IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

Tawana Campbell, individually and on behalf of all others similarly situated,

Plaintiff,

v.

Brand i101, LLC d/b/a Valitic.,

Defendant.

Civil Action No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Tawana Campbell brings this action against Defendant Brand i101, LLC d/b/a Valitic ("Defendant") for false and misleading advertising, unjust enrichment, and violations of federal and state consumer protection laws arising from the marketing and sale of "VALITIC Kojic Acid Dark Spot Remover Soap Bars" (the "Product").

NATURE OF THE ACTION

1. Defendant formulates, manufactures, advertises, and sells its "Valitic Kojic Acid Dark Spot Remover Soap Bars" (the "Product") throughout the United States, including in New York. Because consumers purchase the Product in hopes of treating stubborn skin concerns, Defendant prominently markets it as a "Dark Spot Remover" and "Dark Spot Corrector" that can remove "dark spots and blemishes," "revive skin from sunburns, fine lines, and wrinkles," "reduce scarring," "repair sun damage," and "help clear up acne breakouts,." "

¹ https://www.amazon.com/Valitic-Remover-Vitamin-Collagen%20Turmeric/dp/B09MFMCTRK /(last accessed September 15, 2025)



About this item

- Dark Spot Corrector: Original Japanese Complex for Dark Spots Correction, our soap promotes a balanced, more even tone & a healthy glow; You can use this for your face, hands, neck, bikini area, inner thighs & underarms
- Vitamin C, Retinol, and Collagen: As a combination, these can help your skin stay hydrated from the inside out with minimal sun damage, dark spots, and blemishes to get that smooth and glowing skin
- Turmeric for Skin: Skin-benefiting qualities. Our soap is formulated with skin-cleansing turmeric which helps in restoring the moisture balance and reviving your skin from sunburns, fine lines, and wrinkles;
 Turmeric is also known to reduce scarring; This combination of uses may help your face clear up from acne breakouts
- Rejuvenating, Exfoliating, and Nourishing Dark Spot Areas: Our soap contains Hyaluronic Acid, Vitamin E, Shea Butter, and Castile Olive Oil that penetrates, revitalizes your skin
- SLS and Paraben-Free: Perfect for daily use! This turmeric soap can be used to clean most of the skin;
 First, wet your skin with warm water, apply the turmeric soap evenly on the skin;
 Then, massage for 20-30 seconds, and finally rinse with water
- Instructions for safe use: Do not use this product if you are allergic to any of its ingredients. Perform a
 patch test before use. Discontinue use if irritation occurs. Use within 8 months of opening. Use only as
 directed
- Report an issue with this product or seller
- 2. Unbeknownst to consumers, however, the Product is scientifically incapable of providing those benefits. In fact, the Product's formulation poses a risk of further deteriorating skin conditions. Worse still, Defendant's marketing of the Product as a safe treatment of "dark spots" and "acne" is not only false and misleading but violates the Food and Drug Administration ("FDA") regulations. Both "dark spots" and "acne" are diseases that can only be treated by FDA-approved over-the-counter medications or prescription drugs. Because the Product does not comply with any of these two categories and otherwise lacks FDA disclaimers next to its health claims, the Product is a misbranded "new drug" under the Food, Drug, and Cosmetic Act ("FDCA") and New York's parallel health laws, which incorporate the FDCA by reference.
- 3. Because the Product is an unapproved new drug that cannot be legally sold in the United States or New York, it is worthless as a matter of law. Plaintiff and the proposed class members would not have purchased the Product had they known it was illegal to sell and therefore valueless. In addition, the Product commands a price premium due to its false and misleading health benefits.
 - 4. As a result of its deceptive conduct, Defendant is, and continues to be, unjustly

enriched at the expense of its customers.

JURISDICTION AND VENUE

- 5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(a) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of \$5,000,000.00 exclusive of interest and costs, there are over 100 members of the putative class, and at least one class member is a citizen of a state different than Defendant.
- 6. This Court has personal jurisdiction over Defendant because Defendant maintains its principal place of business in New York. Furthermore, a substantial portion of the events giving rise to Plaintiff's claims occurred in New York, including Plaintiff's purchase of the Product.
- 7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391because Defendant conducts substantial business in this District and a substantial part of the events giving rise to Plaintiff's claims took place within this District.

PARTIES

- 8. Plaintiff Tawana Campbell is a resident of New York. On or about October of 2024, Plaintiff purchased Defendant's Product for her personal use directly from Defendant through Defendant's official Amazon.com while residing in New York.
- 9. Prior to purchasing the Product, Plaintiff saw that the Product was marketed as a "Dark Spot Remover" and "Dark Spot Corrector" that can remove "dark spots and blemishes," "revive skin from sunburns, fine lines, and wrinkles," "reduce scarring," "repair sun damage," and "help clear up acne breakouts." Plaintiff reasonably understood these representations as a promise and warranty that the Product was effective for treating dark spots, blemishes, acne,

wrinkles, scarring, and sun damage. Accordingly, those representations and warranties were part of the basis of her bargain, in that she would not have purchased the Product on the same terms had she known that those representations were not true. Furthermore, in making her purchase, Plaintiff paid a substantial price premium due to Defendant's false and misleading claims regarding the Product's efficacy in treating skin pigmentation. Plaintiff, however, did not receive the benefit of her bargains because the Product is not scientifically capable of achieving those results. Nor was Plaintiff aware that the Product's formulation is capable of worsening skin conditions. In fact, instead of experiencing any meaningful skin pigmentation repair, Plaintiff's skin was irritated after using the Product throughout the week. Had Plaintiff known that Defendant's representations and warranties were false, or known about the omitted health risks associated with using the Product, she would not have purchased the Product or paid substantially less for it.

- 10. In addition, in making her purchase, Plaintiff did not see any disclaimer that the Product's claims and representations had not been "evaluated by the Food and Drug Administration" or that the Product was "not intended to diagnose, treat, cure, or prevent any diseases." Those omissions were material to Plaintiff because had she known that Defendant's representations and warranties were qualified by those disclaimers, she would not have relied on them or believed that the Product was equally efficacious to other FDA-approved products on the market. As such, Plaintiff would not have purchased the Product or would have paid substantially less for it had she seen the FDA-required disclosures on the Product's labeling and marketing.
- 11. Finally, had Plaintiff known that Defendant's Product was adulterated, misbranded, and illegal to sell under Federal and New York laws, she would not have purchased

it at all.

12. Defendant Brand i101, LLC d/b/a Valitic, is a Wyoming limited liability corporation with its principal place of business in Flushing, New York. Defendant manufactures, markets, and sells the Product throughout New York and the United States. For diversity purposes, Defendant's members are Osnat Lachyani Abiri and Raz Lachyani Abiri – residents of a foreign country.

GENERAL ALLEGATIONS

Overview of Defendant's "Dark Spot Remover" Business

- 13. Skin discoloration, acne, and age-related conditions such as wrinkles and sun damage are common concerns affecting millions of consumers in the United States. The skincare market addressing these conditions is massive: American consumers spend billions of dollars annually on products marketed to improve hyperpigmentation, acne, and other skin-related blemishes.
- 14. Although only a limited number of drugs are approved by the U.S. Food and Drug Administration ("FDA") to treat skin conditions like acne and hyperpigmentation, there has been an explosion in consumer demand for "cosmetic" products that promise to achieve the same results. This demand has created a lucrative but legally fraught market for companies making drug-level claims without FDA approval.
- 15. Defendant is one of the companies that has sought to capitalize on this demand. By marketing its Valitic Kojic Acid Dark Spot Remover Soap (the "Product") as a solution for acne, dark spots, wrinkles, scarring, and sun damage, Defendant prominently positions its Product as a treatment for medical conditions. Defendant's marketing is designed to induce consumers to purchase the Product by leading them to believe it is safe, effective, and legally

compliant.

- 16. In reality, however, the Product is none of these things. By making impermissible drug and structure/function claims, Defendant has transformed what it labels as a cosmetic soap into an unapproved, misbranded, and adulterated drug under the FDCA.
- 17. Furthermore, instead of being supported by competent and reliable scientific evidence, the Product's formulation—a rinse-off bar soap with an alkaline pH—renders its purported "active" ingredients chemically unstable and biologically ineffective in treating skin lesions or blemishes.

Defendant's Product Is an Unapproved "New Drug" under the FDCA

- The FDCA defines a "drug" as any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1). The FDCA and its implementing regulations are explicit that "dietary supplements '*intended* for use in diagnosis, cure, mitigation, treatment, or prevention of disease' remain within the definition of a 'drug.'" 65 Fed. Reg. at 1001; *see also* 21 U.S.C. § 321(g)(1)(B). Pursuant to FDA regulations, the "intended use" of an article is determined based on the "objective intent of the person legally responsible for the labeling of the drug," and may be determined for example, "by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." 21 C.F.R. § 201.128. The FDCA defines "label" as, among other things, "a display of written, printed, or graphic matter upon the immediate container of any article," 21 U.S.C. § 321(k); and "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).
- 19. Here, Defendant's Product is a "drug" within the meaning of the FDCA because it's marketing expressly claims that it treats hyperpigmentation, blemishes, acne, wrinkles, sun

damage, and scarring—recognized medical conditions. At a minimum, these statements constitute unlawful structure/function claims that exceed the boundaries of cosmetics.

- 20. FDA regulations make clear that products marketed for treating acne, hyperpigmentation, wrinkles, scars, or sun damage are "new drugs" that require an approved New Drug Application ("NDA") before being sold. Specifically, blemishes and dark spots, yet there are no regulations that permit skin bleaching products to be sold as an over-the-counter drug ("OTC"). The FDA has conclusively stated that "all skin bleaching drug products, whether marketed on a prescription or OTC basis, to be new drugs[.]" 71 FR 51146. The most analogous OTC regulation governing wart removers specifically excluded the application of such products to treat moles and skin marks. *See* 55 FR 33246, 33255 (Aug. 14, 1990); see *also* 45 FR 65609, 65611 (Oct. 3, 1980). Similarly, any "acne" related claims are subject to the labeling and permitted active ingredients regulations set forth under 21 C.F.R. § 333.301, *et seq*.
- 21. Defendant's marketing of the Product to treat "dark spots and blemishes," "revive skin from sunburns, fine lines, and wrinkles," "reduce scarring," "repair sun damage," and "help clear up acne breakouts" clearly violates these regulations. Accordingly, the Product is an unapproved new drug and misbranded under the FDCA.

Defendant Makes Improper Disease Claims

- 22. Assuming arguendo that Defendant's Product is not considered a "new drug" under the FDCA—despite the FDA's abundant warning letters and regulatory history making clear that it is—the Product nonetheless makes improper disease and structure/function claims in violation of federal law.
- 23. Manufacturers of cosmetics are prohibited from making any statement that "claims to diagnose, mitigate, treat, cure, or prevent disease," either explicitly or implicitly. 21

C.F.R. § 101.93(g). The FDA defines "disease" broadly to include conditions such as acne, hyperpigmentation, scarring, and photoaging caused by sun exposure. Claims that a product can "remove," "correct," "heal," or otherwise alter these conditions are drug claims, not cosmetic claims.

- 24. Defendant makes precisely these types of claims in its advertising and labeling for the Product:
 - **Hyperpigmentation, Blemishes, and Acne:** Defendant markets the Product as a "Dark Spot Remover" and "Corrector" that can "remove dark spots and blemishes" and "help your face clear up from acne breakouts." These are textbook disease treatment claims. The FDA has specifically warned that no regulations permit "dark spot removers" to be sold over-the-counter.²
 - Wrinkles and Fine Lines: Defendant claims the Product can revive skin from "fine lines and wrinkles." The FDA explicitly treats wrinkle and fine line reduction as a therapeutic alteration of the skin structure, which requires drug approval.³
 - Sunburns and Sun Damage: Defendant claims the Product can "revive skin from sunburns" and reduce "sun damage." Such claims fall within the FDA's sunscreen monograph framework, with which the Product does not comply.⁴
 - **Scarring:** Defendant claims the Product reduces the appearance of "scarring." The treatment of scars is a drug claim because it implies structural alteration of skin tissue.⁵
- 25. By making these claims, Defendant's Product is marketed not as a cosmetic soap but as a drug intended to treat diseases and alter the structure and function of the body. Yet, the Product is not FDA-approved as a drug and cannot be lawfully sold as one.

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² https://www.fda.gov/consumers/consumer-updates/products-marketed-removing-moles-and-other-skin-lesions-can-cause-injuries-scarring (last accessed September 15, 2025).

³ https://www.fda.gov/cosmetics/cosmetic-products/wrinkle-treatments-and-other-anti-aging-products

⁴ FDA Warning Letter to Vacation Inc. (August 6, 2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vacation-inc-706039-08062025 (last accessed September 15, 2025).

⁵FDA Warning Letter to Bodywell Natural Skin Care Inc. (March 27, 2024), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bodywell-natural-skin-care-inc-677099-03272024 (last accessed September 15, 2025).

Defendant Does Not Provide FDA-Mandated DSHEA Disclaimers

- 26. To make matters worse, all of Defendant's statements about its Product fail to include a mandatory disclaimer that its claims about the Product have not been evaluated by the FDA nor are intended to diagnose, cure, or prevent a disease (the "DSHEA Disclaimer"). 21 U.S.C. §§ 343(f), 6 343(r)(1)(B), 343(r)(6); 21 C.F.R. § 101.93(d) ("On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there [is a structure/function claim].").
 - 27. The DSHEA Disclaimer must be prominent and bolded, and it must read: These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.
 - 21 U.S.C. § 343(r)(6)(C); see also 21 C.F.R. § 101.93(c)(2).
- 28. To be prominent, the disclaimer may not be crowded with voluntary information or imagery and additionally must be in a bold font at least 1/16th of an inch in size. 21 C.F.R. § 101.93(e).
- 29. The disclaimer must appear on all panels with structure/function claims. The Food and Drug Administration has specifically rejected the proposition "that repetition of the disclaimer on every panel or page where a statement [is] made...is unnecessary." 62 Fed. Reg. 49,859, 49,864 (Sept. 23, 1997). To meet statutory requirements, "the disclaimer must be within the same field of vision as the statement itself." Id. at 49865 (emphasis added). See also id. at 49,864 ("FDA has evaluated the comments and concludes that the placement of the

⁶ 21 U.S.C. § 343(f) ("If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customer conditions of purchase and use.").

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disclaimer on a panel other than where the statement is made would not meet the statutory requirement for the placement of the disclaimer....Based on its experience with asterisks within the nutrition label, the agency concludes that consumers are accustomed to using asterisks on labels to associate two discrete pieces of important information when they are in the *same field of vision*.") (emphasis added) (citation omitted).

30. Defendant fails to abide by the disclaimer requirements in labeling and marketing its Product by omitting it altogether.

Defendant's Product Is Adulterated and Illegal to Sell under the FDCA and Worthless

- 31. Because Defendant intended to sell the Product as a drug, or, alternatively, made improper "disease" claims and failed to include adequate Defendant's DSHEA disclaimers within the Product's labeling and marketing, the Product constitutes a "new drug" under the FDCA. 21 U.S.C. § 321(p). A new drug may not be introduced into interstate commerce unless it is approved by the FDA through a New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(a). Defendant's Product was not approved by the FDA under an NDA or ANDA. Furthermore, Defendant's Product is "misbranded "under the FDCA because it is intended for the treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. As such, it is impossible to write adequate directions for the Product's intended purposes as required under 21 U.S.C. 352(f)(1).
- 32. Based on the foregoing, Defendant's Product is illegal to sell because it is both adulterated and an unapproved new drug under the FDCA. 21 U.S.C. §§ 331(a), (d).
- 33. Defendant's marketing of the Product also violates New York parallel laws, which incorporate the requirements set forth by the FDCA. These laws include:

- a. N.Y. Educ. Law § 6817(1)(a): sale of a "new drug" requires "an application ... [to have] become effective ... under the Federal Food, Drug, and Cosmetic Act."
- b. N.Y. Educ. Law § 6815(2)(a): a drug is misbranded "[i]f its labeling is false or misleading in any particular."
- c. N.Y. Educ. Law § 6818(2)(a): a cosmetic is misbranded "[i]f its labeling is false or misleading in any particular."
- d. 24 RCNY Art. 71, § 71.05(f): a drug is misbranded "as set forth in the [FDCA] (21 U.S.C. § 352) or [Educ. Law] § 6815."
- e. 24 RCNY Art. 71, § 71.05(h): a cosmetic is misbranded "as set forth in the [FDCA] (21 U.S.C. § 362) or [Educ. Law] § 6818."

The Product Is Incapable of Delivering Its Promised Efficacy

- 34. The Product's delivery system—a solid bar of soap—is scientifically unsuitable for treating hyperpigmentation. Two core principles of cosmetic science render the Product's efficacy claims invalid from the outset: (1) insufficient contact time and (2) a destructive alkaline pH level.
- 35. **Insufficient Contact Time.** For a topical treatment to change the skin's pigmentation, it must first penetrate the skin's barrier and remain in contact with the cells beneath it for a sufficient duration.⁷ As a rinse-off soap, the Product fails this basic requirement. Scientific literature confirms that the efficiency of active ingredients from rinse-off products is exceedingly low, typically less than 1%.⁸ The vast majority of the Product's advertised "active" ingredients are washed away within seconds. In contrast, clinical studies demonstrating even

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⁷ Zhao, Lin et al. *Topical drug delivery strategies for enhancing drug effectiveness by skin barriers, drug delivery systems and individualized dosing*. Frontiers in pharmacology vol. 14 1333986. 16 Jan. 2024, doi:10.3389/fphar.2023.1333986

⁸ M.A. Davies, Salicylic acid deposition from wash-off products: comparison of in vivo and porcine deposition models, 37 Int'l J. Cosmetic Sci. 526–31 (2015)

modest efficacy for ingredients like Vitamin C^9 or Retinol¹⁰ require daily, leave-on application for months. Likewise, clinical literature evaluating kojic acid's pigment effects involves leave-on creams or serums ($\approx 1-4\%$) used for $\geq 8-12$ weeks—often in combination therapy—and not rinse-off soaps.¹¹ And topical collagen molecules (~ 300 kDa) are too large to traverse the stratum corneum; reported benefits relate to oral supplementation or injected fillers, not momentary contact with a cleanser.¹²

36. **Destructive Alkaline pH.** Solid bar soaps are, by their chemical nature, alkaline, with a pH typically in the range of 9 to 10.¹³ At alkaline pH, ascorbic acid (vitamin C) is deprotonated and undergoes rapid oxidation, retinoids are labile and degrade under

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⁹ Gabriela Correia & Sofia Magina, *Efficacy of topical vitamin C in melasma and photoaging: A systematic review*, 22 J. Cosmet. Dermatol. 1938–45 (2023) (finding that long-term use is often needed for visible change); N. Afzal et al., *Prospective randomized double-blind comparative study of topical vitamin C derivatives*, J. Cosmet. Dermatol. (2024) (noting that due to polarity, ascorbic acid penetrates only at low pH (≤3.5)), doi:10.1111/jocd.16292.

¹⁰ R. Kafi et al., *Improvement of naturally aged skin with vitamin A (retinol)*, 143 Arch. Dermatol. 606–12 (2007) (24-week, randomized, double-blind, vehicle-controlled trial); *One-year topical stabilized retinol treatment improves photodamaged skin in a double-blind, vehicle-controlled study*, J. Drugs Dermatol. (2015) (52-week regimen); N. Nguyen et al., *A prospective, double-blinded, randomized head-to-head clinical trial of topical adapinoid 0.5% vs retinol 0.5%* (12 weeks), Skin Health & Disease (2024).

¹¹ Ghasemiyeh, Parisa et al. *Different therapeutic approaches in melasma: advances and limitations*. Frontiers in pharmacology vol. 15 1337282. 2 Apr. 2024, doi:10.3389/fphar.2024.1337282 (summarizing kojic acid as a leave-on depigmenting agent, commonly 1–4%, often in combination with other actives); Y.F. Chang et al., *Efficacy and safety of topical agents in the treatment of melasma: A systematic review and meta-analysis*, J. Cosmet. Dermatol. (2023) (finding hydroquinone-containing regimens generally more effective than kojic acid alone).

¹² He, Xin et al. *Research Progress on Bioactive Factors against Skin Aging*. International journal of molecular sciences vol. 25,7 3797. 28 Mar. 2024, doi:10.3390/ijms25073797) (noting that due to high molecular weight, topical collagen does not fully penetrate the skin); B. Jadach et al., *Use of Collagen in Cosmetic Products. Current Issues in Molecular Biology*. 2024; 46(3):2043-2070. https://doi.org/10.3390/cimb46030132 (explaining collagen (~300 kDa) remains on the surface as a film-forming moisturizer; injectable or oral routes account for deeper effects).

¹³ Mijaljica D, Harle-Bachor C, Ghinea R. *Skin cleansing without or with compromise: Soaps and syndets.* Cosmetics. 2022;9(2):29. (Typical soap pH 8.5–11; contrasts with syndets.)

heat/oxygen/light in base-leaning media, and kojic acid is susceptible to oxidative inactivation—all of which diminish bioactive availability in a wash-off bar. High-pH cleansing also raises the skin-surface pH above the acid mantle (\approx 4.5–5.5) and impairs lipid-processing enzymes while increasing serine-protease activity, compromising barrier function and further undermining penetration and performance of actives. In fact, to be able to withstand the soap's pH level, the Product would need to contain ingredients in levels that are so high that it would pose a danger if applied to the skin. For example, leave-on L-ascorbic acid above \approx 20% is associated with stinging/irritation without added benefit; leave-on retinol at \geq 0.5–1% commonly produces irritant dermatitis; and kojic acid is a recognized contact sensitizer, with safety reviews supporting use at or below \approx 1% in facial leave-on products.

37. Finally, the Product's formulation, an arbitrary mixture of chemically incompatible and unstable ingredients in a hostile, alkaline base, creates antagonism and

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¹⁴ Lambers H, Piessens S, Bloem A, Pronk H, Finkel P. *Natural skin surface pH is on average below 5, which is beneficial for its resident flora*. Int J Cosmet Sci. 2006;28(5):359–370. (Acid mantle ~4.5–5.5; higher pH impairs functions.); Schmid-Wendtner MH, Korting HC. *The pH of the skin surface and its impact on the barrier function*. Clin Dermatol. 2006;24(1):3–7. (Alkaline cleansing raises pH; barrier and enzyme effects.); Pinnell SR, et al. *Topical L-ascorbic acid: percutaneous absorption studies*. Dermatol Surg. 2001;27(2):137–142. (Dermal uptake requires pH < 3.5; instability at higher pH.) (b) Temova Rakuša Ž, et al. *Retinoid stability and degradation kinetics in commercial cosmetic products*. J Cosmet Dermatol. 2021;20(7):2350–2358. (Retinol instability/decay.) (c) Burnett CL, et al. *Final report of the safety assessment of kojic acid as used in cosmetics*. Int J Toxicol. 2010;29(6 Suppl):S244–S273. (Kojic acid oxidation/stability considerations.)

¹⁵ Telang PS. *Vitamin C in dermatology*. Indian Dermatol Online J. 2013;4(2):143–146. (Limited benefit >~20%; increased irritation at higher concentrations.); Zasada M, Budzisz E. *Retinoids: active molecules influencing skin structure formation in cosmetic and dermatological treatments*. Postepy Dermatol Alergol. 2019;36(4):392–397. (Irritation common with higher % retinol; need for careful formulation.); Nakagawa M, et al. *Contact allergy to kojic acid in skin-care products*. Contact Dermatitis. 1995;32(1):9–13; Burnett, Christina L et al. *Final report of the safety assessment of Kojic acid as used in cosmetics*. International journal of toxicology vol. 29,6 Suppl (2010): 244S-73. doi:10.1177/1091581810385956. (Kojic acid as a sensitizer; concentration limits in face products.)

degradation.¹⁶ For example, Vitamin C and retinol can destabilize each other if not formulated under controlled conditions.¹⁷ Combining multiple potential irritants—such as kojic acid, retinol, and turmeric—creates an additive risk of skin irritation, dryness, and inflammation.¹⁸

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¹⁶ Tarun, J., *et al.*, Evaluation of pH of Bathing Soaps and Shampoos for Skin and Hair, *Indian Journal of Dermatology* 56(1):2–6 (2014) (most soaps pH 9–10); Milosheska, D., & Roškar, R., Use of Retinoids in Topical Antiaging Treatments: A Focused Review of Clinical Evidence for Conventional and Nanoformulations, *Drugs in R&D* 22: 0–0 (2022) (retinoids are *formulation-challenging* due to instability and irritation); Temova Rakuša, Ž., *et al.*, Retinoid stability and degradation kinetics in commercial cosmetic products, *Journal of Cosmetic Dermatology* 20(12): 3972–3981 (2021) (retinoids show marked instability under light/heat/oxygen); Magnani, C., *et al.*, Ascorbic Acid in Cosmetic Formulations: Stability, in vitro Release and Permeation, *Journal of Dispersion Science and Technology* 38(6): 1047–1054 (2016) (ascorbic acid stability is highly pH-dependent).

¹⁷ Pinnell, S.R., *et al.*, Topical L-Ascorbic Acid: Percutaneous Absorption Studies, *Dermatologic Surgery* 27(2):137–142 (2001) (L-ascorbic acid requires pH < 3.5 for skin uptake); Temova Rakuša, Ž., *et al.*, Retinoid stability and degradation kinetics..., *J. Cosmet. Dermatol.* (2021) (retinol is unstable without stabilization systems); Abdulmajed, Kasem, and Charles M Heard. "Topical delivery of retinyl ascorbate co-drug. 1. Synthesis, penetration into and permeation across human skin." *International journal of pharmaceutics* vol. 280,1-2 (2004): 113-24. doi:10.1016/j.ijpharm.2004.05.008; Abdulmajed, K et al. *Topical delivery of retinyl ascorbate co-drug.* 5. *In vitro degradation studies*. Skin pharmacology and physiology vol. 19,5 (2006): 248-58. doi:10.1159/000093980 (co-drug strategy developed specifically to co-deliver vitamin C and a retinoid because of *compatibility/stability constraints*)

¹⁸ Pedersen, L.K., & Johansen, J.D., Augmentation of skin response by exposure to a combination of allergens and irritants – a review, Contact Dermatitis 50(5):265–273 (2004) (combined exposures can augment/add irritant effects); Schliemann, S., et al., Tandem repeated application of organic solvents and detergents increases skin irritation, Skin Pharmacology and Physiology 27(3):158–164 (2014) (additive harmful effects from multiple irritants); Patel, K., et al., Irritant Contact Dermatitis — a Review, Cureus 14(3):e23038 (2022) (recurrent/combined irritant exposure can have additive effects on barrier damage). Nakagawa, M., Kawai, K., & Kawai, K., Contact allergy to kojic acid in skin care products, Contact Dermatitis 32(1):9–13 (1995) (reports contact sensitization to kojic acid); Burnett, C.L., et al., Final Report of the Safety Assessment of Kojic Acid, International Journal of Toxicology 29(3 suppl):244S–273S (2010) (sensitization noted; concentration-dependent safety). Milosheska, D., & Roškar, R., Use of Retinoids in Topical Antiaging Treatments..., Drugs in R&D (2022) (retinoids commonly produce irritation/"retinoid dermatitis"; stability issues require careful formulation). Palaniappan, V., et al., Turmeric: The Yellow Allergen, Indian Dermatology Online Journal 14(4): 0–0 (2023) (case reports/review of allergic contact dermatitis to turmeric/curcumin); Chaudhari, S.P., et al., Curcumin: A Contact Allergen, Journal of Clinical and Aesthetic Dermatology 8(7):43-44 (2015) (documented ACD to curcumin).

38. Defendant's misleading representations, omissions, and illicit sale of the Product proximately caused harm to Plaintiff and the proposed class members who suffered an injury in fact and lost money or property as a result of Defendant's conduct.

CLASS ACTION ALLEGATIONS

39. Plaintiff brings this action on behalf of herself and all other similarly situated persons pursuant to Federal Rules of Civil Procedure 23(a), (b)(1), and (b)(3). Specifically, the Classes are defined as:

Nationwide Class: All persons in the United States who, during the maximum period of time permitted by law, purchased Defendant's Product primarily for personal, family or household purposes, and not for resale.

New York Subclass: All persons residing in New York who, during the maximum period of time permitted by the law, purchased Defendant's Product primarily for personal, family or household purposes, and not for resale.

- 40. The Classes do not include (1) Defendant, their officers, and/or its directors; or (2) the Judge to whom this case is assigned and the Judge's staff.
- 41. Plaintiff reserves the right to amend the above class definitions and add additional classes and subclasses as appropriate based on investigation, discovery, and the specific theories of liability.
- 42. *Community of Interest*: There is a well-defined community of interest among members of the Classes, and the disposition of the claims of these members of the Classes in a single action will provide substantial benefits to all parties and to the Court.
 - 43. *Numerosity*: While the exact number of members of the Classes is unknown to

Plaintiff at this time and can only be determined by appropriate discovery, upon information and belief, members of the Classes number in the millions. The precise number of the members of the Classes and their identities are unknown to Plaintiff at this time but may be determined through discovery. Members of the Classes may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

- 44. Existence and predominance of common questions of law and fact: Common questions of law and fact exist as to all members of the Classes and predominate over any questions affecting only individuals of the Classes. These common legal and factual questions include, but are not limited to:
 - (a) Whether the Product is a new drugs that is illegal to sell;
- (b) Whether the marketing, advertising, packaging, labeling, and other promotional materials for the Product make disease claims in violation of the FDCA;
- (c) Whether Plaintiff and the members of the Classes have suffered damages as a result of Defendant's actions and the amount thereof;
- (d) Whether Plaintiff and the members of the Classes are entitled to statutory damages;
- (e) Whether Plaintiff and the members of the Classes are entitled to attorney's fees and costs.
- 45. *Typicality:* The claims of the named Plaintiff are typical of the claims of other members of the Classes in that the named Plaintiff was exposed to Defendant's false and misleading marketing, purchased Defendant's illegal Product, and suffered a loss as a result of those purchases.
 - 46. *Adequacy*: Plaintiff will fairly and adequately represent and protect the interests

of the Classes as required by Federal Rule of Civil Procedure Rule 23(a)(4). Plaintiff is an adequate representative of the Classes because she has no interests that are adverse to the interests of the members of the Classes. Plaintiff is committed to the vigorous prosecution of this action and, to that end, Plaintiff has retained skilled and experienced counsel.

- 47. Moreover, the proposed Classes can be maintained because they satisfy both Rule 23(a) and 23(b)(3) because questions of law or fact common to the Classes predominate over any questions affecting only individual members and that a Class Action is superior to all other available methods of the fair and efficient adjudication of the claims asserted in this action under Federal Rule of Civil Procedure 23(b)(3) because:
- (a) The expense and burden of individual litigation make it economically unfeasible for members of the Classes to seek to redress their claims other than through the procedure of a class action;
- (b) If separate actions were brought by individual members of the Classes, the resulting duplicity of lawsuits would cause members of the Classes to seek to redress their claims other than through the procedure of a class action; and
- (c) Absent a class action, Defendant likely will retain the benefits of their wrongdoing, and there would be a failure of justice.

CAUSES OF ACTION

COUNT I

Violation of State Consumer Protection Statutes¹⁹ (On Behalf of Plaintiff and the Nationwide)

- 48. Plaintiff incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.
- 49. The Consumer Protection Statutes of the Nationwide Class members prohibit the use of deceptive, unfair, and misleading business practices in the conduct of trade or commerce.
- 50. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices by conspicuously representing on the marketing of the Product that it is a "Dark Spot Remover" and "Dark Spot Corrector" that can remove "dark spots and blemishes," "revive skin from sunburns, fine lines, and wrinkles," "reduce scarring," "repair sun damage," and "help clear up acne breakouts." Despite those representations, however, the

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¹⁹ While discovery may alter the following, Plaintiff asserts that the states with similar consumer fraud laws under the facts of this case include but are not limited to: Alaska Stat. § 45.50.471, et seq.; Ariz. Rev. Stat. §§ 44-1521, et seq.; Ark. Code § 4-88-101, et seq.; Cal. Bus. & Prof. Code § 17200, et seq.; Cal. Civ. Code §1750, et seq.; Colo. Rev. Stat. Ann. § 6-1-101, et seq.; Colo. Rev. Stat. Ann. § 6-1-101, et seg.; Conn. Gen Stat. Ann. § 42-110, et seg.; 6 Del. Code § 2513, et seq.; D.C. Code § 28-3901, et seq.; Fla. Stat. Ann. § 501.201, et seq.; Ga. Code Ann. § 10-1-390, et seq.; Haw. Rev. Stat. § 480-2, et seq.; Idaho Code. Ann. § 48-601, et seq.; 815 ILCS 501/1, et seq.; Ind. Code § 24-5-0.5-2, et seq.; Kan. Stat. Ann. § 50-623, et seq.; Ky. Rev. Stat. Ann. § 367.110, et seg.; LSA-R.S. 51:1401, et seg.; Me. Rev. Stat. Ann. Tit. 5, § 207, et seg.; Md. Code Ann. Com. Law, § 13-301, et seq.; Mass. Gen Laws Ann. Ch. 93A, et seq.; Mich. Comp. Laws Ann. § 445.901, et seq.; Minn. Stat. § 325F, et seq.; Mo. Rev. Stat. § 407, et seq.; Neb. Rev. St. §§ 59-1601, et seq.; Nev. Rev. Stat. § 41.600, et seq.; N.H. Rev. Stat. § 358-A:1, et seq.; N.J. Stat. Ann. § 56:8, et seq.; N.M. Stat. Ann. § 57-12-1, et seq.; N.Y. Gen. Bus. Law § 349, et seq.; N.C. Gen Stat. § 75-1.1, et seq.; N.D. Cent. Code § 51-15, et seq.; Ohio Rev. Code Ann. § 1345.01, et seg.; Okla. Stat. tit. 15 § 751, et seg.; Or. Rev. Stat. § 646.605, et seg.; 73 P.S. § 201-1, et seq.; R.I. Gen. Laws § 6-13.1-5.2(B), et seq.; S.C. Code Ann. §§ 39-5-10, et seq.; S.D. Codified Laws § 37-24-1, et seq.; Tenn. Code Ann. § 47-18-101, et seq.; Tex. Code Ann., Bus. & Con. § 17.41, et seq.; Utah Code. Ann. § 13-11-175, et seq.; 9 V.S.A. § 2451, et seq.; Va. Code Ann. § 59.1-199, et seq.; Wash. Rev. Code § 19.86.010, et seq.; W. Va. Code § 46A, et seq.; Wis. Stat. § 100.18, et seq.; and Wyo. Stat. Ann. § 40-12-101, et seq.

Product is not capable of reliably delivering those promised benefits. Furthermore, Defendant omitted that using the Product can lead to further irritation and dryness of the skin. Finally, the Product is a misbranded and unapproved "new drug" which is illegal to sell under federal and New York law.

- 51. The foregoing deceptive acts and practices were directed at consumers.
- 52. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the nature and value of the Product.
- 53. As a result of Defendant's deceptive practices, Plaintiff and the Nationwide Class members suffered an economic injury because they would not have purchased (or paid a premium for) the Product had they known that the Product was not, in fact, a "Dark Spot Remover" and "Dark Spot Corrector" that can remove "dark spots and blemishes," "revive skin from sunburns, fine lines, and wrinkles," "reduce scarring," "repair sun damage," and "help clear up acne breakouts" and otherwise constitutes an unapproved new drug which is misbranded and illegal to sell.
- 54. On behalf of herself and the Nationwide Class members, Plaintiff seeks to recover their actual damages, statutory damages, punitive damages, and reasonable attorneys' fees and costs.

COUNT II Violation of New York G.B.L. § 349 (On Behalf of Plaintiff and the New York Subclass)

- 55. Plaintiff incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.
- 56. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

- 57. In its sale of Product throughout the state of New York, at all relevant times herein, Defendant conducted business and trade within the meaning and intendment of New York's General Business Law § 349.
- 58. Plaintiff and the New York Subclass members are consumers who purchased the Product from Defendant for their personal use.
- 59. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices by conspicuously representing on the marketing of the Product that it is a "Dark Spot Remover" and "Dark Spot Corrector" that can remove "dark spots and blemishes," "revive skin from sunburns, fine lines, and wrinkles," "reduce scarring," "repair sun damage," and "help clear up acne breakouts." Despite those representations, however, the Product is not capable of reliably delivering those promised benefits. Furthermore, Defendant omitted that using the Product can lead to further irritation and dryness of the skin. Finally, the Product is a misbranded and unapproved "new drug" which is illegal to sell under federal and New York law.
 - 60. The foregoing deceptive acts and practices were directed at consumers.
- 61. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the nature and value of the Product.
- 62. As a result of Defendant's deceptive practices, Plaintiff and the New York
 Subclass members suffered an economic injury because they would not have purchased (or paid a
 premium for) the Product had they known that the Product were not, in fact, a "Dark Spot
 Remover" and "Dark Spot Corrector" that can remove "dark spots and blemishes," "revive skin
 from sunburns, fine lines, and wrinkles," "reduce scarring," "repair sun damage," and "help clear
 up acne breakouts" and otherwise constitutes an unapproved new drug which is misbranded and

illegal to sell.

63. On behalf of herself and the New York Subclass members, Plaintiff seeks to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees and costs.

COUNT III

Violation of New York G.B.L. §350 (On Behalf of Plaintiff and the New York Subclass)

- 64. Plaintiff incorporates by reference each of the allegations contained in the foregoing paragraphs of this Complaint as though fully set forth herein.
- 65. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.
- 66. Defendant violated New York General Business Law § 350 by misrepresenting that the Product is a "Dark Spot Remover" and "Dark Spot Corrector" that can remove "dark spots and blemishes," "revive skin from sunburns, fine lines, and wrinkles," "reduce scarring," "repair sun damage," and "help clear up acne breakouts." Despite those representations, however, the Product is not capable of reliably delivering those promised benefits. Furthermore, Defendant omitted that using the Product can lead to further irritation and dryness of the skin. Finally, the Product is a misbranded and unapproved "new drug" which is illegal to sell under federal and New York law.
- 67. The foregoing advertising was directed at consumers and was likely to mislead a reasonable consumer acting reasonably under the circumstances.
- 68. Defendant's misrepresentations have resulted in consumer injury or harm to the public interest.
 - 69. As a result of Defendant's deceptive practices, Plaintiff and the New York

Subclass members suffered an economic injury because they would not have purchased (or paid a premium for) the Product had they known that the Product was not, in fact, a "Dark Spot Remover" and "Dark Spot Corrector" that can remove "dark spots and blemishes," "revive skin from sunburns, fine lines, and wrinkles," "reduce scarring," "repair sun damage," and "help clear up acne breakouts" and otherwise constitutes an unapproved new drug which is misbranded and illegal to sell.

70. On behalf of herself and the New York Subclass members, Plaintiff seeks to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees and costs.

COUNT IV Breach of Express Warranty (N.Y. U.C.C. § 2-313) (On Behalf of Plaintiff and the New York Subclass)

- 71. Defendant expressly warranted, through its advertising, marketing, and labeling, that the Product was a ""Dark Spot Remover" and "Dark Spot Corrector" that can remove "dark spots and blemishes," "revive skin from sunburns, fine lines, and wrinkles," "reduce scarring," "repair sun damage," and "help clear up acne breakouts." Defendant also expressly warranted that the Product could be legally sold as a cosmetic.
- 72. These affirmations of fact and promises formed the basis of the bargain between Defendant and Plaintiff and the New York Subclass. Plaintiff and the New York Subclass reasonably relied on these representations in purchasing the Product.
- 73. Defendant breached these express warranties because the Product cannot reliably deliver the promised results, is scientifically ineffective, and constitutes an unapproved and misbranded drug that cannot be lawfully sold.
 - 74. As a direct and proximate result, Plaintiff and the New York Subclass members

have suffered economic damages, including the amounts paid for the Product.

75. On behalf of herself and the New York Subclass members, Plaintiff seeks actual damages, rescission, restitution, and such other relief as the Court deems just and proper.

COUNT V

Breach of Implied Warranty of Merchantability (N.Y. U.C.C. § 2-314) (On Behalf of Plaintiff and the New York Subclass)

- 76. Defendant, as the seller of goods, impliedly warranted that the Product was of merchantable quality and fit for the ordinary purpose for which such goods are used.
- 77. The Product was not merchantable at the time of sale. It is marketed and sold as a skin treatment but is, in fact, ineffective, unstable, and incapable of delivering its promised results. Worse, the Product is an adulterated and unapproved new drug under federal and New York law, and therefore illegal to sell at all. A product that cannot be legally sold and that fails to function for its intended purpose is not fit for ordinary use.
- 78. As a direct and proximate result, Plaintiff and the New York Subclass members suffered economic damages, including the purchase price of the Product and the loss of the benefit of their bargains.
- 79. On behalf of herself and the New York Subclass members, Plaintiff seeks actual damages, rescission, restitution, and such other relief as the Court deems just and proper.

COUNT VI

Breach of Implied Warranty of Fitness for a Particular Purpose (N.Y. U.C.C. § 2-315) (On Behalf of Plaintiff and the New York Subclass)

80. Where a seller has reason to know of a particular purpose for which goods are required, and the buyer relies on the seller's skill or judgment to furnish suitable goods, there is an implied warranty that the goods will be fit for such purpose.

- 81. Here, Defendant marketed and sold the Product for the particular purpose of removing dark spots, clearing acne, reducing wrinkles, repairing sun damage, and reducing scarring. Defendant expressly advertised the Product as suitable for these purposes, and Plaintiff and the New York Subclass members relied on Defendant's skill and judgment in purchasing it.
- 82. The Product was not fit for this particular purpose. As alleged herein, the Product is scientifically incapable of delivering the promised results, is unstable in its formulation, and is, in fact, an adulterated and unapproved new drug that cannot be lawfully sold.
- 83. As a direct and proximate result, Plaintiff and the New York Subclass suffered economic damages, including the amounts paid for the Product, and did not receive the benefit of their bargains.
- 84. On behalf of herself and the New York Subclass, Plaintiff seeks actual damages, rescission, restitution, and such other relief as the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendant, as follows:

- (a) For an order certifying the Classes under Rule 23 of the Federal Rules of Civil Procedure; naming Plaintiff as representative of the Classes; and naming Plaintiff's attorneys as Class Counsel to represent the Classes;
- (b) For an order finding in favor of Plaintiff and the Classes on all counts asserted herein;
- (c) For compensatory, statutory and punitive damages in amounts to be determined by the Court and/or jury;
- (d) For prejudgment interest on all amounts awarded;

- (e) For an order of restitution and all other forms of equitable monetary relief; and
- (f) For an order awarding Plaintiff and the Classes their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable as of right.

Dated September 17, 2025

Respectfully submitted,

GUCOVSCHI ROZENSHTEYN, PLLC

By: <u>/s/ Adrian Gucovschi</u> Adrian Gucovschi, Esq.

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Counsel for Plaintiff and the Classes