Albert Haynesworth again fails to take Redskins' conditioning test on Thursday
USATODAY.COM in The Huddle

Ailing Antonio Gates misses Chargers practice, uncertain to play vs. Colts
USATODAY.COM in The Huddle

Amani Toomer: Steelers' Ben Roethlisberger 'should be suspended for at least eight games'
USATODAY.COM in The Huddle

More from the web

What One Longevity Scientist Discovered About What We Need As We Age
Elysium Health on Co.Exist

Dangers of aortic stenosis
Healthgrades

American Baby Boomers Born Between 1936 And 1966 Are In For A Big Surprise
LiveSmarterDaily

Man Unearths Ancient Two-Ton Mystery Buried in Backyard
VeryViral.com

29 Stars Who Gave Their Kids Ups
Stars

[?]

Sponsored Links

USA TODAY Digital Services

[Mobile](#) | [E-Newsletters](#) | [RSS](#) | [Twitter](#) | [Podcasts](#) | [Widgets](#) | [e-Edition](#) | [USA TODAY for iPad](#) | [Kindle Edition](#) | [Subscribe to Home Delivery](#)
[Reprints & Permissions](#) | [USA TODAY Topics](#) | [Reporter Index](#) | [Corrections/Clarifications](#) | [Contact Us](#) | [Archives](#)

[Home](#) | [News](#) | [Travel](#) | [Money](#) | [Sports](#) | [Life](#) | [Tech](#) | [Weather](#)

[Visit our Partners](#) | [USA WEEKEND](#) | [Sports Weekly](#) | [Education](#) | [Space.com](#) | [Travel Tips](#)

[Contact us](#) | [Advertise](#) | [Pressroom](#) | [Jobs](#) | [FAQ](#) | [Reprints/Permissions](#) | [Privacy Notice/Your California Privacy Rights](#) | [Ad Choices](#) | [Terms of Service](#) | [Site Index](#)

© 2012 USA TODAY, a division of Gannett Co. Inc.

A GANNETT COMPANY

EXHIBIT 15

Healing beauty?

More biotechnology cosmetic products that claim drug-like properties reach the market

Beauty—as the saying goes—is in the eye of the beholder, though this relativistic insight has not stopped humans from spending more than 6,000 years striving to artificially enhance their looks. From Ancient Egypt and Sumer until today, the quest for beauty is recorded in our literature, music and art. Even today, many women and men devote considerable amounts of time and money to selecting and applying the right combination of cosmetic products, and thus drive a huge—and still growing—cosmetics industry. In turn, cosmetics companies, in bids to outdo their competitors, are increasingly using the results of basic research in the biological and chemical sciences to create more sophisticated products that promise little less than everlasting beauty.

The latest wave of cosmetics are based on advanced research that includes the use of biotechnology-derived ingredients, genetic profiling for individual skin-care or nutritional regimes, stem-cell-based products and therapies to regenerate ageing tissues, or cell and tissue engineering for cosmetic purposes. “Cosmetics will take advantage from those technologies that will allow one to achieve observable results upon topical application,” commented Paolo Giacomoni, the head of research at a large cosmetics company. “Stabilized enzymes used in topical applications will help to repair [damage] after exposure to solar radiation, or to digest pigments in age spots. Appropriate polymers will tighten the skin and reduce the appearance of lines and wrinkles, or prolong moisturization.”

As a consequence of this increasing application of science to beauty, the line between cosmetic and medical research is becoming blurred; the laboratories of major cosmetic companies perform cutting-edge research in areas such as matrix biology, antioxidants and ageing processes. In addition to the goal of making women and men look younger, this research also benefits the development of therapies against a range of serious disorders.

Vice versa, various biotechnology companies—such as those that are investigating methods to boost DNA repair or wound healing—have licensed some of their molecules to the cosmetic industry, or have even entered the market with a proprietary line of beauty products themselves (Nasto, 2007). Helix Biomedix, for example, a biotechnology company based in Bothell (WA, USA) has recently patented more than 80 proprietary peptides for use in cosmetic and skin-care applications and products. According to the company, there are now more than 20 products on the market that contain Helix’s peptides (www.helixbiomedix.com).

...cosmetics companies [...] are increasingly using the results of basic research in the biological and chemical sciences to create more sophisticated products...

One of the main impetuses for researching cosmetics is that they are not required to undergo the clinical trials for efficacy to which drugs are subject. In the case of biotechnology companies, this provides a new source of income to finance their basic research; however, the blurred line between drugs and cosmetics creates a complex regulatory situation. Many beauty products—which often sell at a high retail price—come with claims that the product is based on advanced scientific research, giving consumers the impression that they are as effective—and as tested—as drugs. Conversely, the cosmetics industry does not want its products to be regulated in a similar manner to drugs as this would involve extensive, lengthy and costly clinical trials for efficacy. It therefore falls to the regulatory agencies to decide whether a product—despite its claims—is a cosmetic, or whether it should be classed as a drug because it has a therapeutic effect.



Credit: Timur Suleymanov/Dreamstime.com

The treatment of damaged or ageing skin is an important area in which the interests of medicine and cosmetics collimate most obviously, and one where the line between cosmetics and medicine is most evanescent (Giacomini, 2005). As our knowledge about the structure of the skin and its underlying repair and maintenance processes improves (Fig 1), scientists are increasingly able to intervene to stop ageing or improve healing. Renovo—a biopharmaceutical company based in Manchester, UK—is approaching phase III of clinical development of a candidate drug that reduces scarring after surgery or injury. Their product, Juvista, is based on a recombinant form of human transforming growth factor- β 3 (TGF- β 3), which is normally present at high levels in developing embryonic skin and in embryonic wounds that heal without a scar, but is almost absent in adult wounds. The intradermal injection of Juvista to the wound margins before or after surgery improves subsequent skin appearance, as scars are less noticeable and resemble normal skin more closely. The

product would benefit consumers who seek to remove small scars and patients with seriously disfiguring scars.

As a consequence of this increasing application of science to beauty, the line between cosmetic and medical research is becoming blurred...

The cosmetics and pharmaceutical industries have also expended considerable effort to understand the ageing processes of the skin and to devise countermeasures. The fragmentation of the collagen matrix in the dermis—the inner layer of skin—is caused by metalloproteinases and is an important characteristic of aged skin; various treatments, supported by clinical evidence, therefore aim to reduce collagen collapse and to stimulate its renewal. Topical retinoic acid, carbon dioxide laser resurfacing and intradermal injection of cross-linked hyaluronic acid—such as Restylane® and

Perlane® (Medicis; Scottsdale, AZ, USA)—are all known to stimulate the production of collagen, and to improve the appearance and health of the skin (Fisher *et al*, 2008). SkinMedica (Carlsbad, CA, USA) is another example of a biotechnology company that has entered this lucrative market with an anti-ageing product that contains soluble collagen, various growth factors and antioxidants among its ingredients to enhance skin texture and elasticity.

Howard Chang's team at Stanford University (CA, USA) are looking at ageing processes from a more systematic point of view, which might open the way for new interventions and further blur the line between cosmetics and drugs. By applying a bioinformatics approach to pinpoint regulators of age-dependent gene expression in humans and mice, Chang's team have identified the transcription factor NF- κ B (nuclear factor- κ B) as a crucial regulator of gene expression programmes associated with mammalian ageing (Adler *et al*, 2007). Blocking NF- κ B activity in the

analysis

epidermis of aged mice reverted tissue characteristics and the global gene expression programme to those of young mice (Fig 2). However, the authors note in a related paper that, “it is unclear whether NF- κ B blockade can become the much sought-after ‘fountain of youth’. The reversal of age-related phenotypes in mouse skin was only short-term; thus we do not know whether long-term reversal of aging is possible or whether tissue longevity has been extended” (Adler *et al*, 2008).

“Work by us and others is showing that the aging process is plastic and potentially amenable to intervention. Even temporary blockade of the aging programme may achieve healthful benefits,” Chang said of the possible implications of their discovery. However, he warned that the “long-term consequences of manipulating genes associated with ageing are not fully understood; these would certainly be a concern for applications in humans.” For example, Chang and colleagues pointed out that blocking NF- κ B in the presence of additional oncogenes might theoretically allow cancerous growth (Adler *et al*, 2008).

The research division of L’Oreal (Paris, France), the world’s largest cosmetics and beauty company, uses similarly advanced tools. While looking for a treatment to restore the hair’s natural appearance and health after excessive exposure to environmental and other stresses—such as chemical products or repeated washing and drying—L’Oreal’s researchers focused on the hair’s cuticle, its external protective sheath. Under the electronic microscope, the scales that make up the cuticle appear to be firmly held together by a cement rich in lipids, in particular, ceramides. Subsequent research confirmed that damaged hair is deprived of ceramides and L’Oreal developed a synthetic ceramide, Ceramide R, which is now incorporated into various products that the company claims will “genuinely repair damaged hair” (www.hair-science.com/).

More recently, L’Oreal developed its so-called ‘Episkin’ model—a human epidermis reconstructed on collagen (www.invitroskin.com). Episkin is not only a good research tool, but was also validated by the European Centre for the Validation of Alternative Methods (Ispra, Italy) as a potential replacement for current methods to assess the skin-irritancy potential of cosmetic ingredients and products, without using animals.

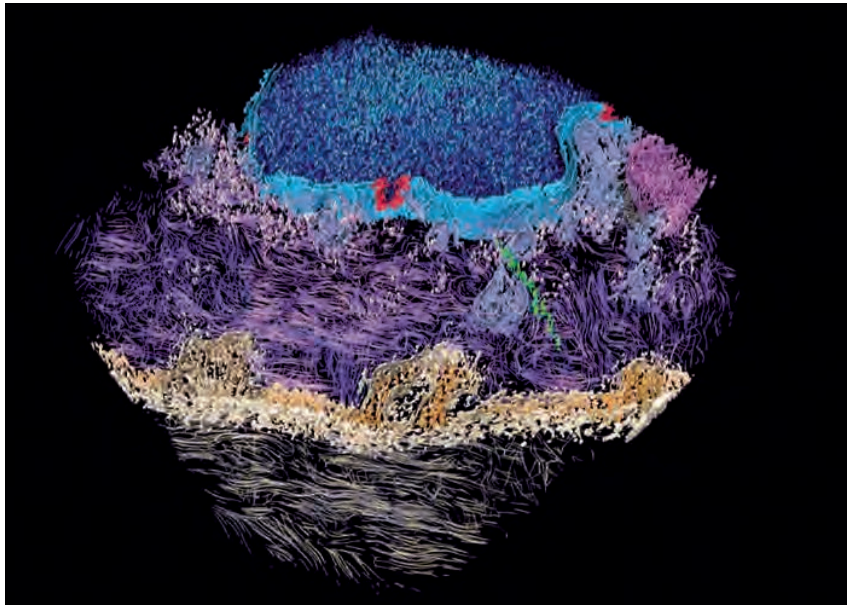


Fig 1 | Three-dimensional reconstruction of a human skin cell using cryo-electron tomography. The image shows organelles in various colours: regions of cell–cell contact (sandy brown), nucleus and nuclear envelope (blue) with pores (red), microtubules (green), mitochondria (purple), and endoplasmic reticulum (steel blue). Credit: Achilleas Frangakis, European Molecular Biology Laboratory, Heidelberg, Germany. Reproduced with permission from Nature Publishing Group; Al-Amoudi *et al*, (2007) *Nature* **450**: 832–837.

Stem cells have attracted similar interest from the cosmetics industry and various companies are already exploring their potential for skin-care products. Proteonomix, a biotechnology company in Mountainside (NJ, USA), for example, has recently launched a line of anti-ageing products that contain proteins derived from specialized stem-cell lines. The inspiration came from the apparently ‘glowing’ appearance of pregnant women. “During pregnancy, a woman’s body increases the production of specific proteins in response to secretions produced by the embryo. These specific proteins affect specific receptors in both fibroblasts and keratinocytes that increase the production of collagen,” explained Proteonomix’s CEO Michael Cohen in a white paper (Cohen, 2008). The company now produces these proteins in human stem-cell derivatives as a treatment for various dermatological conditions, including the adverse consequences of ageing, wrinkling, altered pigmentation, altered viscoelasticity and altered thickness.

Similarly, RNL Bio, a South Korean biotechnology company based in Seoul, which made the headlines earlier this year for undertaking the world’s first commercial

...various biotechnology companies [...] have licensed some of their molecules to the cosmetic industry, or have even entered the market with a proprietary line of beauty products themselves...

pet cloning, is developing a stem-cell-based cream for cosmetic applications. According to press reports, the new product will exploit the anti-ageing properties attributed to the human placenta (Wohn, 2008). The active ingredients of RNL Bio’s rejuvenation booster are proteins from cultured placenta stem cells, rather than directly extracted from the placenta. This approach, the company claims, produces more active and stable compounds, thus assuring the faster regeneration of skin cells. RNL Bio and Seoul National University are also investigating whether intravenous injections of stem cells might mitigate the degenerative effects of ageing processes.

Giacomoni, however, remains critical of the role of stem cells in cosmetics. “Stem cell technology is still far from biomedical applications, let alone cosmetic ones,” he said.

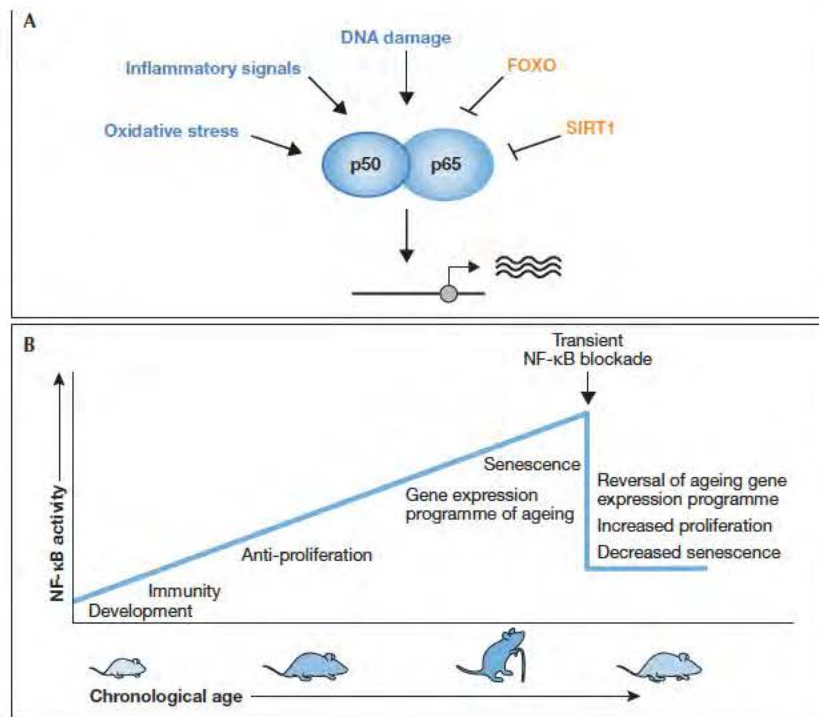


Fig 2 | NF-κB action in ageing. (A) NF-κB (shown as a p50–p65 heterodimer) is an ideal integrator of ageing signals: NF-κB is activated by stressors that shorten lifespan (blue text), and it can be repressed by signals that extend lifespan (orange text). (B) Many age-specific functions of NF-κB are revealed as its activity accumulates with chronological age. Continual NF-κB activity seems to be required for age-associated phenotypes (in the skin), as transient blockade of NF-κB reverses multiple ageing phenotypes to that of young phenotypes. FOXO, forkhead box class O transcription factor; NF-κB, nuclear factor-κB; SIRT1, sirtuin 1. Redrawn with permission from Landes Bioscience; Adler *et al.*, (2007) *Cell Cycle* 7: 556–559.

As the cosmetics industry and its research laboratories perform increasingly cutting-edge research, the difference between some cosmetic products and some pharmaceutical products is shrinking further—a development that will inevitably attract the attention of the regulatory agencies, such as the increasing scrutiny of Botox (see Sidebar A). Current legislations generally require that cosmetics must not cause harm to human health with normal or reasonably foreseeable use, and that the product itself and its ingredients must have been tested for safety. In addition, health claims made on the label and in commercials must be substantiated, which is the main problem for so-called cosmeceuticals—products that are claimed to have drug-like benefits.

In its 2007 survey, the UK Advertising Standards Authority (ASA; London, UK) classified several medicinal claims for cosmetic

products as breaches of the British codes of advertising and sales promotion. They spotted misleading or unsubstantiated anti-ageing and regenerating claims made for skin creams; claims of skin repair achieved through increased collagen production; claims of the ability to neutralize environmental damage through the use of antioxidants; and promises that moisturisers can strengthen immunity and improve circulation (ASA, 2008). Although the overall compliance rate for cosmetics to advertising standards was as high as 93%, “the greatest cause for concern was the relatively poor compliance rate for skin cream ads; 19% were found to breach the Code,” the ASA concluded. “The Compliance team considers that future problems with skin creams could revolve around claims referring to DNA stress, environmental damage, the delaying of wrinkles, cell renewal, cell regeneration and stem-cell-derived

products. Ads for new products seen since the survey have included such claims.”

Given that the cosmetic industry in Europe has an estimated market size of €65 billion, and creates half a million direct and indirect jobs, the European Union takes such problems seriously. The main regulatory framework to regulate the trade and safety of cosmetic products is the Council Directive 76/768 of 27 July 1976, and various guidance documents help regulators to decide on the exact nature of ‘borderline’ products that can fall under a different regulation, especially the one pertaining to medicinal products. “As a general rule a particular product cannot be regulated by both the Cosmetics Directive and the Medicinal Products Directive at the same time. The two regulatory frameworks are mutually exclusive. However, it is recognised that some products may fulfil at the same time the definition of a cosmetic product as well as the definition of a medicinal product. In these cases the question may arise as to which regulatory framework should apply,” explains a European Commission guidance document (EC, 2004). In these cases a ‘non-cumulation principle’ provides that the Medicinal Products Directive is applied (EC, 2004). The demarcation between the two directives—and thus between cosmetics and medicinal products—therefore remains unclear, and decisions are taken on a case-by-case basis by competent authorities as high as the European Court of Justice in Luxembourg.

The European Commission has proposed to recast the European laws on cosmetics and to simplify more than 3,500 pages of legal text from national legislations and the EU Cosmetics Directive with its 55 amendments into a new, single regulation. The aim is to strengthen product safety while reducing costs for businesses and enhancing consumer confidence. Linked to this is the recent launch of ‘CosIng’ (COSmetic INGredients; <http://ec.europa.eu/enterprise/cosmetics/cosing/>), a new online database of more than 15,000 ingredients used in the production of cosmetics—with details of current and past regulation since 1976—which will make it easier for producers to ensure that new formulations comply with existing regulations.

The US Food and Drug Administration (FDA; Bethesda, MD, USA) is facing the same problem of drawing the line between cosmetic and medicinal products, but the outcome differs to

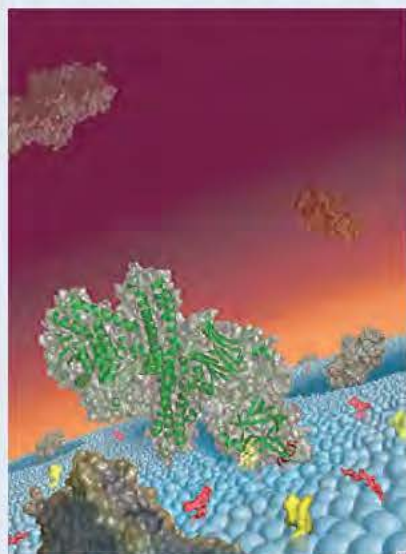
Sidebar A | A blurry future for Botox?

The cosmetic use of botulinum neurotoxins (BoNTs) to remove wrinkles might face an uncertain future. Produced by the bacterium *Clostridium botulinum*, BoNTs are among the most deadly natural toxins known; they interfere with the release of neurotransmitters—mainly acetylcholine—at the junction of nerves and muscles. These paralyzing properties have been exploited to treat a range of serious pathological conditions such as cervical dystonia (severe neck muscle spasms), facial spasticity and strabismus (abnormal aligning of the eyes), and, more recently, to reduce facial wrinkles.

Until now, the use of BoNTs for cosmetic purposes—under the brand and popular name Botox—had been considered safe, in large part because it was assumed that the toxin remained confined to the injection site. However, an Italian research team at the National Research Council's Institute of Neuroscience in Pisa recently showed that this assumption might be wrong. To study the potential use of BoNT type A to block epilepsy, these researchers injected the toxin at various points in the face and brain of rats, including the whisker muscles and hippocampus. Days later, they found that the substance had unexpectedly spread from the whisker pad to the brain stem and crossed from one side of the brain to the other in the hippocampus, blocking hippocampal activity in the untreated hemisphere (Antonucci *et al*, 2008). This should raise some concerns about the safety of BoNT injections as it revealed the ability of the toxin to travel along nerve cells while remaining active.

Earlier this year, the US Food and Drug Administration (FDA) had already warned that it had “received reports of systemic adverse reactions including respiratory compromise and death following

the use of botulinum toxins [...] The reactions reported are suggestive of botulism, which occurs when botulinum toxin spreads in the body beyond the site where it was injected” (FDA, 2008). The question is whether this is enough evidence to ban the cosmetic use of BoNTs. “I don't think that fear is warranted. Thousands of people have already taken the drug for cosmetic purposes, with few reports of side effects”, said Matteo Caleo, the study's lead author. “At the same time, I believe that the issue of BoNT/A trafficking should be further investigated. It is important to characterize completely the spectrum of actions of a drug that is so widely used.”



Botulinum neurotoxin (see image) hijacks synaptic vesicle recycling at neuromuscular junctions. The toxin first docks to the active zone (blue) by binding to two membrane-anchored receptors, synaptotagmin (red) and ganglioside (yellow). The toxin-receptor complexes are then internalized by endocytosis. Credit: Axel Brunger/HHMI at Stanford University, California, USA.

some extent. As the FDA does not apply the non-cumulation principle, a product can have intended uses as both a cosmetic and as a drug. According to the FDA, the intended use might be established in several ways, including “[c]laims stated on the product labeling, in advertising, on the Internet, or in other promotional materials; [c]onsumer perception, which may be established through the product's reputation; [i]ngredients that may cause a product to be considered a drug because they have a well known (to the public and industry)

therapeutic use” (FDA, 2002). Such products must comply with the requirements for both cosmetics and drugs.

In the end, cosmetics are not primarily about science, but about the age-old promise of beauty. “Cosmetics will take more advantage from socio-psychology than from biotech,” concluded Giacomoni. “The psychology of the elderly, the social games of children, the well-being resulting from skin care, make up and fragrances will be pointed out and will help to create new concepts and claims for cosmetic products.”

However, the lure of products with ‘scientific’ names such as ‘DNAge’ and ‘Nuvectin’, which invoke the idea of defeating ageing with the help of science, will remain irresistible for many consumers because they sound like they should work. Conversely, the increasing use of scientific research in the development of new cosmetics should ultimately benefit the consumer, as it contributes to the next generation of safer and more efficient beauty products.

REFERENCES


- Adler AS, Sinha S, Kawahara TLA, Zhang JY, Segal E, Chang HY (2007) Motif module map reveals enforcement of aging by continual NF- κ B activity. *Genes Dev* 21: 3244–3257
- Adler AS, Kawahara TL, Segal E, Chang HY (2008) Reversal of aging by NF- κ B blockade. *Cell Cycle* 7: 556–559
- Al-Amoudi A, Díez DC, Betts MJ, Frangakis AS (2007) The molecular architecture of cadherins in native epidermal desmosomes. *Nature* 450: 832–837
- Antonucci F, Rossi C, Gianfranceschi L, Rossetto O, Caleo M (2008) Long-distance retrograde effects of botulinum neurotoxin A. *J Neurosci* 28: 3689–3696
- ASA (2008) Compliance Report. Cosmetics Advertising Survey 2007. London, UK: Advertising Standards Authority. <http://www.asa.org.uk/asa>
- Cohen M (2008) Secreted Matrix™ and Matrix NC-138™. White Paper. Mountinside, NJ, USA: Proteoderm Inc. <http://www.proteoderm.com>
- EC (2004) Guidance Document on the demarcation between the Cosmetics Products Directive 76/768 and the Medicinal Products Directive 2001/83 as agreed between the Commission services and the competent authorities of Member States. European Commission, Enterprise and Industry Directorate General. http://ec.europa.eu/enterprise/cosmetics/html/cosm_borderline_docs.htm
- FDA (2002) Is it a cosmetic, a drug, or both? (Or is it soap?). Published 8 July. <http://www.cfsan.fda.gov/~dms/cos-218.html>
- FDA (2008) Early communication about an ongoing safety review. Botox and Botox cosmetic (Botulinum toxin Type A) and Myobloc (Botulinum toxin Type B). Published 8 February. http://www.fda.gov/cder/drug/early_comm/botulinum_toxins.htm
- Fisher GJ, Varani J, Voorhees JJ (2008) Looking older: fibroblast collapse and therapeutic implications. *Arch Dermatol* 144: 666–672
- Giacomoni PU (2005) Ageing, science and the cosmetics industry. *EMBO Rep* 6 (Suppl): S45–S48
- Nasto B (2007) Biotech at the beauty counter. *Nat Biotechnol* 25: 617–619
- Wohn Y (2008) Using stem cells for cosmetics. Lab obtains proteins from placenta. [suite101.com](http://medical-biotechnology.suite101.com/article.cfm/using_stem_cells_for_cosmetics). Published 30 April. http://medical-biotechnology.suite101.com/article.cfm/using_stem_cells_for_cosmetics

Andrea Rinaldi

doi:10.1038/embor.2008.200

EXHIBIT 16

Stem cell lotions: Cutting edge or pure hype?

 **Brent Schrotenboer**, USA TODAY Sports 7 p.m. EDT September 1, 2015



(Photo: Lifeline Skin Care)

To help reduce the appearance of aging, stem cell scientists in California have created a new lotion for the face.

It contains water, sunflower seed oil and stem cell peptides from donated human eggs.

Just smear some on the face at a cost of \$160 per 1-ounce bottle.

"This new and superpotent formulation vis bly firms, tones and defends skin every day," says the company, Lifeline Skin Care.

Does it really work?

The legal answer can be found on the company's website, in smaller print:

"Lifeline Skin Care and its affiliates do not guarantee specific results. Results may vary."

It's one of many cosmetic products to hit the market in recent years with claims of using human or plant-based stem cells to help restore the appearance of youth.

Many of these products — including this one — do moisturize and improve the appearance of skin, at least according to anecdotal evidence.

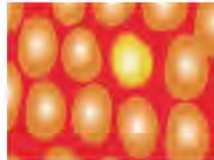
The question, experts say, is whether any improvement can be attributed to the stem cell science, a budding field of regenerative technology that's largely unproven by U.S. scientific standards.

"Stem cells that are in contact with skin are not really alive anymore," said Margaret Foster Riley, a law professor and expert on food and drug law at the University of Virginia. "So I don't really see how a stem cell product is working on the skin. I suppose some of them may actually work in a way that cosmetics work otherwise, because of moisturizing capability. But it's not stem cell capability that's working there to the degree we know how stem cells work."

Much is unknown about how — or if — these ingredients work because cosmetic products in the USA aren't held to the same regulatory standards as new drugs. To gain approval for widespread use in this country, new drugs must show they are safe and effective based on data from long and expensive clinical trials.

By contrast, over-the-counter cosmetics generally aren't subject to this same pre-market approval. Companies just have to be careful about what they claim the products do. If they promise to change the structure or function of the body, that would make them a drug requiring pre-market testing.

In recent years, the FDA has sent warning letters to companies that go too far in making claims in this field. For example, Cell Vitals of Irvine, Calif., was marketing a product called "ReLuma Advanced Stem Cell Facial Moisturizer" derived from human fat. The company said its product increased collagen and stimulated fibroblast cell growth, among other things, which made it a drug, according to the



• STEM CELLS & SPORTS SERIES

- [Ex-NFL star RB Tony Dorsett turns to controversial stem cell treatments](http://www.usatoday.com/story/dorsett-jackie-sherrill-stem-cell-treatments-mexico-gordie-howe/73480230/)
- [Companies offer athletes hope with questionable treatments](http://www.usatoday.com/story/cells-fda-athletes-joseph-purita-rolando-mcclain/71504998/)
- [Fetal stem cells and the sports heroes they revitalized](http://www.usatoday.com/story/stem-cells-gordie-howe-john-brodie-tijuana-stroke-stemedica/27501717/)
- [How Soviet Union science helped American sports heroes](http://www.usatoday.com/story/howe-stem-cells-john-brodie-stemedica-soviet-union-fetal/27504019/)
- [Bart Starr walking again after stem cell treatment](http://www.usatoday.com/story/bart-starr-walking-again-after-stem-cell-treatment-start-improving-after-stem-cell-treatment/30540473/)

FDA.



USA TODAY

Companies offer athletes hope with questionable stem cell treatments

(<http://www.usatoday.com/story/sports/2015/09/01/stem-cells-fda-athletes-joseph-purita-rolando-mcclain/71504998/>)

The company's website is no longer working after the FDA sent it a warning letter in November.

Other cosmetic companies claim to use plant-based stem cells. In a strike against such competition, Lifeline Skincare notes that it uses stem cells derived from unfertilized human eggs, not plant stem cells. The company says it uses "the same human stem cells that are active early in life to create new, young skin."

"We haven't seen clinical studies to support or prove that human skin responds or relates to plant stem cells," the company's website says.

Yet few have seen any rigorous studies to determine if human skin responds to human stem cell ingredients, either.

"Potions and lotions may in fact work really well, but at the end of the day, let's be data-driven, so the consumer doesn't have to worry about whether they think it might work," said Stanford professor Michael Longaker, an expert in plastic surgery and regenerative medicine.

A spokeswoman for Lifeline Skin Care in California says independent studies have been conducted that show its stem cell ingredients to be effective. USA TODAY Sports asked the company for data from such studies but didn't receive any that proved whether the same lotion produced better results with the stem cell ingredient than without it.

The spokeswoman, Meghan Austin, conceded that if you "put an actual human stem cell on the skin, it wouldn't do anything." She said Lifeline instead extracts contents from the cells and processes them in a way that ensures they are absorbed and effective.

All cosmetic companies need to claim their products are effective in different ways. But it can be a fine line: Is it a drug, or is it a cosmetic? Riley said the FDA has been wrestling with that question since Congress passed the Food, Drug and Cosmetic Act in 1938.

"If they are selling it as a cosmetic, it all depends on the claim they are making," she said. "These companies actually have pretty big legal departments, and the claims they will make are very carefully designed to thread the needle. They don't want to make a drug claim, but they obviously do want to make a claim so they can sell it and make a claim that it has an effect."

EXHIBIT 17

Short on evidence

Gagnon, Louise **Dermatology Times** 32.3 (Mar 2011): 36,40.

[Full text](#) [Abstract/Details](#)

Search ProQuest...

- Cite
- Email
- Print
- Save

Add to Selected items

Abstract [Translate](#)

Metairie, La.- Stem cell products hold the promise of skin rejuvenation and skin repair, and the science that supports the claims of their benefits makes sense, but there are scant clinical studies in human subjects that demonstrate their efficacy and safety. According to manufacturers, the active ingrethent in Amatokin is polypeptide 153, Dr. Farris says.

Full Text [Translate](#)

Headnote

Aesthetic products claiming to contain stem cells are scant on clinical studies

Metairie, La.- Stem cell products hold the promise of skin rejuvenation and skin repair, and the science that supports the claims of their benefits makes sense, but there are scant clinical studies in human subjects that demonstrate their efficacy and safety.

"We know that as you age, stem cells reduce in function and number," says Patricia Farris, M.D., a board-certified dermatologist and dermatologie surgeon in Metairie, La. "Stem cells are important in maintaining skin homeostasis and function and for repairing skin after injury."

It appears that stem cell dysfunction or loss of function is the result of several key factors including oxidative stress, ultraviolet light, inflammation and telomere attrition, Dr. Farris says.

"The logic is that if we can boost stem cell function, we can rejuvenate the skin, making it function more like it did when it was young. And this makes total sense as an anti-aging strategy," Dr. Farris says.

Stem cells' role

Stem cells are found in the epidermis, dermis, bulge region of the hair follicle and sebaceous glands.

"Stem cells help regenerate the epidermis, maintain epidermal barrier

Related items

Search with indexing terms


Subject

- Stem cells
- Wound healing
- Telomerase
- Studies
- Human subjects

More...

[Search](#)

ebrary e-books

1.  Reference Manual for Scientific Evidence (3)

2.  Applied Legal Philosophy : Legal Evidence and Proof : Statistics, Stories...

Short on evidence - ProQuest

function, and also support the dermal matrix," Dr. Farris says. This, she says, is why in intrinsic aging, poor wound healing, skin dehydration, wrinkling and loss of elasticity are seen.

"Stem cells are important for keeping skin healthy and looking young," Dr. Farris says. "We know that as we get older, aging fibroblasts don't work as well. They produce excessive amounts of MMPs and less collagen."

Stem cell cosmeceuticals do not actually contain stem cells. Most product lines tout enzymes or peptides that serve to protect or improve stem cell function. Some of the first stem cell cosmeceuticals to market contained the enzyme telomerase. Telomerase protects telomeres from shortening, thus preserving stem cells.

Lack of evidence

Dr. Farris says the products that are available on a retail basis are costly, and she hesitates to recommend them to patients in the absence of good clinical studies.

"As stem cells get older, there is telomere attrition," she says. "It makes sense that if you repair the telomeres, you can restore the activity of the stem cells."

"We don't have proof in human skin yet that when these skincare products are applied to the skin that they can really boost stem cell activity, and, more importantly, make the skin look younger," Dr. Farris says. Most of the research on stem cell products has been done in vitro and needs to be translated to the clinical setting with human subjects, she adds.

There have been concerns regarding cosmeceuticals containing telomerase, in that it has been shown that telomerase may promote tumor growth and invasion of skin cancer cells.

"We have no evidence to suggest that any of these topical skincare products containing telomerase pose a danger to patients, but it remains a theoretical concern," Dr. Farris says. "We have to demand that good studies are performed to ensure patient safety."

Cosmeceutical advances

Natural or botanical telomerase-activating compounds are also finding their way into nutraceuticals and cosmeceuticals. Geron Corporation holds patents on the compound telomerase activation-65 (TA- 65) found in the Chinese herb astragalus. Pivotal studies demonstrated that oral supplementation with this natural telomerase activator resulted in an improvement in skin condition in male patients age 60 to 85.

"Consumers always favor products that are natural, making this

3. Evidence, Decision and Causality



supplement an attractive option for some anti-aging enthusiasts," she says.

Yet Dr. Farris says she believes more studies are warranted. "We have a lot more to learn about TA-65 before we can give it a thumbs-up," she says.

Amatokin, marketed by Voss Laboratories, launched in 2007 and remains a popular stem cell cosmeceutical. According to manufacturers, the active ingredient in Amatokin is polypeptide 153, Dr. Farris says.

"It is a peptide that was discovered in burn patients," she says. Much of what is known about the natural repair process of the skin is found by observing what happens in the natural wound-healing process, she notes. How this peptide affects stem cells remains unclear, but manufacturers claim it activates dormant stem cells. Although Amatokin is sold widely, Dr. Farris says she has been unable to find clinical studies supporting its efficacy.

"At the end of the day, what our patients want to know is, 'Will this product make my skin look better?' Only with good clinical studies can we assure them that it's really worth the money," she says.

Mibelle Biochemistry takes a different approach to stem cell activation with its patented ingredient Swiss apple stem cell extract.

"We know that plants have stem cells," Dr. Farris says. "If you wound a plant, the callus tissue that forms is rich in plant stem cells."

Mibelle Biochemistry has patented a technology to culture and process a rare Swiss apple known for its long shelf life. This stem cell extract, called PhytoCellTec Malus Domestica, has been shown to slow cellular senescence in vitro.

"The extract can make old cells regenerate much like they did when they were young," she says.

Stem cell extract study

A small study of 20 patients age 37 to 64 demonstrated the impact of a Swiss apple stem cell extract on skin wrinkling. The test cream contained 2 percent Swiss apple stem cell extract, and subjects applied the cream twice daily to their crow's feet for 28 days. The test cream reduced wrinkle depth by 8 percent in two weeks and 15 percent in four weeks over baseline.

"It's important to note that this was a small user study with no control group," Dr. Farris says. "There are some products on the market that contain this ingredient."

Short on evidence - ProQuest

Dr. Farris is serving as medical monitor on a double-blind, vehiclecontrolled study on NeoStrata's Skin Active, which contains Swiss apple stem cell extract as well as other cosmeceuticals actives.

Swiss apple stem cell extract has created a buzz since it was reported that first lady Michelle Obama is a fan of it, according to Dr. Farris.

"This is something your patients may ask you about," she says.

Stem cells undoubtedly represent a growing focus of research, Dr. Farris says.

"There is more to come on stem cells," she says. "It is an interesting area of research for skin biologists to look at to see if we can turn on stem cells in a positive way to rejuvenate skin." DT

Sidebar

quick read

More studies on stem cell products are needed to determine their safety in human skin.

Sidebar

"The logic is that if we can boost stem cell function, we can rejuvenate the skin, making it function more like it did when it was young."

Patricia Farris, M.D.

Metairie, La.

Sidebar

Disclosures: Dr. Farris is a consultant for NeoStrata.

AuthorAffiliation

By Louise Gagnon

Staff Correspondent

Word count: **1125**

Copyright Advanstar Communications, Inc. Mar 2011

EXHIBIT 18

Direct-to-Consumer Stem Cell Marketing and Regulatory Responses

DOUGLAS SIPP

RIKEN Center for Developmental Biology, Kobe, Japan

SUMMARY

There is a large, poorly regulated international market of putative stem cell products, including transplants of processed autologous stem cells from various tissues, cell processing devices, cosmetics, and nutritional supplements. Despite the absence of rigorous scientific research in the form of randomized clinical trials to support the routine use of such products, the market appears to be growing and diversifying. Very few stem cell biologics have passed regulatory scrutiny, and authorities in many countries, including the United States, have begun to step up their enforcement activities to protect patients and the integrity of health care markets. *STEM CELLS TRANSLATIONAL MEDICINE* 2013;2:638–640

THE INDUSTRY LANDSCAPE

Charlatans are drawn to frontiers. The scientific frontier of stem cell biology has attracted an unusual amount of dubious business activity, despite the paucity of credible evidence for the efficacy of these cells in the treatment of indications for which they are marketed. The first company to sell stem cell treatments in the United States opened in 2002, just 4 years after the derivation of human embryonic stem cells triggered a wave of optimism and hyperbole surrounding this nascent field of research. In the decade that followed, an industry encompassing hundreds of private clinics advertising stem cells (derived from bone marrow, umbilical cord blood and other perinatal tissue, fat, fetal tissue, etc.) for the treatment of medical conditions too numerous to list sprang up in countries around the world. If such companies' claims are to be believed, many tens of thousands of patients have paid many hundreds of millions of dollars pursuing stem cell dreams unsupported by rigorous scientific research. It is a vast medical experiment, uncontrolled, unsupervised, unreported, and conducted on a for-profit basis.

This industry has, however, seen its share of innovation in the form of developing business plans that avoid premarket testing for safety and efficacy. Clinical outfits have proliferated and diversified to cultivate demand for stem cell remedies in neurology, orthopedics, cosmetic surgery, general rejuvenation, even pediatric conditions. (Worryingly, studies have shown that nearly half of the patients whose treatments are described in social media are children [1].) A niche industry of companies providing ancillary services ranging from patient recruitment and travel support to physician training has also emerged, and numerous "AstroTurf" organizations (meaning groups that seek to portray their sponsored activities as driven by grassroots initiatives), such as industry-operated foundations and professional societies, have been formed to lobby for weaker regulations and rally members of the public against government intervention. Those efforts notwithstanding, the sector of the industry that markets stem cell transplants, injections, and infusions has also received significant reg-

ulatory attention. In numerous smaller countries, national medical councils and ministries of health have taken actions such as issuing public warnings on the risks of unapproved stem cell interventions or restricting the activities of clinics operating within their borders. The European Medicines Agency, the competent regulatory authority in the European Union, has also been active in its development of a regulatory framework for advanced therapeutic medicinal products, which includes many forms of human cell biologics, and placing limits on the ability of commercial operators to exploit the "hospital exemption" that allows for nonroutine experimental care for individual patients. The U.S. federal government has been especially active in this regard over the past 2 years, as outlined below.

Some companies follow other, less rigorous pathways to the market for their putative therapeutics. Makers of point-of-care cell processing devices, for example, have sought and, in some cases, obtained 510(k) clearance from the U.S. Food and Drug Administration (FDA), a form of market authorization that does not require advance testing for safety and efficacy for devices deemed to have substantially equivalent predicates already on the market, whereas individual physicians frequently use marketed devices not approved for stem cell applications for harvesting, minimal processing, and retransplantation of autologous cells as part of the same surgical procedure, thereby bypassing the more stringent federal standards over stem cell biologics. A review of the 510(k) clearance process by the Institute of Medicine in 2011 recommended that the system be scrapped, on the basis that it does not require premarket testing of safety and efficacy for potentially risky devices [2], and the FDA rejected applications for two cell processing devices submitted for 510(k) clearance [3], which may have implications for the future of this pathway to the market.

Regulatory shopping remains a commonplace strategy for circumventing inconvenient laws, with companies based in countries with stringent regulatory oversight setting up shop in border

Correspondence: Douglas Sipp, RIKEN Center for Developmental Biology, Kobe, Japan. Telephone: 81-78-306-3043; Fax: 81-78-306-3090; E-Mail: sipp@cdb.riken.jp Received March 4, 2013; accepted for publication July 10, 2013; first published online in *SCTM EXPRESS* August 9, 2013. ©AlphaMed Press 1066-5099/2013/\$20.00/0; <http://dx.doi.org/10.5966/sctm.2013-0040>

Table 1. U.S. Food and Drug Administration warning letters relating to stem cell companies

Date	Company	Subject
August 15, 2011	TCA Cellular Therapy	Autologous bone marrow-derived mesenchymal cells
March 13, 2012	Intellicell Biosciences	Autologous adipose-derived stem cells
April 20, 2012	Young Medical Spa	Autologous adipose-derived stem cells
September 7, 2012	Lancôme	Cosmetic products claiming bioactivity on stem cells
September 7, 2012	Greek Island Labs	Cosmetic products claiming bioactivity on stem cells
September 20, 2012	Celltex Therapeutics	Autologous adipose-derived stem cells
September 24, 2012	Texas Applied Biomedical Services	Institutional Review Board employed by Celltex, above

towns and sending patients to clinics in less strictly policed neighboring countries, often on a same-day basis. This form of arbitrage also pads the bottom line, as operating costs in many of the destination countries are a fraction of what they would be in the country of origin. More importantly, this practice externalizes a great deal of liability to patients, who not only assume the risks of undergoing invasive procedures outside the standard of care, but also effectively abandon many of the legal protections they would enjoy in more closely supervised settings.

Even in cases in which patients do not travel outside their home country, significant ethical considerations surround any commercial activity in which products or procedures are marketed as potentially therapeutic without having been validated scientifically. Although it appears that most businesses selling stem cells seek to indemnify themselves by indicating the “experimental” nature of their interventions on websites and informed consent forms, it seems fair to observe that such waivers of responsibility are weighted in favor of the provider, rather than the patient. Also concerning is that many such companies target vulnerable populations, such as patients with neurological conditions and parents of children with developmental and other diseases, with stem cell interventions that lack not only rigorous evidence but often a plausible basis in science.

Other firms have accessed consumer markets by developing nutritional supplements (nutraceuticals) purported to increase the number of endogenous stem cells in circulation or otherwise boost stem cell activity. In the United States, such products are regulated under the porous and ineffectual Dietary Supplement Health and Education Act, which creates a third category of product that is neither food nor drug and over which the FDA has only limited regulatory authority [4]. One of the first such product lines to use “stem cell” in its advertising was introduced via a multilevel marketing scheme; the company (Stemtech Health Sciences) claimed to have netted more than \$1,000,000 in its first month [5]. This is symptomatic of the larger movement to portray stem cells as a component of alternative or complementary medicine, rather than a nascent and unproven form of orthodox biomedicine. A cursory survey of online advertisements reveals stem cells offered as adjuncts to or therapeutic targets of acupuncture, homeopathy, ayurvedic medicine, and phytotherapy, among others [6].

The cosmetics industry has also caught the stem cell fever. Numerous makers have introduced lines of so-called cosmeceuticals, such as skin creams, lotions, hair products, and even sunscreens, that claim to contain either stem cell extracts or bioactive compounds that stimulate stem cells within the skin or hair follicles, ostensibly promoting the regeneration of surface tissue. A growing subcategory of these products invoke the rejuvenating power of plant stem cells extracted from Swiss apple, argan, bilberry, or edelweiss, to name a few. As the FDA has shown generally limited ability to challenge cosmetics manufacturers

on efficacy claims [7], the industry remains very much governed by a caveat emptor ethic, although there have been signs of increased scrutiny in the past year, as described in the following section.

Of greater concern than stem cell cosmetics, a significant number of aesthetic plastic surgeons have embraced a range of expensive and invasive procedures using autologous adipose-derived stem cells (or stromal vascular fraction) in breast and buttocks augmentation and so-called stem cell facelifts, with only sketchy evidence to support their routine use. To their credit, the American Society of Plastic Surgeons and American Society for Aesthetic Plastic Surgery issued a joint statement asserting that “the marketing and promotion of stem cell procedures in aesthetic surgery is not adequately supported by clinical evidence at this time” [8].

REGULATORS TAKE ACTION

Regulators have begun to respond to these alarming developments. In the United States, the FDA has inspected sites and issued untitled or formal warning letters to companies in violation of the relevant section of the Code of Federal Regulations (CFR 1271) [9]. The first federal action against a self-styled stem cell clinic was initiated against BioMark International Inc. in 2005 (the proprietors subsequently fled the country and resumed business using a new corporate identity) [10]. In 2008, the FDA sent an untitled letter to Regenerative Sciences Inc., triggering a protracted legal battle that centered on the question of whether processed autologous stem cells should be classified as a biologic drug, and therefore federally regulated, or subsumed within the practice of medicine, which is not under federal jurisdiction. The case was resolved in July 2012, with the court upholding the FDA’s authority and issuing a permanent injunction against the company [11]. The FDA took no public action against other domestic stem cell companies in 2009 or 2010, a hiatus that may have been a consequence of the uncertainties introduced by the ongoing litigation. But beginning in 2011, the FDA began to signal its renewed interest reining in unapproved stem cell products (or perhaps greater confidence that the courts would affirm its authority in the area), and in a 1-year period issued multiple warning letters and injunctions to companies and individual physicians (Table 1).

The nature of the businesses that triggered regulatory responses suggests that the authorities were selective in their targeting. Four of the seven companies that were issued Warning Letters had been engaged in the sale of autologous stem cell products that the agency determined to be more than minimally manipulated and/or intended for nonhomologous use, either of which triggers classification as a biologic drug under CFR 1271. Two others had made unsupported marketing claims about the activity of their cosmetic products on endogenous skin stem

cells. The last was a private institutional review board that had provided services to one of the companies (Celltex Therapeutics) involved in unauthorized clinical use of autologous adipose-derived cells. This was a particularly pointed exercise of federal authority in this area, as only a few months prior to these actions the state medical board in Texas (where both Celltex and its institutional review board [IRB] are located) published new rules that appeared to allow investigational uses of stem cell products to be approved by private IRBs without FDA authorization [12]. Celltex has since announced that it will begin offering stem cell interventions to patients across the border in Mexico [13].

State medical boards and law enforcement agencies have also taken action against individuals making commercial stem cell claims. Proprietors of purported stem cell businesses have been arrested in Nevada, Texas, and California for making fraudulent claims regarding their products and services; convictions were returned in all cases [14–16]. In Florida, the state board of medicine first restricted and then suspended the license of a local doctor who had begun offering injections of autologous stem cells to patients within the state [17]. His attorney has sought to portray this activity as off-label use within the ordinary practice of medicine or, alternatively, as alternative medicine [18]. Seemingly undeterred, the physician launched a new stem cell business even as his administrative hearing proceeded [19].

CONCLUSION

Despite these numerous enforcement actions, dozens of companies and private medical practices within the United States continue to openly market stem cell interventions directly to consumers. Although some of these companies send patients to Mexico, Central America, or the Caribbean, a surprising number appear to deliver their unlicensed interventions domestically. A researcher at the University of Minnesota has identified 20 such clinics in the state of Texas alone [20]. It appears for now that the considerable profit incentive outweighs the perceived risks inherent in violating the law. Presumably this situation will prevail until either the federal authorities take greater action against individuals and firms that persist in the unapproved marketing of stem cell interventions or fully validated safe and effective stem cell biologics receive market authorization and are covered by health care insurance, which would allow them to outcompete the current range of stem cell nostrums on their own terms.

AUTHOR CONTRIBUTIONS

D.S.: manuscript writing, final approval of manuscript.

DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

The author indicates no potential conflicts of interest.

REFERENCES

- Zarzewicz A, Caulfield T. Stem cell tourism and doctors' duties to minors: A view from Canada. *Am J Bioeth* 2010;10:3–15.
- Institute of Medicine of the National Academies. *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*. Consensus report. Washington, D.C.: Institute of Medicine of the National Academies, 2011.
- Cytori Therapeutics Inc. v. FDA, D.C. Cir., No. 11-1268.
- Cohen PJ. Science, politics, and the regulation of dietary supplements: It's time to repeal DSHEA. *Am J Law Med* 2005;31:175–214.
- Stemtech Health Sciences. Everything Stemtech. Available at <http://rsvp4life.net>. Accessed March 4, 2013.
- Sipp D. Stem cell stratagems in alternative medicine. *Regen Med* 2011;6:407–414.
- Liang BA, Hartman KM. It's only skin deep: FDA regulation of skin care cosmetics claims. *Cornell J Law Public Policy* 1999;8:249–280.
- Eaves FF 3rd, Haeck PC, Rohrich RJ. ASAPS/ASPS position statement on stem cells and fat grafting. *Plast Reconstr Surg* 2012;129:285–287.
- U.S. Code of Federal Regulations, Title 21, Part 1271 (2012). Available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1271>. Accessed March 4, 2013.
- Casewatch. Stem cell swindler charged with fraud. Available at <http://www.casewatch.org/doj/blomark/indictment.html>. Accessed March 4, 2013.
- United States of America v. Regenerative Sciences, LLC et al., Civil Action No. 2010-1327 (RMC) U.S. District Court DC (2012). https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2010cv1327-47. Accessed March 4, 2013.
- Kaiser J. Stem cells: Texas Medical Board approves rules for controversial treatment. *Science* 2012;336:284.
- Cyranoski D. Stem cells in Texas: Cowboy culture. *Nature* 2013;494:166–168.
- Preventive therapy [Editorial]. *Nature* 2013;494:147–148.
- U.S. District Attorney's Office, Southern District of Texas. Convictions entered in two separate Texas cases involving stem cells. Available at <http://www.justice.gov/usao/txs/1News/Releases/2012%20September/120907%20Morales%20and%20Stowe.html>. Accessed March 4, 2013.
- CBS News. Encinitas woman pleads guilty to treating patients without a license. Available at <http://www.cbs8.com/story/19867994/encinitas-woman-pleads-guilty-to-treating-patients-without-a-license>. Accessed March 4, 2013.
- Florida Dept. of Health v. Zannos G. Grekos. DOAH Case No. 11-4240PL.
- Freeman L. Bonita Springs stem-cell doctor asks judge to dismiss state's case against him. *Naples News*. February 9, 2013. Available at <http://www.naplesnews.com/news/2013/feb/09/bonita-springs-stem-cell-doctor-grekos-license/>. Accessed March 4, 2013.
- Intercellular Sciences website. Available at <http://www.intercellularsciences.com>. Accessed March 4, 2013.
- Turner L. Adult stem cell banks and clinics marketing stem cell procedures in Texas. *Health In the Global Village* blog. September 17, 2012. Available at <http://www.healthintheglobalvillage.com/2012/09/17/adult-stem-cell-banks-and-clinics-marketing-stem-cell-procedures-in-texas/>. Accessed March 4, 2013.

EXHIBIT 19

News Feature

Nature Reports Stem Cells

Published online: 15 January 2009 | doi:10.1038/stemcells.2008.163

A superficial success

Bryn Nelson¹

The promise of stem cells in reconstructive surgery has prompted a surge in rejuvenating skin creams that claim to stimulate them. But commercial success says nothing about efficacy

It's not immediately clear what connects the sobering images of cancer survivors on Jeremy Mao's computer screen in Manhattan's Upper West Side with the breathlessly hyped skin creams sold by the city's Midtown retail giants.

But as researchers like Mao expand the potential for stem-cell-aided reconstruction for patients missing a breast or sizeable chunk of lower lip, the cosmetic promise of perkier breasts and fuller lips is following fast behind. So too are the skin-care companies determined to make a little dab of stem cell science go a long way toward plumping up sales in stores such as Macy's, Bloomingdale's and Neiman Marcus.

Mao, director of the Tissue Engineering and Regenerative Medicine Laboratory at Columbia University College of Dental Medicine in New York, doesn't care much for beauty aids; he wants to figure out how to use stem cells for soft-tissue reconstruction that dramatically improves on existing methods of plastic surgery: transferred fat is problematic because it shrinks, silicon implants because they leak. For Mao's strategy to succeed, implants seeded with stem cells must attract new blood vessels and maintain their designated shape in the long term.

In a proof-of-principle study, Mao's group implanted hydrogel plugs patterned after Eppendorf tube caps into immunodeficient mice. For a subset of the plugs, the researchers added microchannels seeded with adipogenic stem cells derived from human mesenchymal stem cells, and also added basic fibroblast growth factor¹. Blood vessels grew into the channels to support new adipose tissue formed within the plug's boundaries. That vascularization, Mao says, offers both a nutrient source for the stem cells and an anchor to which host tissue can attach. The next step on the path toward US Food and Drug Administration (FDA) approval is demonstrating the same success in a sheep or goat model.

The encouraging science behind stem-cell-aided tissue regeneration has led the US Department of Defense to commit \$85 million in funding to the new Armed Forces Institute of Regenerative Medicine (AFIRM). (See [Stem cells drafted for war on wounds.](#))

Peter Rubin, co-director of the Adipose Stem Cell Center at the University of Pittsburgh Medical Center in Pennsylvania and a member of an AFIRM-funded consortium, says researchers are pursuing two main

strategies. One is to seed adipose-derived stem cells onto carriers such as microbeads or biodegradable hydrogels, introduce them into a tissue bed and allow them to differentiate — the general approach also adopted by Mao. The second is to introduce multiple growth factors to recruit a patient's own adipose stem cells for wound healing.

Could either strategy create more youthful-looking skin? "I think there is absolutely potential to do that," Rubin says. However, the cosmetic skin-care products on offer can't use such invasive strategies. Instead, companies have seized on the regenerative potential of stem cells to promote topically applied cosmetic solutions whose effectiveness is highly debatable.

Skin deep

Creams, serums, emulsions and lotions with names such as Plazan, Amatokin, Peau Magnifique, TSN Recovery and HydroPeptide Serum are all angling for well-off shoppers with a strong aversion to crow's feet or laugh lines. One "resets your skin's 'aging clock' by a minimum of five years". Another offers "improved overall skin appearance by 350%". Most are produced in the United States; none of the claims has been evaluated by the FDA.



Jessica Kolman

Despite celebrity endorsements in glossy magazines, most researchers remain unimpressed. "I have yet to see any solid scientific evidence," says Mao. Rubin is likewise sceptical. "There is a paucity of real data on topical creams that claim to impact stem cells," he says.

The topical products contain stem-cell-stimulating peptides and enzymes ranging from epidermal growth factor to telomerase as active ingredients, but unless those ingredients can get past the epidermal layer, says Rubin, "nothing worthwhile is going to come from it". In a relatively unregulated industry susceptible to marketing ploys, there's little assurance that the current crop of wrinkle-banishing potions contains anything remotely useful, he says. "It could be stem cells, or bacon grease."

Sam Most, a facial reconstructive surgeon at Stanford School of Medicine in California, says stem-cell-related cosmetic marketing is following the time-tested tactic of climbing aboard the bandwagon of hot topics, from collagen to FDA-approved Botox injections. Most says

There is a paucity of real data on topical creams that claim to impact stem cells.

he hasn't specifically analysed the claims of stem-cell-related creams, but his own laboratory experience suggests another major issue: growth factors and enzymes are notoriously temperature-sensitive. "They don't just sit there on the shelf and last," he says.

Peter Rubin, University of Pittsburgh Medical Center

To do any good, the ingredients would have to remain stable for weeks or months at room temperature, get past the epidermal layer, go into the right cells, and exert the proper stimulation once reaching their destination. And if marketers demonstrated they could do all that, Most thinks, the creams would probably require FDA approval.

Not surprisingly, some companies have finessed their message to avoid such scrutiny. Steve Peck, president of Issaquah, Washington-based Azure Cosmeceuticals, says his company's HydroPeptide Serum (\$119 per 30 ml) "forms a film over the skin that feeds the skin the active ingredients over time, similar to a time-release capsule that you would ingest". Liposomes and nanotechnology help to deliver the stem cell factors and plant- and animal-derived peptides deeper into the skin, he says. So does the use of short-chain amino acids — many bound with fatty acids — and the inclusion of the phospholipid lecithin, according to a chemist working with the company.

Peck cautions that FDA regulations don't allow him to claim that the serum works directly in the living dermis layer, although he says the ingredients work indirectly to firm and plump skin cells. The company has commissioned user-group studies, but has yet to publish any data in a peer-reviewed journal.

Going for fat

Even more pricey than the new cosmetics are stem-cell-based skin rejuvenation procedures being offered by a few private clinics. Last year, New Jersey-based plastic surgeon Vincent Giampapa began publicizing his \$5,000 "stem cell facelift" — a strategy meant to overcome the natural barrier posed by the epidermis. According to a press release, the "revolutionary technique" involves transplanting stem cells and fat from a patient's lower abdominal area to the subcutaneous fatty layers of her face, "and awakening them as well as the local stem cells within the face with specific stem cell growth factors". Exactly which factors aren't specified, and Giampapa, whose clinic has performed the procedure for four years, didn't respond to repeated inquiries.

Karl-Georg Heinrich, a cosmetic surgeon based in Vienna, Austria, with offices in Moscow and Dubai, has similarly begun extracting adipose-tissue-derived stem cells from his patients in Vienna and reinserting the cells, either mixed with fat or by themselves, for reconstructions elsewhere in the body or face. Heinrich sees the procedure as little more than a liposuction combined with a fat transfer, both of which are already offered at university hospitals. As such, he sees no regulation issues "as long as you use sensible means to process the fat". Yet he concedes a lack of data regarding the cells' post-injection longevity.

Instead of skin creams, Heinrich favours mesotherapy — a series of injections into the patient's

subcutaneous fat layer. The technique offered in his clinic is similar to that used for intramuscular Botox injections, but instead uses either stem-cell-related growth factors or a patient's own harvested stem cells to achieve a rejuvenating effect on local adipose tissue.

Of the roughly 60 peer-reviewed articles on mesotherapy published within the past two decades, more than half focus on complications and unwanted side-effects, including delirium with psychotic features, facial cutaneous ulcers, and multifocal scalp abscess with subcutaneous fat necrosis. No study has yet focused on stem-cell-based mesotherapy, although doctors in Thailand are sounding the alarm about a potentially deadly treatment on offer that allegedly removes facial wrinkles with injected animal stem cells. Several doses, a doctor told Bangkok's *The Nation*, could lead to fatal anaphylactic shock.

Beyond the safety concerns, merely injecting enzymes, peptides or a few thousand stem cells into subcutaneous tissue does not ensure that they are likely to work as intended, says Stanford's Most. "It's like if you find the best wrench ever and throw it onto the car seat. Is your engine going to run better?"

Name your price

For both topical and injected treatments, Most says he knows of no clinical studies demonstrating rejuvenation at the microscopic level, which would be apparent through features such as a thicker epidermal layer and collagen arranged in more parallel bundles. This void hasn't stopped a host of miracle claims. Amatokin, available at high-end department stores such as Macy's and Bloomingdales in New York and Harvey Nichols in London, sells for \$190 per 30 ml and comes with a bizarre back-story involving a "super secret" Russian lab whose research on burn victims apparently required razor wire and machine-gun-toting guards. Despite in-house hype that this 'underground' celebrity wrinkle cream represents "the most profound skincare advancement in more than three decades", its alleged success at stimulating expression of stem cell markers in the skin so far lacks peer-reviewed evidence.

Basic Research, Amatokin's parent company in Salt Lake City, Utah, did not respond to enquiries. The United Kingdom's Advertising Standards Authority, however, concluded in July 2008 that claims implying a physiological effect were not supported by product-specific evidence and could mislead consumers. On the basis of its findings, the advertising authority asked Basic Research-owned Voss Laboratories to remove the challenged claims from its Amatokin advertising in the UK.

A direct competitor, RéVive Skincare's Peau Magnifique, retails for \$1,500 (for four 1-ml ampoules) at Neiman Marcus and at online retailers. RéVive, of Louisville, Kentucky, has collected the covers of more than 40 glossy magazines to publicize its serum. Beyond the serum's telomerase ingredient that supposedly "converts resting adult stem cells to newly-minted skin cells", the serum contains fibroblast growth factor to stimulate collagen synthesis and "Nobel Prize winning" epidermal growth factor to promote cell turnover.

The identification of epidermal growth factor — along with nerve growth factor — did win its co-discoverers the Nobel Prize in Physiology or Medicine in 1986. And RéVive president and founder Gregory Bays Brown

published a cluster of studies in the 1980s and early 90s supporting the benefits of bioengineered epidermal growth factor in treating chronic wounds and second-degree burns. Whether those benefits extend to resetting the wearer's 'aging clock' is less clear.

Insoo Hyun of Case Western Reserve University and co-chair of the Task Force on the Clinical Translation of Stem Cells established by the International Society for Stem Cell Research (ISSCR), says his task force's newly released guidelines focus primarily on disease applications. Nevertheless, he says, many of the same concerns and questions apply to cosmeceuticals, such as whether the claims have been adequately peer reviewed.

A company's reluctance to publish its results because of fears that its secrets will be stolen is neither a new nor a valid argument, Hyun says. The independent review process already incorporates confidentiality agreements designed to protect intellectual property, he says. "You can't hide behind that."

The success and proliferation of these products suggests, however, that the market for beauty will provide ample cover for the foreseeable future.

Related articles:

[Stem-cell banking: lifeline or sub-prime?](#)

[Stem cell researchers face down stem cell tourism](#)

[Offshore stem cell treatments require sensitive regulation](#)

[Stick to the guidelines and fewer get hurt](#)

Reference

1. Stosich, M.S. *et al.* Bioengineering strategies to generate vascularized soft tissue grafts with sustained shape. *Methods* doi:10.1016/j.ymeth.2008.10.013 (2008) | [Article](#) |

Author affiliations

1. Bryn Nelson is a freelance science writer based in Seattle.

Nature Reports Stem Cells [EISSN](#) 1754-8705

Banner image © Andrew Paul Leonard, **APL Microscopic**

[About us](#)

[Contact us](#)

[Accessibility statement](#)

[Help](#)

[Privacy policy](#)

[Use of cookies](#)

[Legal notice](#)

[Terms](#)

[Naturejobs](#)

[Nature Asia](#)

[Nature Education](#)

[RSS web feeds](#)

Search:

go

SPRINGER NATURE

© 2016 Macmillan Publishers Limited, part of Springer Nature. All Rights Reserved.

partner of AGORA, HINARI, OARE, INASP, ORCID, CrossRef, COUNTER and COPE

EXHIBIT 20

entrepreneur profile

Adore Organic Lifting the Face



A dazzling array of beauty products. Cutting-edge innovations. A sleek upscale boutique look. All why Adore Cosmetics is set to make waves in the specialty retail industry.

Emily Lambert

If you're a specialty retailer or shopping center developer, there's a good chance you've seen Adore's sister concept, Deep Sea Cosmetics, a line of products with ingredients from the Dead Sea, in more than a few shopping centers. It would be hard not to – there are now 700 specialty retailers selling the concept throughout the world.

With a foundation richly steeped in skin care experience, and a wealth of relationships with specialty retailers and shopping center developers alike, the first Adore Organic Innovation store

Innovation: of Specialty Retail



opened its doors in September 2012. One short year later, that number has multiplied to 40 stores.

“By having Deep Sea Cosmetics as a sister company for ten years, we had already built a platform of operators and shoppers,” says Shay Sabag Segev, President of Adore Cosmetics, based in Miami, FL.

Thus retailers who have bought into the Adore concept have largely been Deep Sea specialty retailers, 80% in fact, that desired to upgrade their business to a permanent inline store, whether keeping their existing Deep Sea RMU, or not. “There

isn't competition between the two companies because the concept and technology of the products differ – having two different skin care brands at the same mall in different lease programs does not contradict each other,” Segev says.

“We created a blend between temporary and permanent leasing. The growth into permanent leasing is an extension of the retailer's experience, our knowledge and our product reputation. Everything is born from specialty retail,” he adds.

Tziyona Cohen the VP of Adore emphasizes that retailers are eager and excited – many want to branch out and grow into a



permanent and stable business for years to come. “Many of the retailers in the skin care industry are looking to expand,” Cohen says. “The potential to grow with a permanent program is much higher and stable.”

Adore is offered as a permanent inline option. Occasionally, kiosks are taken *only* in high-end malls, but when a permanent store deal is confirmed, the kiosk is transitioned into the permanent store. Because Deep Sea has established relationships with major mall developers, assisting Adore retailers with store locations becomes that much easier. Deep Sea Cosmetics is the biggest bidder in the specialty retail market in the last five years for common area space, says Segev. “We have more than 180 leases. We work with major developers, such as Simon Malls, General Growth Properties and Westfield,” he says.

“Back when I started as a cart owner in 2001, I was knocking on the doors of leasing management offices, waiting for specialty leasing managers to get back to me. It is much different for our retailers. We offer the service of a leasing department,” says Segev. “This service includes assisting with finding locations around the globe and brokering between parties,” he says.

In addition to a leasing department, Adore supports its retailers with a retail and service department. The retail department answers any questions or concerns about

Resource Box

Name of Company: Adore Cosmetics

Contact: 866.539.3337

adorecosmetics.com

HQ: Miami, FL

Warehouse Locations: Miami, FL, Israel

Number of Stores: 40

Projected Number of Stores, 4th Quarter 2016: 120

Countries: World Wide

Employees: More than 60 + freelancers.

Mission: To be the leading innovator skin care company delivering anti-aging products through organic innovation.

Strength: The experience we have. The long relationships we have. There’s millions of businesses out there. It’s the people who care to move it forward.



products and their uses. We are there to back our retailers up," says Segev. The service department handles mall management issues and assists with order tracking. "Everything is through us. It is much more fluent," he says.

Specialty retailers need to be comfortable with their finances, as permanent stores come with substantially higher rents (keep in mind, sales will be approximately 4-5 times higher than those on an RMU, says Segev). They also need to be comfortable with the length of a long-term lease, as permanent leases run an average of 5-10 years. And last, but certainly not least, are build-out expenses. These can run between \$60,000 (min renovation)—\$250,000 and up for a full renovation (Shell structure), says Segev, as opposed to \$3,000-\$5,000 for a cart. On the plus side, Adore provides all drawings, designs and professional services by an in-house architect and graphic designer, eliminating high expenses.

Because the stakes are higher, Adore carefully screens potential retailers to make sure they have what it takes. "Operators who come in to open an

inline store need much more experience than a cart operator going into business for the first time," says Segev. "They have to have the experience to operate a store and they need the finances to support it," he adds.

[Adore will be a fully functioning franchise very soon. Specific details are not available at this time. "Not too much changes," says Segev, other than, "Customers will know they are in an Adore store. Each store will have the same layout and design."]

Organic innovation

You might have heard of stem cells before, but probably not about all their amazing potential for skin care. Stem cells deliver the anti-aging magic found in every Adore product. They are the key to the skin's ability to renew itself. According to the National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, in Bethesda, MD, "The primary roles of adult stem cells in a living organism are to maintain and repair the tissue in which they are found."

To fully understand their capability: "Researchers are working toward using stem cells to replace damaged heart cells and literally restore cardiac function," reports the NIH. If stem cells can be used in life threatening situations, it isn't hard to imagine the wonders they hold for the skin.

"Stem cells prevent aging," says Segev. "Scientists have found that the stem cells of apples are similar to the stem cells in human beings. Through the use of biotechnology, science is able to utilize these fruit stem cells by using them in cosmetics, so they are able to penetrate the skin," says Segev.

According to Adore, studies have shown plant stem cells protect against UV damage, reduce wrinkles and delay natural aging by maintaining skin stem cell activity. Plant stem cell formula is in every Adore product (there are approximately 90 in total).

"This is anti-aging technology; creating new cells and helping exhausted cells renew themselves, like a Botox injection," says Segev.

Added to this stem cell formula is a rich blend of vitamins, essential oils, organic flower extracts and organic vegetable proteins, to further promote and restore healthy-looking skin. For anti-aging benefits to take place, an entire treatment needs to be applied. There are six treatments in all (including a men's line), each one targeting a specific skin type. "We made it simple. It's not about multiple sales. It's about the complete treatment," says Segev. Most treatments break down into three steps: pre-treatment, treatment and post-treatment.

Adore's newly introduced new treatments series are:

- Oxygen Booster Microdermabrasion line, created to deliver oxygen to the skin's capillary system, which provides a boost to collagen production. Adore's Vitamin C series was created to eliminate the appearance of age-related discolorations, such as pigments, stains and uneven skin





holding apples (plant stem cells waiting in the wings) to the words “Organic Innovation,” customers are stepping over the common area threshold to the sleek and shiny boutique-like atmosphere of Adore. Carefully placed among neighbors who mirror this image.

Spaciously placed throughout the store are beauty demo stations and plush seating. Perhaps customers enjoy an espresso or a glass of wine, different operators offer different refreshments. “We want them to enjoy being there, to feel like they are at home,” says Segev.

tones. This line is gaining in popularity as the awareness of Vitamin C’s effectiveness becomes more widely known, says Segev.

- Adore’s CELLMAX line contains the highest concentration of stem cells, and is one of the top-selling series. This series features CELLMAX Superior Facial Mask, CELLMAX Elite Facial Serum and CELLMAX Redefining Facial Cream.

- Adore Overnight Complete Treatment features Chronogen, a bio-engineered peptide that is proven, Segev says, to restore proper rhythmic gene expression, boosting natural cellular defense against UV damage during the day and improving skin’s DNA repair at night. Segev says the result: complexion is refreshed, restored and rejuvenated.

Also worthy of mention is The Golden Touch series, featuring the power of pure gold. Pure gold reduces the appearance of sun damage by slowing down melanin (a dark pigment) secretion, as well as the breakdown of elastin (a protein in connective tissue), reports Adore.

Every Adore product comes with a certificate of authenticity. “This is very important,” says Segev. “In order to preserve and keep the brand from grey marketing [when a product is bought and sold outside of the manufacturer’s authorized trading channels], we are monitored 24/7 by a law firm that specializes in intellectual property and manages online activity. It is the reason we are strict about who we sell to. We want to keep the brand as strong as possible,” he says.

A door to Adore

Adore communicates their technological edge in every corner of their store. From giant graphics picturing youthful models

Demo stations offer customers the ability to see how their skin reacts right before their very eyes and feel confident about the products they are buying. Associates are at the ready to target their needs and guide them to a series that will serve them best, says Segev.

If customers are interested in a full treatment, the treatment room is suggested. “We created a treatment room so the shopper can be isolated in a spa-like environment with no pressure from outside. They can receive personalized attention and are better able to focus on the product knowledge from the demonstration,” says Segev.

Tzyiona Cohen, the VP of Adore Cosmetics states; “by having a boutique skin care store, a solid confidence is gained among the customers. “Shoppers enjoy the feeling of purchasing from a permanent store and definitely from a high-end boutique which employs professional employees as ours,” Cohen says.

Adore feels strongly about staying innovative, always evolving and always being first through excellence. “We have made it a company mission to introduce a minimum of twenty new products every year,” says Segev.

“This is time for revolution to evolution, it’s a promise that you will Adore it.”

Emily Lambert is a freelance writer residing in Philadelphia, PA. You can reach her at emilylambert@comcast.net.





Canonical ID: 09TELAVIV423_a
Subject: DEAD SEA COSMETICS AND SKINCARE INDUSTRY FRAUD
From: Israel Tel Aviv
To: Italy Rome, Secretary of State
Original Classification: UNCLASSIFIED
Current Classification: UNCLASSIFIED
Previous Handling Restrictions: -- Not Assigned --
Archive Status: -- Not Assigned --
Type: TE
Locator: TEXT ONLINE
Reference(s): -- N/A or Blank --
Executive Order (E.O.): -- Not Assigned --
Markings: -- Not Assigned --
Enclosure: -- Not Assigned --
Concepts: -- Not Assigned --
TAGS: Consular Affairs--Consular Administration and Management [CMGT]
Consular Affairs--Visas [CVIS]
Economic Affairs--Labor and Manpower; Labor Sector Affairs [ELAB]
Fraud Prevention Programs [KFRD]
Israel [IS]
Social Affairs--Social Conditions [SOCI]
Office: -- N/A or Blank --
Document Character Count: 21213
Date: 2009 February 20, 05:15 (Friday)

UNCLAS TEL AVIV 000423

DEPT FOR CA/FPP, SARAH SEXTON
CA/FPP: PLEASE PASS DHS AND DOL
ROME FOR DHS/ICE

SIPDIS

E.O. 12958: N/A
TAGS: CVIS, CMGT, KFRD, ELAB, SOCI, IS
SUBJECT: DEAD SEA COSMETICS AND SKINCARE INDUSTRY FRAUD

1. SUMMARY: In the past few years, sales of Dead Sea cosmetics and skincare products at kiosks in shopping malls across America has grown into a huge industry. A lesser-known, but problematic, aspect of the Dead Sea industry is that its personnel is comprised of many young Israelis working on tourist visas, on expired temporary work visas and on training visas. Visa issues are likely to be just the tip of the Dead Sea industry's tax and labor issues iceberg, which has attracted Department of Homeland Security (DHS) and Department of Labor (DOL) investigators' attention in a number of U.S. jurisdictions.

2. SUMMARY CONTINUED: Tel Aviv, which issues the majority of these Israelis' visas, is working closely with ICE Rome and various U.S.-based DHS investigators to uncover the extent of Dead Sea fraud and associated criminal activity. Each investigation holds a piece of the larger puzzle, which Tel Aviv believes can best be pieced



together through close, inter-agency collaboration. To date, Tel Aviv has implemented a variety of actions to help combat and prevent this type of fraud. In the interest of updating investigators or others who may encounter Dead Sea fraud, this lengthy cable summarizes many of Tel Aviv's actions, delineates this fraud's inherently nebulous nature and highlights current Dead Sea fraud trends. END SUMMARY.

Background on the Dead Sea Industry

3. Sales of Dead Sea cosmetic and skin care products form a billion-dollar industry in the United States. This industry is based upon the Dead Sea products' unique key ingredients-mud and minerals from the Dead Sea. Tel Aviv's Dead Sea fraud began in a low-key fashion several years ago and escalated with its 715% increase in H2B visas processed over the past three fiscal years. Tel Aviv handled 204 H2Bs in FY 2006; 1,077 in FY 2007 (a 428% increase); and 1,662 in FY 2008 (a 54 % increase). The fraud appears to have spread from the H2B and H3 categories into the B1/B2, J, L and E categories, and if our increased knowledge leads to a higher refusal rate on the visa line, it could potentially affect Israel's keen wish to join the Visa Waiver Program.

4. For some time, Tel Aviv's line officers and CBP officers have been deceived by young Israelis, generally newly released military (IDF) draftees, who end up selling Dead Sea products at kiosks in shopping malls across the United States in contravention of their issued visa category or beyond their permitted duration of stay. Complicating things for both Tel Aviv and CBP is that Israelis usually return from abroad after their U.S. stay. Hence, Tel Aviv's focus has shifted to another consideration within 214b: being satisfied that the applicant will lawfully engage in activities consistent with the requested NIV status.

5. One of several Dead Sea fraud's modus operandi: Israelis in their early 20's who have just finished their compulsory IDF service come to the Embassy to apply for B1/B2 visas, indicating to the interviewing officer that they intend to visit family and/or friends in the United States as part of Israel's entrenched rite of passage: a year traveling around the world. Knowing that these particular Israelis eventually return, the officers generally decide to issue them B1/B2s. Unbeknownst to the officers, these Israelis had been well-coached for their interview. After obtaining their visa, they then obtain/purchase documents for B1 in lieu of H3 status for "training" in the Dead Sea industry and submit them to CBP at the POE. Secondary investigations revealed that their true intent was to earn lots of money quickly by selling Dead Sea products at mall kiosks. The financial incentive is great; post-IDF salaries are low and jobs scarce-hence their "need" to find a way to quickly finance their university education and/or onward travels. The fact that working and receiving a U.S. salary is illegal on B1/B2s really does not bother them. From their perspective, "not many Israelis are caught."

6. For Tel Aviv's newly arrived Fraud Prevention Manager (FPM), the



Dead Sea fraud case began with a pile of H2B substitution letters. As she reviewed a huge stack of letters to glean information about companies selling Dead Sea products at kiosks in shopping malls across the United States and employing young Israelis looking to make a quick buck in a short period of time, she decided to gather the companies' contact information and organize it in an Excel spreadsheet in order to see which patterns emerged. After the Dead Sea worksheet's creation, she followed the initial data mining exercise with a far more extensive CCD search on the companies' names, U.S. contacts, U.S. phone numbers, etc. The numbers of H2B applicants from each company were also noted.

7. The FPM operated on the detective-like assumption that all relevant new information could potentially yield other avenues of information. In other words, the data mining process is not unlike the ability of a single yarn to unravel a knit sweater; pull on it and more yarn follows. To illustrate: a CCD search on a U.S. phone number, A, brought up all NIV cases associated with that phone number. Clicking on the Excel button would put all the search's results into a spreadsheet, with easily sortable data, such as names of U.S. contacts for these cases, company names associated with this phone number, other U.S. contact phone numbers, etc. After analyzing the data, the clearly Dead-Sea connected results would be added to the file and the FPM would do further CCD searches with the newly acquired information. In sum: A would lead to B and B would lead to C, and so on down the alphabet-all relevant data were pursued to the end of their individual chains in order to obtain the largest "picture" possible as well as additional, useful insights.

8. Israeli workers in the Dead Sea industry have caught the media's attention. A Wall Street Journal article, published December 3, 2008, "Shalom, Christmas Shoppers: Israelis Sell Cosmetics, Toys at the Mall" <http://online.wsj.com/article/SB122826483720274329.html> explains how "shoppers are being besieged by a determined crop of salespeople: young Israelis who man mobile carts and have a no-holds-barred selling style" as well as the strong economic appeal these sales jobs have for Israelis. One of the Israelis interviewed for the WSJ article worked while in B1/B2 status. A more cross-cultural perspective is provided in "Slinging Mud," a June 12, 2008 Jerusalem Post article; another illegal worker is interviewed at <http://www.jpost.com/servlet/Satellite?cid=1212659713050&pagename=JPost%2FJPArticle%2FPrinter> (readers must join the link to access article).

Recruitment of Dead Sea Workers in Israel

9. Israelis have a vast array of sources for learning about what they think are potentially lucrative, short-term jobs in the United States. Word of mouth is especially compelling; they hear from friends and family members who had good experiences selling Dead Sea products and decide to do the same thing. Another primary recruiter is the Web. Sites such as http://www.maka.co.il/show_jobs_list.asp?f_id=7 and



http://www.jobsource.co.il/usa_jobs.php lure Israeli workers by promoting the possibility of salaries as big as USD 1,500 - 3,000 per week and other positive aspects of jobs selling Dead Sea products in the United States. You Tube videos, newspaper ads and visa vendors (some of whom are lawyers) are other key recruitment sources. As mentioned above, there have been problems with some recruiters because they are coaching Israelis for their visa interviews and advising them how to complete visa application forms. One such recruiter instructed successful Israeli applicants to avoid flying into Atlanta as that POE "will turn you around." In addition to advertising for Israelis, large numbers of Israeli-Americans and Israelis with VWP-country passports also have been recruited.

Dead Sea Companies' Generic Structure

10. There are bona fide Dead Sea companies in this segment of the cosmetic, skin-care industry; however, their legitimacy has been tainted by egregious abuses committed by other corporations. These companies, many of which are LLCs, generally promise Israelis a commission percentage from their sales, and offer discounted housing and assistance with plane tickets. However, some companies have been abusing U.S. labor laws and evading U.S. taxes in addition to engaging in marriage fraud to keep their key officers in the United States. A key player in the industry has a holding company that has more than 50 companies connected to it--shell companies are not unlikely.

11. With the huge amounts of cash the industry generates, money laundering could well be part of the scene. There is evidence of money transport: last fall, an Israeli was stopped at a mid-western airport for failing to declare the USD 23,000 s/he was carrying back to Israel. This February, Customs agents caught the parents of a kiosk owner/worker at an East Coast airport with USD 17,000 they were bringing back to Israel; they had declared only USD 7,000. Right now, there seem to be at least two distinct Dead Sea entities involved in fraudulent activities. Aside from the United States and Canada, one of the larger Dead Sea companies has a presence in Europe, Australia and New Zealand.

12. The "Brand Name Dead Sea" companies' general structure: the "parent" company (i.e. the Brand Name Dead Sea) purchases kiosks at malls (e.g. Westfield) across the United States. The "parent" company then sublets this contract out to a specific kiosk manager. The control of this kiosk manager is locked in through a person from the "parent" company who holds a "Regional Manager" position. At this point the "parent" company operates Web sites which "rent" out Israeli employees to the individual kiosk managers. The "parent" company is listed as the employer for all legal forms and applications for the workers although, in fact, this "parent" company has no idea who has been hired. The kiosk managers then assume responsibility for securing and providing housing and transportation for each employee. The kiosk managers often charge each kiosk employee about USD 400-500 per month for housing, which perpetuates a system of earning cash-based profit while also



creating debt bondage for the employers.

13. Of note: like money laundering, executive owners of these "parent" companies create a series of additional bona fide and legitimate managerial layers between themselves and the actual, illegal kiosk worker. Thus, it has been extremely difficult for investigators working to combat Dead Sea fraud to move beyond simply denying entry to young Israelis and make long-term progress towards shutting down the "root operations."

Negatives Experienced by Israeli Workers

14. In some instances, passports are held by the employer. An Israeli on an H2B said his/her employment at a kiosk was "sketchy" and that s/he did not receive a wage unless they were selling. Though Israelis may be in the United States legally on the right temporary work visas, there could be fraudulent/incorrect labor certificates. A company had jobs advertised as paying \$7.50 an hour plus commission; when the paperwork was filed, every worker was paid exactly the same amount, raising suspicions and implying that they were being paid in cash and off the books. Some companies have used financial shenanigans to create the appearance that all their workers were being paid minimum wages. Some Israelis have complained about the long hours they needed to work each day (e.g. 12 hour shifts), and the resulting inadequate pay, which did not fulfill their recruitment promises. Tel Aviv has found more Israelis willing to share their negative experiences-one was arrested and jailed in a cell with a murderer for several days.

Key Characteristics of Dead Sea Fraud

15. B1/B2: Israelis tell their interviewing officer that they are going to the USA for tourism, or to visit family and friends when they intend to work at the kiosks. Previously refused B1/B2ers have had the chutzpah to return to our NIV windows for H2Bs two days later. B1/B2ers have been known to overstay and/or attempt to change status several times while in the United States.

H2B/J1 SWT: Taxes, personal and corporate, owed are not paid. Labor violations exist. After receiving a J1 visa, some Israelis search online for kiosk jobs and then stay in the United States post-SWT program to work; to do so, they have had lawyers apply for their change of status. Tel Aviv is aware of cases in which the status requested was B1.

H3 and the J1 18 month program: "Training," which in reality has Israelis selling Dead Sea products. An Israeli thinks that s/he is going for legitimate training in the U.S. market-yet, s/he is unaware that the 'training' is to be just kiosk work. Hence, there is reason to believe that some recruiters have been lying to and/or exploiting Israelis.

E and L: Qualifying Israelis fresh out of the army as "managers," when in reality they will only be selling Dead Sea products. Companies have drafted false contract wages for their E1



applicants--to satisfy Tel Aviv.

Who's Combating Dead Sea Fraud?

16. Quite a few people/agencies have been combating Dead Sea fraud. To name a few: ICE Rome/Buffalo, FDNS Laguna Niguel/Phoenix, CBP Newark, DOL LA, DS and CA/FPP. There are a number of US- and overseas-based investigations; each one holds a piece of the larger puzzle, which we believe could usefully be pieced together via a Dead Sea conference, pending availability of funds. Collaboration among the interested agencies and offices is the most effective way to attack this hydra-headed problem.

Tel Aviv's Fraud Efforts and Consular Leadership

17. Tel Aviv has been trying very hard to improve detection of Dead Sea fraud at the visa window-this has not been easy as, on our end, the fraud is nebulous-many Israelis travel for a while after finishing the army as part of their national rite of passage. Yet, we do know that the Dead Sea industry specifically targets these young, post-army Israelis for recruitment.

18. Before detailing Tel Aviv's efforts, a brief word should be given on one of the Consular Leadership tenets:

Delegate Authority-but Not Responsibility

We give employees ownership over their work, issue clear and concise instructions, and provide coaching and further clarification if needed. We stand behind our people and take responsibility when mistakes are made or calculated risks don't work out.

19. One of post's leadership initiatives under this tenet includes the creation of a democratic, team-based system for managing its eight NIV ELOs. As part of this team-oriented ethos, the NIV Chief/FPM and ELOs regularly brainstorm problems with the goal of coming up with the best all-around solution(s) possible. This approach has yielded positive results in our efforts to combat and prevent Dead Sea fraud.

20. Brainstorming the known aspects of Dead Sea fraud led to:

-- ELOs' toughening of their guidelines for B1/B2 issuances to the post-army segment of Tel Aviv's applicant pool;

-- the addition of more detailed issuance notes to help CBP with their secondary interviews;

-- a new tracking system for these B1/B2 issuances by inquiring whether the applicant intends to work in the United States and, upon hearing "no", entering a standard phrase, "applicant says no intent to work illegally" in the NIV case notes (replicated to the CCD and easily searchable for validation/trend studies);

-- a temporary "insurance" exercise in which a tiny minority of visa recipients have their 10-year visas annotated, "First trip, visiting family in XYZ, State" to discourage illegal work and to give CBP a



heads up that the Israeli falls within the Dead Sea segment of the applicant pool;

-- institution of comprehensive interviews of Dead Sea-related DHS bond case Israelis regarding their work experience to obtain new information and insights; and,

-- to counteract the numerous rosy, promotional online videos recruiting Israelis, the decision to produce a short video in which several Israelis are interviewed about their negative experiences working in the Dead Sea industry.

21. Since the implementation of its fraud prevention efforts in October 2008, post's adjusted B1/B2 refusal rate for Israeli nationals has gone up from .87% for the October 1, 2007-January 31, 2008 time frame to 3.59% for October 1, 2008-January 31, 2009. Yet, there's only so much our line officers can do when "flying blind" in terms of determining which post-army Israelis are likely to work in the United States-quite a few of them have been extremely well coached. This frustrates them, for, in many cases, these Israelis are qualified for the B1/B2 in that they may be enrolled in top-notch universities, provide sufficient funds for the trip and are in stable employment situations in Israel. To illustrate: one Israeli who had been with the Israeli National Police for a while, resigned his job post-B1/B2 visa issuance to work at a kiosk; this Israeli was caught by CBP at POE.

22. Tel Aviv's FPM also has established strong working contacts with CBP at several POEs. This effort has truly benefited both parties; CBP has been notifying FPM via e-mail about Dead-Sea related turnarounds as they happen and FPM has been sharing information with CBP about the Dead Sea industry and visa applicants from its perspective. Upon receiving CBP's information, the FPM is able to immediately look up the turnaround's visa case and analyze how his/her visa was issued and glean useful details. Key to this mutual effort, from Tel Aviv's point of view, is the fact that CBP can "see" trends that we do not see here in Tel Aviv. We each have a small piece of the puzzle; putting the pieces together yields a larger picture. To put together as many pieces of the puzzle as possible, the FPM has been in regular contact with the above-mentioned agencies that have been investigating other aspects of Dead Sea fraud such as marriage fraud, possible money laundering, underpayment of kiosk workers, lawyers involved in filing fraudulent H2B petitions, etc. To date, there has been one conference call amongst Tel Aviv, ICE Rome, FDNS Laguna Niguel and DOL in Los Angeles.

23. On the more mundane, but no less important, side, the FPM has been using LexisNexis in conjunction with the CCD to research the Dead Sea industry. Through this ongoing process, the FPM maintains an up-to-date Excel worksheet on the companies involved in the Dead Sea industry; this worksheet has been shared with ICE/Rome, FDNS Laguna Niguel, FDNS Phoenix, ICE Buffalo, CBP officers at various POEs, and other State offices such as the ECA Compliance Unit, which handles J visa trainee programs. In addition, the FPM and the FPU



have used this information to add numerous CCD watch phrases to help catch B1/B2 (and other visa categories) applicants who list "Dead Sea" connected phone numbers, contacts, addresses, and etc. on their DS-156s prior to their visa interviews.

24. Our ARSO-I also has been working closely with the FPM, ICE/Rome, and more uniquely, with an NEA analyst in DS/IGI/GR. This analyst, who visited Tel Aviv several months ago, has been researching core Dead Sea companies and charting them in such a way that we can visually see all the connections between the various corporate entities, U.S. addresses and key players. Making all this possible is a software program called: i2 Chart Reader. Tel Aviv has installed this software at all FPU computers as well as the ARSO-I's.

25. Tel Aviv FPU has submitted two validation study requests through FPP's new ADIS/ATS program. One focused on the 1,350 H2Bs Tel Aviv issued between June 1, 2007 and May 30, 2008. The other focused on 510 B2 and J cases that contained data known to be connected to the Dead Sea industry. Generally speaking, the validity studies' analysis has thus far uncovered overstays along with numerous extensions and changes of status while in the United States.

26. Tel Aviv is becoming increasingly concerned that the Dead Sea model is also being applied to the locksmith industry. Both share the same initial start-up geographical areas, CA, AZ and TX. There is also a presence in OH and MA.

27. Tel Aviv FPM looks forward to hearing from others who have been working on Dead Sea industry fraud and is willing to share information accordingly. Wendy Vincent can be reached via vincentwm@state.gov.

CUNNINGHAM

EXHIBIT 21

LAW OFFICES OF
RONALD A. MARRON

A PROFESSIONAL LAW CORPORATION

651 Arroyo Drive
San Diego, California 92103

Tel: 619.696.9006
Fax: 619.564.6665

April 25, 2016

Via: Certified Mail, (receipt acknowledgment with signature requested)

Universal Handicraft Inc.
ATTN: Shay Segev
President and Agent for Service
1400 Alton Road
Suite 201
Miami Beach, FL 33139

Adore Organic Innovation
ATTN: LEGAL DEPARTMENT
332 Rodeo Drive
Beverly Hills, California 90210

Universal Handicraft Inc.
ATTN: LEGAL DEPARTMENT
1005 Park Centre Blvd.
Miami, FL 33169

RE: *NOTICE: Violations of Consumer Protection Laws, Breach of Warranties, and Duty to Preserve Evidence*

Dear Sir or Madam,

PLEASE TAKE NOTICE that this law firm represents Lisa Mollicone, a purchaser of Adore CELLMAX® Products. All further communications intended for our client must be directed through this office. This notice and demand letter provides **Universal Handicraft, Inc. d/b/a “Adore Organic Innovation”** (“YOU”) with notice and demand for corrective action arising from YOUR breaches of warranties, and is meant to comply with the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*, and the laws requiring pre-suit demand and notice, including the California Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.* (“CLRA”).

YOU manufacture, distribute, market, and sell the Adore Cosmetics® line of beauty products, including the CELLMAX® product line that YOU claim is “today’s most advanced anti-aging biotechnology for skincare.” YOUR CELLMAX® product line claims to have “the highest concentration” of YOUR “exclusive Plant Stem Cell Formula.” Additionally, YOUR marketing materials claim that plant stem cells “can activate, protect and delay aging of the skin’s most important cells, namely the stem cells, thereby:

- Triggering rejuvenation of the skin
- Delaying the natural aging process by maintaining skin stem cell activity
- Reducing wrinkles
- Protecting against UV damage
- Maintaining skin stem cells’ self-renewing capacity, representing a breakthrough in anti-aging.”

YOUR website also makes the following statements about the CELLMAX® Product line:

CELLMAX - Redefining Facial Cream Net Wt. 50ml 1.7 Oz Formulated with revolutionary CELLMAX, featuring the highest concentration of our exclusive ***Plant Stem Cell formula, today’s most advanced anti-aging biotechnology for skincare.*** This remarkable formula is proven to restore youthful appearance by protecting your skin’s own stem cells and encouraging them to regenerate healthy texture. To amplify its age-defying properties, we infuse it with extracts of chamomile, linden blossom and other all-natural flora to regenerate tone and promote smoother appearance. Meanwhile, Allantoin deeply hydrates by binding moisture to dry skin. ***This phenomenal anti-aging cream helps erase the look of deep wrinkles and restore youthful texture, leaving skin fresher, harmonized and renewed. You’ll see results with every application.***

CELLMAX Elite Facial Serum Net Wt. 50ml 1.7 Oz With the passage of time, skin cells suffer damage from aging and environmental elements. This extraordinary facial serum from Adore Organic Innovation helps halt and reverse the aging process using CELLMAX, a breakthrough combination of age-defying active ingredients. ***It features the highest concentration of our exclusive Plant Stem Cell formula, today’s most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin’s own stem cells and encouraging them to regenerate***

healthy texture. Its anti-aging action is increased with a special complex of Vitamin C, which regenerates the skin's appearance cell by cell, promoting production of collagen for skin firmness and elasticity. This is suspended in a formulation of jojoba seed oil, which makes it readily absorbed to minimize fine lines and wrinkles. Vitamin E revitalizes each layer of your skin, preventing damage and protecting skin from future harm, while Bisabolol soothes the skin and prevents irritation. With each application, this innovative serum promotes skin suppleness and works to restore what time and the elements take away.

CELLMAX - Superior Supplement Facial Thermal Mask Net Wt. 50ml 1.7 Oz
Treat your skin to the most advanced anti-aging science available today with CELLMAX Superior Facial Thermal Mask from Adore Organic Innovation. This unique self-heating mask not only smoothes deep lines and wrinkles but also encourages your skin to renew itself. As it gently warms to the touch, the mask prepares your skin to absorb our highest concentration of breakthrough anti-aging Plant Stem Cell formula. We enrich this anti-aging nutrient with extracts of chamomile, linden blossom and other all-natural ingredients to promote smooth skin texture. Vitamin E revives skin's appearance, leaving it fresh, clean and vibrant, while promoting youthful elasticity. ***All combined, it gives you phenomenal anti-aging action that helps reduce the look of wrinkles in moments while encouraging your skin to respond naturally by amplifying collagen levels that help restore youthful tone.***

These statements are reiterated to consumers through YOUR marketing campaigns and through YOUR in-store sales representatives who use high pressure tactics to induce consumers into paying premium prices for YOUR products.

Unfortunately, all reliable scientific evidence concludes that plant stem cells do not provide the anti-aging benefits that YOU promise to consumers. In fact, Plant stem cell extracts don't likely interact with human stem cells at all. Jörg Gerlach, M.D., Ph.D., Professor of surgery at the University of Pittsburgh was quoted saying that "Stem cells need specific nutrition via blood supply in the tissue to survive and function — if they were layered onto intact skin the stem cell would just die." That conclusion has been echoed by other leading experts in the fields of medicine and biology. For example, a leading Professor of Botany at Oxford University was quoted by *The Daily Mail* saying, "I don't see how plant stem could interact with human stem cells in this way."

But despite this lack of evidence, YOU mislead consumers into believing that the plant stem cells in YOUR CELLMAX® product line can help reverse the signs of aging. YOUR hoax

involves charging consumers a super premium price for YOUR CELLMAX® Products, some of which cost more than \$1,000 per bottle.

Our client, Ms. Mollicone, purchased the CELLMAX® kit containing the CELLMAX® facial cream, CELLMAX® facial mask, and the CELLMAX® facial serum. Ms. Mollicone purchased the CELLMAX® kit from an Adore Organic Innovations store in Los Angeles, California in or around June of 2014. Ms. Mollicone paid approximately \$1,000 for her purchases of the Adore products. Ms. Mollicone purchased the products in reliance on YOUR statements that the purported plant stem cells in the products would provide proven anti-aging benefits. Ms. Mollicone would not have purchased the products at all, or would have paid less for the products, had she known the truth about the Adore products.

I. VIOLATIONS OF THE CALIFORNIA CONSUMERS LEGAL REMEDIES ACT AND OTHER STATE CONSUMER PROTECTION STATUTES

The Adore CELLMAX products do not work as advertised to provide the touted anti-aging benefits. A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence, consumers would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding YOUR Products.

YOUR material misrepresentations are deceiving customers into purchasing the Adore Products when in fact the Products provide no anti-ageing benefits.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices are in violation of the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*, but are not necessarily limited to:

§ 1770(a)(2): Misrepresenting the source, sponsorship, approval, or certification of goods or services;

§ 1770(a)(3): Misrepresenting the affiliation, connection, or association with, or certification by, another.

1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

Moreover, YOU have violated the consumer protection statutes of other states, including but not limited to, the consumer protection laws of the state of New Jersey where Ms. Mollicone resides. Specifically, YOU have violated the New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1 *et seq.*) among other statutes.

II. BREACH OF EXPRESS AND IMPLIED WARRANTIES AND VIOLATIONS OF THE FEDERAL MAGNUSON-MOSS WARRANTY ACT

This letter further serves to notify you that the Adore Products' packaging and advertising as contained in quotes herein created express and implied warranties under the Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.* and state warranty laws. Those warranties formed part of the benefit of the bargain and when the Products were not as warranted by YOU, my client and all putative class members suffered economic loss.

III. DEMAND FOR CORRECTIVE ACTION

YOU have failed to honor your consumer protection obligations. Based upon the above, demand is hereby made that YOU (1) cease and desist from further sales and distribution of the CELLMAX® Products; (2) issue an immediate recall of the CELLMAX® Products; (3) Cease and desist from making false and misleading claims about the CELLMAX® Products; and (4) Make full restitution to all purchasers of the CELLMAX® products of all purchase money expended on the products.

Please be advised that your failure to comply with this request within thirty (30) days may subject you to the following remedies, available for violations of the CLRA as well as other consumer warranty and consumer protection statutes, which will be requested in a class action complaint on behalf of our client and all other similarly situated consumers:

- (1) The actual damages suffered;
- (2) An order enjoining you for such methods, acts or practices;
- (3) Restitution of property (when applicable);
- (4) Disgorgement of profits;
- (4) Punitive damages;
- (5) Court costs and attorneys' fees;

- (6) Costs of class action notice and administration; and
- (7) Any other relief which the court deems proper.

VI. DUTY TO PRESERVE EVIDENCE

Lastly, I remind you of your legal duty to preserve all records relevant to such litigation. *See, e.g., Convolv, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Zubulake v. UBS Warburg LLC*, 220 F.R.D. 212, 216-18 (S.D.N.Y 2003) (“Once a party reasonably anticipates litigation, it must suspend its routine document retention/destruction policy and put in place a ‘litigation hold’ to ensure preservation of relevant documents.”). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that are related to the formulation, marketing, advertising, and promotion of the CELLMAX® products since the time the products entered into the stream of commerce will be sought in the forthcoming discovery process. In addition, YOU must place a litigation hold on documents that relate to underlying data that was generated in the clinical studies that YOU contend support the efficacy claims of CELLMAX® Products. YOU therefore must inform any employees, contractors, and third-party agents to preserve all such relevant information.

YOU are directed to immediately initiate a litigation hold for potentially relevant Electronically Stored Information (“ESI”), documents and tangible things, and to act diligently and in good faith to secure and audit compliance with such litigation hold. YOU are further directed to immediately identify and modify or suspend features of your information systems and devices that, in routine operation, operate to cause the loss of potentially relevant ESI. Examples of such features and operations include:

- Purging the contents of e-mail repositories by age, capacity or other criteria;
- Using data or media wiping, disposal, erasure or encryption utilities or devices;
- Overwriting, erasing, destroying or discarding back up media;
- Re-assigning, re-imaging or disposing of systems, servers, devices or media;
- Running antivirus or other programs effecting wholesale metadata alteration;
- Releasing or purging online storage repositories;
- Using metadata stripper utilities;
- Disabling server or IM logging; and,

- Executing drive or file defragmentation or compression programs.

This firm expects that YOU will act swiftly to preserve data on office workstations and servers. YOU should also determine if any home or portable systems may contain potentially relevant data. To the extent that officers, board members or employees have sent or received potentially relevant e-mails or created or reviewed potentially relevant documents away from the office, you must preserve the contents of systems, devices and media used for these purposes (including not only potentially relevant data from portable and home computers, but also from portable thumb drives, CD-R disks and the user's PDA, smart phone, voice mailbox or other forms of ESI storage.). Similarly, if employees, officers or board members used online or browser-based email accounts or services (such as AOL, Gmail, Yahoo Mail or the like) to send or receive potentially relevant messages and attachments, the contents of these account mailboxes (including Sent, Deleted and Archived Message folders) should be preserved.

Please confirm by **May 25, 2016** that you have taken the steps outlined in this letter to preserve ESI and tangible documents potentially relevant to this action. If YOU have not undertaken the steps outlined above, or have taken other actions, please describe what YOU have done to preserve potentially relevant evidence.

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.


Sincerely,

THE LAW OFFICES OF RONALD A. MARRON

/s/ Ronald A. Marron

Ronald A. Marron

Attorney for Lisa Mollicone, all others similarly situated, and the general public

SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY												
<ul style="list-style-type: none"> ■ Complete items 1, 2, and 3. ■ Print your name and address on the reverse so that we can return the card to you. ■ Attach this card to the back of the mailpiece, or on the front if space permits. 	<p>A. Signature <input checked="" type="checkbox"/> Agent <input type="checkbox"/> Addressee</p>												
<p>1. Article Addressed to:</p> <p style="text-align: center;">Adore Organic Innovation ATTN: LEGAL DEPARTMENT 332 Rodeo Drive Beverly Hills, CA 90210</p>	<p>B. Received by (Printed Name) <i>Adore Org.</i></p> <p>C. Date of Delivery <i>4/28/16</i></p>												
<p>2. Article Number (Transfer from service label)</p> <p style="text-align: center;">7015 1730 0001 6926 4673</p>	<p>D. Is delivery address different from Item 1? <input type="checkbox"/> Yes If YES, enter delivery address below: <input type="checkbox"/> No</p>												
 9590 9403 0472 5173 0652 14	<p>3. Service Type</p> <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Adult Signature</td> <td><input type="checkbox"/> Priority Mail Express®</td> </tr> <tr> <td><input type="checkbox"/> Adult Signature Restricted Delivery</td> <td><input type="checkbox"/> Registered Mail™</td> </tr> <tr> <td><input checked="" type="checkbox"/> Certified Mail®</td> <td><input type="checkbox"/> Registered Mail Restricted Delivery</td> </tr> <tr> <td><input type="checkbox"/> Certified Mail Restricted Delivery</td> <td><input checked="" type="checkbox"/> Return Receipt for Merchandise</td> </tr> <tr> <td><input type="checkbox"/> Collect on Delivery</td> <td><input type="checkbox"/> Signature Confirmation™</td> </tr> <tr> <td><input type="checkbox"/> Collect on Delivery Restricted Delivery</td> <td><input type="checkbox"/> Signature Confirmation Restricted Delivery</td> </tr> </table>	<input type="checkbox"/> Adult Signature	<input type="checkbox"/> Priority Mail Express®	<input type="checkbox"/> Adult Signature Restricted Delivery	<input type="checkbox"/> Registered Mail™	<input checked="" type="checkbox"/> Certified Mail®	<input type="checkbox"/> Registered Mail Restricted Delivery	<input type="checkbox"/> Certified Mail Restricted Delivery	<input checked="" type="checkbox"/> Return Receipt for Merchandise	<input type="checkbox"/> Collect on Delivery	<input type="checkbox"/> Signature Confirmation™	<input type="checkbox"/> Collect on Delivery Restricted Delivery	<input type="checkbox"/> Signature Confirmation Restricted Delivery
<input type="checkbox"/> Adult Signature	<input type="checkbox"/> Priority Mail Express®												
<input type="checkbox"/> Adult Signature Restricted Delivery	<input type="checkbox"/> Registered Mail™												
<input checked="" type="checkbox"/> Certified Mail®	<input type="checkbox"/> Registered Mail Restricted Delivery												
<input type="checkbox"/> Certified Mail Restricted Delivery	<input checked="" type="checkbox"/> Return Receipt for Merchandise												
<input type="checkbox"/> Collect on Delivery	<input type="checkbox"/> Signature Confirmation™												
<input type="checkbox"/> Collect on Delivery Restricted Delivery	<input type="checkbox"/> Signature Confirmation Restricted Delivery												
<p>PS Form 3811, April 2015 PSN 7530-02-000-9053</p>	<p style="text-align: center;">Exhibit 21</p> <p style="text-align: center;">Page 142 of 143 Domestic Return Receipt</p>												

UNITED STATES POSTAL SERVICE



First-Class Mail
Postage & Fees Paid
USPS
Permit No. G-10

• Sender: Please print your name, address, and ZIP+4® in this box•

Law Offices of Ronald A. Marron
651 Arroyo Drive
San Diego, CA 92103



USPS TRACKING#



9590 9403 0472 5173 0632 14

Exhibit 21

Page 143 of 143

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Lawsuit: Adore's CELLMAX Anti-Aging Products Are Ineffective](#)
