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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

AILEEN BROOKS, on behalf of herself and all others similarly situated, Plaintiff, v. IT WORKS MARKETING, INC., IT WORKS! GLOBAL, INC., MARK PENTECOST, and PAUL NASSIF Defendants.	Case No: _____ **CLASS ACTION** **CLASS ACTION COMPLAINT FOR VIOLATIONS OF:** **CAL. BUS. & PROF. CODE §§17200 *et seq*. and** **CAL. BUS. & PROF. CODE §§17500 *et seq.* and** **CAL CIV. CODE §§ 1750 *et seq*** **DEMAND FOR JURY TRIAL**

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Plaintiff Aileen Brooks, on behalf of herself, all others similarly situated, and the general public, by and through her undersigned counsel, hereby sues Defendants It Works Marketing, Inc., It Works! Global, Inc. and Mark Pentecost (collectively "Defendants" or "It Works"), and upon information and belief and investigation of counsel, alleges as follows:

I. JURISDICTION AND VENUE

1. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(d)(2) (The Class Action Fairness Act) because the matter in controversy exceeds the sum or value of $5,000,000 exclusive of interest and costs and because more than two-thirds of the members of the class defined herein reside in states other than the states of which Defendants are residents.

2. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Plaintiff Aileen Brooks suffered injuries as a result of Defendants' acts in this District; many of the acts and transactions giving rise to this action occurred in this District; and Defendants: (1) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets of this District through the distribution and sale of its products in this District, and (2) are subject to personal jurisdiction in this District.

II. NATURE OF THE ACTION

3. Defendants manufacture, market, distribute, and sell Thermofight pills ("Thermofight"), a purported "thermogenic weigh loss formula" purchased by Plaintiff.

4. It Works engaged in a consistent, long-term effort to fraudulently market Thermofight as a safe and effective fat burner and rapid weight loss solution on its website and Amazon.com.

5. The claims made on the Thermofight's label, website, and Amazon page are misleading under California's Consumer Legal Remedies Act, Unfair Competition Law, and False Advertising Law. Moreover, the labeling and advertising of Thermofight also violates California's "baby FDCA" statute, also known as the Sherman Law.

6. Similarly, the claims made on Thermofight's label, website, and Amazon page throughout the class period are contrary to those allowed by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. ("FDCA"), and subject any individual manufacturing or selling it to liability for the sale of an unapproved new drug.

7. Defendants' misrepresentations and omissions, described in detail herein, deceive consumers into believing that Thermofight is a safe and effective rapid weight loss solution and fat burner.

8. Plaintiff Aileen Brooks purchased and used Thermofight in reliance upon these deceptive claims, and with the belief that the product was sold in compliance with state and federal regulations.

9. Ms. Brooks used Thermofight as directed, but the product failed to deliver the advertised benefits.

10. This action is brought to remedy Defendants' unfair, deceptive, immoral, and unlawful conduct. On behalf of the class defined herein, Plaintiff seeks an order compelling It Works to, *inter alia*: (1) cease marketing and selling Thermofight as an unapproved new drug; (2) conduct a corrective advertising campaign; (3) destroy all misleading and deceptive materials and products; (4) award Plaintiff and the Class members restitution; and (5) pay costs, expenses, and reasonable attorney fees.

III. PARTIES

11. Plaintiff Aileen Brooks is a resident of Bakersfield who purchased Thermofight for personal and household use during the class period defined herein.

12. Defendant It Works Marketing, Inc. is a Florida corporation headquartered in Palmetto, FL. It Works Marketing, Inc. manufactures, markets, distributes, and sells Thermofight.

13. Defendant It Works! Global, Inc. is a Florida corporation headquartered in Palmetto, FL. It Works! Global, Inc. manufactures, markets, distributes, and sells Thermofight.

14. Defendant Mark Pentecost is an individual who resides in Florida and is sued in his individual capacity. Pentecost is the founder and CEO of It Works Marketing, Inc. and It Works! Global, Inc.

15. At all relevant times, Pentecost has aided and abetted the manufacturing, marketing, distribution, and sale of Thermofight. Pentecost controls the corporate defendants and created them for the primary purpose of engaging in crime, in particular the sale of illegal products, the sale of fraudulent weight loss products, and unlawful auto-billing fraud. He runs the corporations for the primary purpose of engaging in these crimes, and does not observe the corporate formalities of legitimate businesses.

16. Paul Nassif is a plastic surgeon and reality show star who resides in Los Angeles County, California and who co-hosts the E! network shows Botched and Botched by Nature. Nassif's former wife

was one of the "Real Housewives of Beverly Hills."

17. Nassif developed several products for the other defendants and works as a celebrity doctor endorser, giving them the legitimacy of a product developed by a physician when he knows them to be ineffective and fraudulently marketed.

IV. PLAINTIFF'S PURCHASE OF THERMOFIGHT

18. Plaintiff Aileen Brooks purchased Thermofight from the It Works website on May 11, 2020. She paid $39.95 plus shipping and handling for a total of $48.25.

19. When purchasing Thermofight, Plaintiff read and relied on Defendants' various representations, described herein, which render Thermofight misleading under California's Unfair Competition Law and False Advertising law and further render Thermofight an unlawful, unapproved new drug.

20. Relying on Defendants' claims, Plaintiff believed that Thermofight would boost her metabolism, burn fat, and provide rapid weight loss.

21. Ms. Brooks used Thermofight as directed, but the product did not deliver the advertised benefits, nor any results at all.

22. Because Plaintiff expected these statements to be true and honest, but they were not, she did not receive the benefit of her purchases.

V. SPECIFIC MISREPRESENTATIONS, MATERIAL OMISSIONS, AND DRUG CLAIMS

23. During the Class Period, Defendants manufactured, advertised, and sold Thermofight in packaging bearing misleading claims relating to Thermofight's efficacy as a fat burner and rapid weight loss solution. Defendants also made misleading representations relating to Thermofight's efficacy on their website and Amazon page.

24. Thermofight's label, website, and Amazon page included the following claims which are not only false and misleading, but also show that the product is intended to affect the structure and function of the body, and to cure, mitigate, treat, or prevent disease.

A. Thermofight's Packaging

25. An exemplar of Thermofight's packaging, purchased by Plaintiff, is as follows:

Supplement Facts

Serving Size: 1 Caplet
Servings Per Container: 60

	Amount Per Serving	%DV
Calcium	140 mg	11%
Chromium (as chromium dinicotinate glycinate)	200 mcg	571%
Proprietary Green Tea Blend Greenselect® Phytosome green tea leaf/sunflower phospholipid complex and green tea leaf extract [provides min. 112.5 mg epigallocatechin-3-O-gallate (EGCG) and 62.5 mg caffeine]	437.5 mg	*
Green coffee bean extract *(Coffea robusta)* (provides min. 45 mg chlorogenic acids)	100 mg	*
Proprietary Thermogenic Blend Jalapeño pepper (fruit), Black pepper (fruit), ginger (root), cinnamon (bark), cayenne pepper (fruit).	75 mg	*

*Daily value (DV) not established.

Other ingredients: Calcium carbonate, microcrystalline cellulose, stearic acid, croscarmellose sodium, hypromellose, silicon dioxide, magnesium stearate, spirulina (color), glycerin, hydroxypropyl cellulose.

26. The specific deceptive and unlawful claims made on Thermofight's packaging include:

- "Next Gen Fat Burn 2.0"
- "Thermogenic Weight Loss Formula"

27. These claims suggest Thermofight is a safe and effective fat burner and weight loss solution and further render Thermofight a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

B. <u>It Works Website</u>

28. The specific deceptive and unlawful claims relating to Thermofight made on Defendants' website include:

- "extraordinary impact"
- "designed to boost your metabolism and melt away fat."
- "contains Caffeine and Jalapeno Pepper to help you achieve and maintain an ideal fat-burning mode"
- "Fire up your thermogenic weight loss"
- "Uses a clinically proven weight-loss ingredient that helps you lose an average of 31 pounds in 90 days!"

- "Activates enhanced thermogenesis and boosts your energy"
- "Accelerates ketosis by supporting rapid ketone generation"
- "Packs powerful ingredients like Green Coffee Bean, Chromium, Jalapeno Pepper, and increased levels of Caffeine"
- "Boosts fat, carb, macronutrient, and stored energy metabolism"
- "Helps keep blood sugar under control and decreases sugar cravings"
- "Supports energy levels and combats tiredness"
- "Includes Green Tea, renowned for fat loss and nutritional properties"
- "simple and convenient way to burn more fat—even without exercise"
- "powering up your fat metabolism"
- "Chromium – Boosts metabolism"

29. These claims suggest Thermofight can burn fat, increase energy, and provide rapid weight loss, "even without exercise." However, Thermofight fails to deliver any of the advertised benefits. Further, these claims render Thermofight a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

30. A true and correct copy of the "Product Info" page from Thermofight, which was downloaded from Defendants' website, is attached hereto as **Exhibit 1**.

31. Thermofight's illegal drug promotion and fraud extends to its Amazon product pages.

- "Activates enhanced thermogenesis and boosts your energy"
- "Accelerates ketosis by supporting rapid ketone generation"
- "Increased levels of Caffeine and the addition of Jalapeno Pepper to help you achieve and maintain an ideal fat-burning mode"

32. These claims render Thermofight a "drug" within the meaning of 21 U.S.C. § 321(g)(1).

VI. THERMOFIGHT IS FALSE, MISLEADING, AND MISBRANDED.

33. It is unlawful to manufacture or sell any drug that is misbranded. 21 U.S.C. § 331(a), (b), (c), & (g).

34. A drug is misbranded "[i]f its labeling is false or misleading in any particular."[1] 21 U.S.C.

[1] Under the FDCA, "'labeling' means all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). This

§ 352(a)(1).

> If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

21 U.S.C.S. § 321(n).

35. Defendants' deceptive acts render the Thermofight label misbranded under Cal. Health & Saf. Code § 110100 (adopting all FDA labelling regulations as state regulations), § 110398 ("It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded."), § 111330 (drug label misbranded if false or misleading in any particular), as well as Cal. Bus. & Prof. Code § 17200 (Unfair Competition Law "Fraudulent" Prong) § 17500 (False Advertising Law) and Cal. Civ. Code § 1750 (CLRA).

36. Because Thermofight claims to treat conditions not amenable to self-diagnosis, directions are not and likely cannot be written such that a layperson can safely use this product to treat those conditions. The Thermofight label therefore lacks "adequate directions for use," rendering the product misbranded. 21 U.S.C. § 352(f)(1); *see also* 21 C.F.R. § 201.5 ("'Adequate directions for use' means directions under which the layman can use a drug safely and for the purposes for which it is intended.").

37. Plaintiff used Thermofight as directed, but it failed to deliver the advertised benefits.

VII. THERMOFIGHT IS AN UNAPPROVED NEW DRUG.

38. "The term 'drug' means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1). Here, Thermofight is a drug because it is advertised as a product which will affect the structure or function of the body or cure, mitigate, treat, or prevent disease.

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includes websites associated with the products. *See Sandoval v. Pharmacare US, Inc.*, 730 Fed. App'x 417, 420 (9th Cir. 2018).

39. The claims on the packaging and website of Thermofight render it an unapproved new drug.

40. Attached hereto as **Exhibit 2** are FDA Warning Letters relating to similar claims that the FDA determined are drug claims.

41. A "new drug" is any drug "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1). Here, Thermofight is a "new drug" within the meaning of the FDCA because it is not generally recognized as safe and effective for the intended uses. *See* Title 21 of the Code of Federal Regulations, Chapter I, Subchapter D; 21 C.F.R. § 330.1.

42. "No person shall introduce or deliver for introduction into interstate commerce any new drug . . ." without approval by the FDA. 21 U.S.C § 355(a); *see also* 21 U.S.C. § 331(d).

43. Defendants have not received approval from the FDA to sell Thermofight.

44. The sale of unapproved new drugs is illegal and dangerous. First, consumers risk purchasing and using a product that will endanger their health. Second, consumers risk purchasing a product that will not effectively treat their condition, forgoing actual treatment of that condition in lieu of an unapproved new drug which may not treat their condition. The FDA's regulatory regimen helps ensure that such products are kept away from consumers. Defendants' failure to comply with these regulations puts consumers at risk and gives it an unfair advantage over competitors that do commit the time and expense of complying with such necessary regulations.

45. Thermofight does not qualify for the reduced level of regulation applicable to certain nutrition supplement products for several reasons. The Thermofight label, website, and Amazon page neither describe the role of any nutrient or dietary ingredient intended to affect the structure or function in humans, characterize the documented mechanism by which any nutrient or dietary ingredient acts to maintain such structure or function, nor describes general well-being from consumption of any nutrient or dietary ingredient. 21 U.S.C. § 343(r)(6)(A).

46. The claims on the Thermofight label, website, and Amazon page do not relate to any classical nutrient deficiency, and Defendant does not have substantiation that its statements are truthful

and not misleading pursuant to 21 U.S.C. § 343(r)(6).

47. The label of Thermofight states that "This statement has 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).

48. California similarly prohibits the sale of unapproved new drugs. Cal. Health & Saf. Code § 111550.

VIII. DEFENDANTS UTILIZE FAKE AMAZON REVIEWS TO PROMOTE THERMOFIGHT.

49. In addition to deceptively marketing Thermofight through misleading claims, It Works paid for and procured thousands of fake reviews to promote its products.

50. Fake online reviews are considered to be a rapidly growing problem by the FTC.

51. As of April 21, 2021, It Works' Thermofight Amazon page listed a total of 289 customer reviews.

52. ReviewMeta is a program which collects reviews for a particular product on Amazon and uses a proprietary algorithm and statistical modeling to determine whether or not reviews are credible.

53. Overall, It Works' Thermofight Amazon page failed ReviewMeta's analysis, and found that 27% of the reviews provided were deemed probable frauds. Such a high percentage of unreliable reviewers suggests a campaign of fake reviews. A true and correct copy of the ReviewMeta report for the Thermofight Amazon page is attached hereto as **Exhibit 3**.

IX. DEFENDANTS EMPLOY UNFAIR AND UNLAWFUL AUTO-BILLING PRACTICES AND "MEMBERSHIP FEES" TO EXTRACT MORE MONEY FROM CONSUMERS.

54. In addition to deceptively marketing Thermofight as a safe and effective weight loss solution, Defendants utilize unfair auto-billing methods and charge consumers unauthorized "membership" fees to extract additional money from consumers. This illegal practice includes not just Thermofight, but a large number of other dubious products such as "slimming" gummy candy, a "Skinny Wrap" containing seaweed and green tea that supposedly makes the stomach, hips, love handles, thighs, and arms "tightened, toned, and beautifully smooth"; a "body contouring gel"

55. Hidden within what appears to be a normal online retail checkout is the "It Works! Loyal

Customer Agreement," stating any consumer wishing to purchase any It Works! product must either (1) "make a three (3) consecutive month minimum commitment to a monthly autoshipment order," or (2) "enroll by making a $50 Membership Fee payment." *See* **Exhibit 4**.

56. Consumers are thus forced into making "a three (3) consecutive month minimum commitment to a monthly auto-shipment order," which well exceeds the cost of the "$50 Membership Fee payment" that Loyal Customer Agreement policy claims to offer in **Exhibit 4**.

57. If a consumer receives an ineffective product from It Works! while enrolled in an auto-shipment program and wishes to cancel future shipments "prior to completing the three (3) month minimum commitment," the consumer is "charged a $50 Membership Fee." *See* **Exhibit 4**.

58. Thus, consumers are forced to pay the $50 Membership Fee upfront, pay for three-months' worth of ineffective products, or pay the $50 Membership Fee to get out of their three-month commitment.

59. Further, Defendants prevent class members from cancelling auto-billing.

60. The Better Business Bureau ("BBB") notes that It Works! "has failed to resolve underlying cause(s) of a pattern of complaints." *See* **Exhibit 5**. For this reason, the BBB gave It Works! a 1.75/5 star rating. "The BBB rating is based on information BBB is able to obtain about the business, including complaints received from the public." *See* **Exhibit 5**.

61. The BBB

> has received a pattern of complaints from consumers alleging that after trying to cancel with the business, they continue to receive additional products. Consumers also state that they have found additional charges being taken that the business has not informed them would be occurring. Complaints also allege that the business continues to bill after cancellation, and consumers are not informed that there is a $50.00 cancellation fee.

Exhibit 5.

62. In the last year alone, the BBB received 190 complaints about It Works!, the vast majority of which relate to the auto-billing/Membership Fee scheme described above.

63. On May 26, 2021, Ellis G filed one such complaint, stating:

> If [I] could give negative stars, best believe I would. I have just recently gone through some difficulties due to medical expenses and I notice a $138 charge trying to go through on my account. After calling the customer service line, or sad excuse for one, they basically told me the only options are pay to cancel, or pay and still get a product. And after talking with an emotionless supervisor, I'm then told that all they can do at that point is refund me a

measly $88. THAT. IS. NOT. GOOD. ENOUGH. They need to be shut down IMMEDIATELY as they are money greedy thieves.

64. On May 19, 2021, JR filed a similar complaint, stating:

This company is highly misleading. I signed up for a three month trial of Keto Coffee. You had to buy a three month subscription for a three month supply. So I tried it and paid roughly 54$ for a months supply for three months. Turns out a months supply is 15 packets. They charge you 50$ to cancel before the three months is over. Total scam.

65. On May 12, 2021, Rebecca S filed complaint stating:

I purchased the firming neck cream which broke me out in an itchy rash. I contacted ItWorks to get a refund or credit. They told me that they don't guarantee their products or offer a money back guarantee. I also was told that I can't cancel my autoship before my 3rd shipment or I'll have to pay a $50 fee. I'm very disappointed and will not order any more products from this company.

66. Similarly, on March 22, 2021, Teresa K complained:

My husband and I tried the Slimming gummies. They did not work. We actually gained weight. It was only a few pounds but still was not what we bought the gummies for to lose weight. Went to cancel the autoship and was notified my card would be charged the $50, well okay. As stated in another review, will pay the $50 for a product that doesn't work. Will never use anything from ITWORKS!! again. Thank you for your time. WISH I COULD GIVE THIS COMPANY A ZERO STAR.

67. It Works! utilizes these unfair auto-billing practices and "Membership Fees" to extract every penny possible from consumers.

68. Plaintiff was similarly enrolled in an auto-shipment program without knowledge of her enrollment.

69. When making her initial purchase, Ms. Brooks was not made aware that she had been signed up for the It Works! Loyal Costumer Membership, any terms of agreement, the auto-shipment policy, or fees relating to the membership and cancelation. Ms. Brooks did not receive any of this information until after her purchase of Thermofight was complete.

70. Defendants did not alert Plaintiff that she had fraudulently signed up for It Works! Loyal Customer Membership, which requires a minimum auto-shipment agreement of three purchases of Thermofight, prior to her initial purchase of the product.

71. In fact, she did not know that she was enrolled in an auto-shipment program until she saw

additional charges on her credit card statement and contacted Defendants' customer service line.

72. Plaintiff was charged for two months' worth of Thermofight before she realized that she was fraudulently enrolled in an auto-shipment agreement.

73. California's Automatic Purchase Renewal Statue, Cal. Bus. & Prof. Code § 17601 provides:

> (a) "Automatic renewal" means a plan or arrangement in which a paid subscription or purchasing agreement is automatically renewed at the end of a definite term for a subsequent term.
>
> (b) "Automatic renewal offer terms" means the following clear and conspicuous disclosures:
>
> (1) That the subscription or purchasing agreement will continue until the consumer cancels.
>
> (2) The description of the cancellation policy that applies to the offer.
>
> (3) The recurring charges that will be charged to the consumer's credit or debit card or payment account with a third party as part of the automatic renewal plan or arrangement, and that the amount of the charge may change, if that is the case, and the amount to which the charge will change, if known.
>
> (4) The length of the automatic renewal term or that the service is continuous, unless the length of the term is chosen by the consumer.
>
> (5) The minimum purchase obligation, if any.
>
> (c) "Clear and conspicuous" or "clearly and conspicuously" means in larger type than the surrounding text, or in contrasting type, font, or color to the surrounding text of the same size, or set off from the surrounding text of the same size by symbols or other marks, in a manner that clearly calls attention to the language. In the case of an audio disclosure, "clear and conspicuous" and "clearly and conspicuously" means in a volume and cadence sufficient to be readily audible and understandable.
>
> (d) "Consumer" means any individual who seeks or acquires, by purchase or lease, any goods, services, money, or credit for personal, family, or household purposes.
>
> (e) "Continuous service" means a plan or arrangement in which a subscription or purchasing agreement continues until the consumer cancels the service.

74. Defendant's auto-billing practices constitute an "automatic renewal" as defined by Cal. Bus. & Prof. Code § 17601(a).

75. The It Works! Loyal Customer Agreement"[2] is an "automatic renewal offer" as defined by Cal. Bus. & Prof. Code § 17601(b).

76. Cal. Bus. & Prof. Code § 17602 provides:

> (a) It shall be unlawful for any business that makes an automatic renewal offer or continuous service offer to a consumer in this state to do any of the following:
>
> (1) Fail to present the automatic renewal offer terms or continuous service offer terms in a clear and conspicuous manner before the subscription or purchasing agreement is fulfilled and in visual proximity, or in the case of an offer conveyed by voice, in temporal proximity, to the request for consent to the offer. If the offer also includes a free gift or trial, the offer shall include a clear and conspicuous explanation of the price that will be charged after the trial ends or the manner in which the subscription or purchasing agreement pricing will change upon conclusion of the trial.
>
> (2) Charge the consumer's credit or debit card, or the consumer's account with a third party, for an automatic renewal or continuous service without first obtaining the consumer's affirmative consent to the agreement containing the automatic renewal offer terms or continuous service offer terms, including the terms of an automatic renewal offer or continuous service offer that is made at a promotional or discounted price for a limited period of time.
>
> (3) Fail to provide an acknowledgment that includes the automatic renewal offer terms or continuous service offer terms, cancellation policy, and information regarding how to cancel in a manner that is capable of being retained by the consumer. If the automatic renewal offer or continuous service offer includes a free gift or trial, the business shall also disclose in the acknowledgment how to cancel, and allow the consumer to cancel, the automatic renewal or continuous service before the consumer pays for the goods or services.
>
> (b) A business that makes an automatic renewal offer or continuous service offer shall provide a toll-free telephone number, electronic mail address, a postal address if the seller directly bills the consumer, or it shall provide another cost-effective, timely, and easy-to-use mechanism for cancellation that shall be described in the acknowledgment specified in paragraph (3) of subdivision (a).
>
> (c) In addition to the requirements of subdivision (b), a consumer who accepts an automatic renewal or continuous service offer online shall be allowed to terminate the automatic renewal or continuous service exclusively online, which may include a termination email formatted and provided by the business that a consumer can send to the business without additional information.

[2] **Exhibit 4** hereto.

> (d) In the case of a material change in the terms of the automatic renewal or continuous service that has been accepted by a consumer in this state, the business shall provide the consumer with a clear and conspicuous notice of the material change and provide information regarding how to cancel in a manner that is capable of being retained by the consumer.
>
> (e) The requirements of this article shall apply only prior to the completion of the initial order for the automatic renewal or continuous service, except as follows:
>
> (1) The requirement in paragraph (3) of subdivision (a) may be fulfilled after completion of the initial order.
>
> (2) The requirement in subdivision (d) shall be fulfilled prior to implementation of the material change.

77. Defendants' auto-billing practices violate Cal. Bus. & Prof. Code § 17602(a) because the It Works! Loyal Customer Agreement

> fail[s] to present the automatic renewal offer terms or continuous service offer terms in a clear and conspicuous manner before the subscription or purchasing agreement is fulfilled and in visual proximity, or in the case of an offer conveyed by voice, in temporal proximity, to the request for consent to the offer.

78. Specifically, the auto-billing provisions in the It Works! Loyal Customer Agreement are not "clearly and conspicuously" disclosed because they are not set forth

> in larger type than the surrounding text, or in contrasting type, font, or color to the surrounding text of the same size, or set off from the surrounding text of the same size by symbols or other marks, in a manner that clearly calls attention to the language.

Cal. Bus. & Prof. Code § 17601(c); Rather, the auto-renewal offer terms appear in the same font size and typeface as the rest of the Loyal Customer Service Agreement.

79. Though the auto-renewal offer terms are not "clearly and conspicuously" disclosed in the Loyal Customer Agreement as required, other terms within the Agreement are "clearly and conspicuously" disclosed.

80. For example, the following provision from the Agreement is set forth in bolded font and all capital letters:

> **PLEASE NOTE: LOYAL CUSTOMERS MAY PURCHASE PRODUCT FOR PERSONAL USE ONLY AND MAY NOT RESELL THE PRODUCT FOR ANY REASON. ONLY IT WORKS! INDEPENDENT DISTRIBUTORS ARE AUTHORIZED TO SELL IT WORKS! PRODUCTS. ANYONE OTHER THAN A CURRENT IT WORKS! INDEPENDENT DISTRIBUTOR FOUND TO BE**

SELLING OR ADVERTISING IT WORKS! PRODUCTS WILL IMMEDIATELY HAVE THEIR RIGHTS TO BUY PRODUCTS TERMINATED.

Exhibit 4 (Loyal Customer Agreement).

81. Defendants also violate Cal. Bus. & Prof Code § 17602(b) because they

> Charge the consumer's credit or debit card, or the consumer's account with a third party, for an automatic renewal or continuous service without first obtaining the consumer's affirmative consent to the agreement containing the automatic renewal offer terms or continuous service offer terms, including the terms of an automatic renewal offer or continuous service offer that is made at a promotional or discounted price for a limited period of time.

82. In Ms. Brooks' case, she did not know she was being continually charged until she saw the charge for a second bottle of Thermofight on her credit card statement.

83. Defendants also violate Cal. Bus. & Prof Code § 17602(c) because "consumer[s] who accept[]" Defendants' "automatic renewal or continuous service offer online" are not "allowed to terminate the automatic renewal or continuous service exclusively online, which may include a termination email formatted and provided by the business that a consumer can send to the business without additional information."

84. In Ms. Brooks case, she was required to call Defendants' customer service department in order to cancel her auto-renewal.

X. DEFENDANTS' PRACTICES ARE "UNFAIR" WITHIN THE MEANING OF THE CALIFORNIA UNFAIR COMPETITION LAW.

85. Defendants' practices as described herein are "unfair" within the meaning of the California Unfair Competition Law because their conduct is immoral, unethical, unscrupulous, and substantially injurious to consumers, and the utility of this conduct to Defendants does not outweigh the gravity of the harm to Defendants' victims.

86. In particular, while Defendants' use of fraudulent advertising to sell an unlawful product may have had some utility to Defendants in that it allows it to realize higher profit margins than if it did not use fraudulent advertising tactics, this utility is small and far outweighed by the gravity of the economic harm Defendants inflicts upon consumers. Further, the injury to consumers from Defendants' practices is substantial, not outweighed by benefits to consumers or competition, and not an injury that

consumers themselves could reasonably have avoided.

87. Additionally, while Defendants' practice of enrolling consumers in auto-billing programs without complying with Cal. Bus. & Prof Code § 17600 *et seq.* may have had some utility to Defendants in the form of increase profits, this utility is small and far outweighed by the gravity of the economic harm Defendants inflicts upon consumers. Further, the injury to consumers from Defendants' practices is substantial, not outweighed by benefits to consumers or competition, and not an injury that consumers themselves could reasonably have avoided.

XI. DEFENDANTS' PRACTICES ARE "UNLAWFUL" UNDER THE UNFAIR COMPETITION LAW.

88. Defendants' practices as described herein are "unlawful" within the meaning of the California Unfair Competition Law because the marketing, sale, and distribution Thermofight violates the Federal Food, Drug, and Cosmetic Act, as well as California's Sherman Food, Drug, and Cosmetic Law.

89. Defendants' conduct described herein is "unlawful" because it violated the following portions of the Federal Food, Drug, and Cosmetic Act ("FDCA"):

- **21 U.S.C. § 331(a)**, prohibiting the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded";
- **21 U.S.C. § 331(b)**, prohibiting the "adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce";
- **21 U.S.C. § 352(f)(1)**, requiring drugs to have adequate directions for use
- **21 U.S.C. § 355(a)**, prohibiting the sale of unapproved new drugs.

90. Defendants' conduct described herein also violates multiple provisions of California law including, *inter alia*:

- **Cal. Health & Saf. Code § 110100 *et seq.***, which adopts all FDA labeling regulations as state regulations;
- **Cal. Health & Saf. Code § 111330**, "Any drug or device is misbranded if its labeling is false or misleading in any particular.";
- **Cal. Health & Saf. Code § 110398**, "It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.";

- **Cal. Health & Saf. Code § 111440**, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.";
- **Cal. Health & Saf. Code § 111445**, "It is unlawful for any person to misbrand any drug or device.";
- **Cal. Health & Saf. Code § 111450**, "It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.";
- **Cal. Health & Saf. Code § 111550**, prohibiting sale of new drug unless approved under 21 U.S.C. § 355;
- **Cal. Civ. Code § 1770(a)**, prohibiting misleading practices in relation to the sale of goods;
- **Cal. Bus. & Prof. Code § 17500 *et seq.***, prohibiting false or misleading advertising;
- **Cal. Bus. & Prof. Code § 17200 *et seq.***, prohibiting fraudulent business activity.

91. The fraudulent marketing and advertising of Thermofight constitutes a violation of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.

92. Defendants' practices are further unlawful because they violate Cal. Bus. & Prof. Code § 17602(a) because the It Works Loyal Customer Agreement constitutes an "auto-renewal offer" within the meaning of Cal. Bus. & Prof. Code § 17601, but the terms of the offer are not "clearly and conspicuously" in "larger type than the surrounding text, or in contrasting type, font, or color to the surrounding text of the same size, or set off from the surrounding text of the same size by symbols or other marks, in a manner that clearly calls attention to the language."

93. Defendants' practices also violate Cal. Bus. & Prof. Code § 17602(b) because Defendants

> Charge the consumer's credit or debit card, or the consumer's account with a third party, for an automatic renewal or continuous service without first obtaining the consumer's affirmative consent to the agreement containing the automatic renewal offer terms or continuous service offer terms, including the terms of an automatic renewal offer or continuous service offer that is made at a promotional or discounted price for a limited period of time.

94. Defendants also violate Cal. Bus. & Prof Code § 17602(c) because "consumer[s] who accept[]" Defendants' "automatic renewal or continuous service offer online" are not "allowed to terminate the automatic renewal or continuous service exclusively online, which may include a termination email formatted and provided by the business that a consumer can send to the business without

additional information."

95. Defendants' unlawful acts allowed it to sell more units of the Thermofight than it would have otherwise, and at a higher price and higher margin.

96. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and to commence a corrective advertising campaign.

97. Plaintiff also seeks an order for the disgorgement and restitution of all revenue received by Defendants from the sale of Collagen Peptides.

XII. RELIANCE AND INJURY

98. When purchasing Thermofight, Plaintiff was seeking products of particular qualities, including a product that safely and effectively boost her metabolism, burn fat, control blood sugar levels, and provide rapid weight loss.

99. Plaintiff read and relied on, for her Thermofight purchase, the product's packaging and the misrepresentations made by It Works on Defendants' website and the efficacy messages they conveyed, which were substantial factors in her purchase.

100. Plaintiff further relied on the reviews posted on It Works' Thermofight product page, many of which were fake or altered.

101. Plaintiff purchased Thermofight believing it had the qualities she sought based on the product's deceptive labeling and website and the natural assumption that products sold in stores and online by large companies would deliver advertised benefits, such as those touted on the packaging of Thermofight. The purchased product was instead unsatisfactory to her for the reasons described herein.

102. Plaintiff purchased Thermofight instead of competing products based on the false statements and misrepresentations described herein.

103. Plaintiff suffered economic injury when she purchased Thermofight because it did not provide the advertised benefits, and she would not have purchased it absent Defendants' unlawful conduct.

104. Thermofight was offered for sale in violation of California and federal law and has a value of $0 because it is both illegal and ineffective.

105. Plaintiff would not have purchased Thermofight had she known that it was offered for sale

in violation of California and federal law.

106. When Plaintiff purchased Thermofight, she was unaware that she would be subject to Defendants' unlawful auto-renewal practices described herein.

107. Had Ms. Brooks known that Defendants would utilize these unfair and unlawful auto-renewal practices to extract additional money from her, she would not have purchased Thermofight.

XIII. CLASS ACTION ALLEGATIONS

108. Plaintiff brings this action on behalf of herself and all others similarly situated (the "Class"), excluding Defendants' officers, directors, and employees, and the Court, its officers, and its families.

109. The Thermofight Class is defined as follows:

> All individuals who purchased Thermofight in the United States for their own personal or household use, and not for resale, from September 1, 2017 to the present.

110. The Automatic Billing Class is defined as follows:

> All individuals Defendants charged under their automatic renewal program in the United States from September 1, 2017 to the present.

111. Questions of law and fact common to Plaintiff and the Class include:

a. Whether Defendants communicated efficacy messages through Thermofight's labeling, packaging, and website;

b. Whether those messages were material, or likely to be material, to a reasonable consumer;

c. Whether those messages were false, at variance with the truth, misleading, likely to deceive, and/or had the capacity to deceive the public and/or a reasonable consumer;

d. Whether Defendants' conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers;

e. Whether Thermofight is an unapproved new drug;

f. Whether the slight utility Defendants realize as a result of their conduct outweighs the gravity of the harm the conduct causes to its victims;

g. Whether Defendants' conduct violated public policy as declared by specific

constitutional, statutory, or regulatory provisions;

h. Whether the injury to consumers from Defendants' practices is substantial;

i. Whether Defendants fraudulently omitted material information in advertising Thermofight as safe and effective;

j. Whether Defendants sold and distributed Thermofight to the public in misleading packaging that was likely to deceive the public;

k. Whether the Class is entitled to restitution and attorneys' fees and costs, injunctive, and/or any other relief;

l. Whether Defendants' conduct was knowing, or whether Defendants reasonably should have known of the conduct;

m. Whether Defendants' conduct constitutes violations of the California's False Advertising Law;

n. Whether Defendants' conduct constitutes a violation of the unlawful prong of California's Unfair Competition Law;

o. Whether Defendants acted willfully, recklessly, negligently, or with gross negligence in violation of the law as alleged herein;

p. Whether any applicable statute of limitations should be tolled on behalf of the Class;

q. Whether members of the Class are entitled to restitution and, if so, the correct measure of restitution;

r. Whether members of the Class are entitled to an injunction and, if so, its terms; and

s. Whether members of the Class are entitled to any further relief.

112. By purchasing Thermofight, all Class members were subjected to the same wrongful conduct.

113. Because all Subclass members were enrolled in an unlawful and unfair auto-renewal program, they were all subjected to the same wrongful conduct.

114. Absent Defendants' material deceptions, misstatements, and omissions, and unlawful sale, distribution, and marketing of Thermofight, Plaintiff and other Class members would not have purchased

Thermofight.

115. Plaintiff's claims are typical of Class's claims and the Subclass's claims.

116. All Class members were subjected to the same economic harm when they purchased Thermofight and suffered economic injury.

117. Plaintiff will fairly and adequately protect the interests of the Class, has no interests that are incompatible with the interests of the Class, and has retained counsel competent and experienced in class litigation.

118. The Class is sufficiently numerous, as it includes thousands of individuals who purchased Thermofight during the Class Period.

119. The Subclass is sufficiently numerous, as it includes thousands of individuals who purchased Thermofight and were enrolled in an unfair and unlawful auto-renewal program during the Class Period.

120. Class representation is superior to other options for the resolution of the controversy. The relief sought for each Class member is small, as little as $50 for some Class members. Absent the availability of class action procedures, it would be infeasible for Class members to redress the wrongs done to them.

121. Defendants have acted on grounds applicable to the Class, thereby making final injunctive relief or declaratory relief appropriate concerning the Class as a whole.

122. Questions of law and fact common to the Class predominate over any questions affecting only individual members.

XIV. CAUSES OF ACTION

First Cause of Action

California Unfair Competition Law, Unlawful Prong

Cal. Bus. & Prof. Code §§ 17200, *et seq.*

123. In this and every cause of action, Plaintiff realleges and incorporates the preceding allegations as if fully set forth herein.

124. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "unlawful" business acts and practices in that Defendants' conduct violates the

California False Advertising Law, and the California Consumer Legal Remedies Act, as alleged herein.

125. Defendants' conduct is further "unlawful" because it violated the following portions of the Federal Food, Drug, and Cosmetic Act ("FDCA"):

- **21 U.S.C. § 331(a)**, prohibiting the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded";
- **21 U.S.C. § 331(b)**, prohibiting the "adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce";
- **21 U.S.C. § 352(f)(1)**, requiring drugs to have adequate directions for use;
- **21 U.S.C. § 355(a)**, prohibiting the sale of unapproved new drugs.

126. Defendants' conduct also violates other provisions of California law including, *inter alia:*

- **Cal. Health & Saf. Code § 110100 *et seq.***, which adopts all FDA regulations as state regulations;
- **Cal. Health & Saf. Code § 111330**, "Any drug or device is misbranded if its labeling is false or misleading in any particular.";
- **Cal. Health & Saf. Code § 110398**, "It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.";
- **Cal. Health & Saf. Code § 111440**, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.";
- **Cal. Health & Saf. Code § 111445**, "It is unlawful for any person to misbrand any drug or device.";
- **Cal. Health & Saf. Code § 111450**, "It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.";
- **Cal. Health & Saf. Code § 111550**, prohibiting sale of new drug unless approved under 21 U.S.C. § 355;
- **Cal. Civ. Code § 1770(a)**, prohibiting misleading practices in relation to the sale of goods;
- **Cal. Bus. & Prof. Code § 17500 *et seq.***, prohibiting false or misleading advertising;
- **Cal. Bus. & Prof. Code § 17200 *et seq.***, prohibiting fraudulent business activity.

127. The challenged labeling statements made by Defendants thus constituted violations of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.

128. Defendants leveraged their deception to induce Plaintiff and members of the Class to purchase products that were of lesser value and quality than advertised.

129. The fraudulent marketing of Thermofight described herein constitutes a violation of the

FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.

130. Had Plaintiff known that Thermofight was offered for sale in violation of California and federal regulations, she would not have purchased it.

131. Plaintiff suffered injury in fact and lost money or property as a result of Defendants' deceptive advertising: she was denied the benefit of the bargain when she decided to purchase Thermofight over competing products, which are legal, less expensive, and do not make misleading or false drug claims on their packaging.

132. Defendants' practices are further unlawful because they violate Cal. Bus. & Prof. Code § 17602(a) because the It Works Loyal Customer Agreement constitutes an "auto-renewal offer" within the meaning of Cal. Bus. & Prof. Code § 17601, but the terms of the offer are not "clearly and conspicuously" in "larger type than the surrounding text, or in contrasting type, font, or color to the surrounding text of the same size, or set off from the surrounding text of the same size by symbols or other marks, in a manner that clearly calls attention to the language."

133. Defendants' practices also violate Cal. Bus. & Prof. Code § 17602(b) because Defendants

> [c]harge the consumer's credit or debit card, or the consumer's account with a third party, for an automatic renewal or continuous service without first obtaining the consumer's affirmative consent to the agreement containing the automatic renewal offer terms or continuous service offer terms, including the terms of an automatic renewal offer or continuous service offer that is made at a promotional or discounted price for a limited period of time.

134. Defendants also violate Cal. Bus. & Prof Code § 17602(c) because "consumer[s] who accept[]" Defendants' "automatic renewal or continuous service offer online" are not "allowed to terminate the automatic renewal or continuous service exclusively online, which may include a termination email formatted and provided by the business that a consumer can send to the business without additional information."

135. Defendants' unlawful acts allowed it to sell more units of the Thermofight than it would have otherwise, and at a higher price, and higher margin.

136. Had Plaintiff been aware of Defendants' false and misleading advertising tactics and unlawful auto-billing practices, she would not have purchased Thermofight, and had Defendants not

advertised it in a fraudulent manner, Plaintiff would have paid less for it.

Second Cause of Action

California Unfair Competition Law, Fraudulent Prong

Cal. Bus. & Prof. Code §§ 17200, *et seq*.

137. Cal. Bus. & Prof. Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."

138. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "fraudulent" business acts and practices in that Defendants' conduct has a likelihood, capacity or tendency to deceive Plaintiff, the Class, and the general public.

139. Defendants leveraged their deception to induce Plaintiff and members of the Class to purchase products that were of lesser value and quality than advertised.

140. Plaintiff suffered injury in fact and lost money or property as a result of Defendants' deceptive advertising: she was denied the benefit of the bargain when she decided to purchase Thermofight over competing products, which are legal, less expensive, and do not make misleading or false drug claims on their packaging.

141. Had Plaintiff been aware of Defendants' false and misleading advertising tactics, she would not have purchased Thermofight, and had Defendants not advertised it in a fraudulent manner, Plaintiff would have paid less for it.

Third Cause of Action

California Unfair Competition Law, Unfair Prong

Cal. Bus. & Prof. Code §§ 17200, *et seq*.

142. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "unfair" business acts and practices because Defendants' conduct is:

- immoral, unethical, unscrupulous, and offends public policy;
- the gravity of Defendants' conduct outweighs any conceivable benefit of such conduct; and
- the injury to consumers caused by Defendants' conduct is substantial, not outweighed by any countervailing benefits to consumers or competition, and not one that consumers themselves could reasonably have avoided.

143. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendants to commence a corrective advertising campaign; and awarding the class restitution of all monies from the sale of Thermofight.

Fourth Cause of Action

California False Advertising Law

Cal. Bus. & Prof. Code §§ 17500, *et seq*.

144. In violation of Cal. Bus. & Prof. Code §§ 17500 *et seq*., the advertisements, labeling, policies, acts, and practices described herein were designed to, and did, result in the purchase and use of Thermofight without the knowledge that the products make misleading and unapproved claims.

145. Defendants knew and reasonably should have known that the claims made on Thermofight's label, packaging, and website were untrue and misleading.

146. As a result, Plaintiff, the Class, and the general public are entitled to injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which Defendants were unjustly enriched.

147. Plaintiff seeks an order enjoining Defendants from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendants to commence a corrective advertising campaign; awarding Plaintiff and the class restitution of all monies from the sale of Thermofight in an amount of $5 million or a greater amount to be proven at trial, actual and punitive damages, and interest to Plaintiff, an incentive award to Plaintiff in conjunction with a class award or injunction, and for attorney fees and costs to be awarded by the Court in accordance with applicable law, including the Private Attorney General Statute.

Fifth Cause of Action

California Consumer Legal Remedies Act

Cal. Civ. & Prof. Code §§ 1750, *et seq*.

148. The CLRA prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.

149. Defendants' policies, acts and practices were designed to, and did, result in the purchase

and use of Thermofight for personal, family, or household purposes, and violated and continue to violate the following sections of the CLRA:

- **Cal. Civ. Code § 1770(a)(5),** representing that goods have characteristics, uses, or benefits which they do not have;
- **Cal. Civ. Code § 1770(a)(7),** representing that goods are of a particular standard, quality, or grade if they are of another;
- **Cal. Civ. Code § 1770(a)(9)**, advertising goods with intent not to sell them as advertised; and
- **Cal. Civ. Code § 1770(a)(16),** representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

150. As a result, Plaintiff, the Class, and the general public are entitled to injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which Defendants were unjustly enriched.

151. As a further result, Plaintiff and the Class have suffered damages, and because the conduct was deliberate, immoral, oppressive, made with malice and contrary to public policy, they are entitled to punitive or exemplary damages.

152. Pursuant to section 1782 *et seq*. of the CLRA, Plaintiff notified Defendants in writing by certified mail of the particular violations of § 1770 of the Act as to Thermofight and demanded that Defendants rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act.

153. Defendants received Plaintiff's written notice on April 19, 2021.

XV. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself, all others similarly situated, and the general public, prays for judgment against Defendants as follows:

a. An order confirming that this class action is properly maintainable as a class action as defined above, appointing Plaintiff Aileen Brooks and her undersigned counsel to represent the Class, and requiring Defendants to bear the cost of class notice;

b. An order requiring Defendants pay $500 in restitution, damages, and interest to Plaintiff;

c. An order requiring Defendants pay $5 million or a greater amount to be proven at trial in restitution to Class members, and $2000 to Plaintiff as an incentive award, or such greater amount the Court deems fair and reasonable;

d. An order requiring Defendants to disgorge any benefits received from Plaintiff and its unjust enrichment realized as a result of its improper and misleading advertising, marketing, sale, and distribution of Thermofight;

e. An Order declaring the conduct complained of herein violates the Unfair Competition Law;

f. An order requiring Defendants to cease and desist its deceptive, unconscionable, and fraudulent practices;

g. An order requiring Defendants to engage in a corrective advertising campaign;

h. An award of prejudgment and post judgment interest;

i. An award of attorney fees and costs of $500,000, or such greater amount the Court awards as fair and reasonable; and

j. Such other and further relief as this Court may deem just, equitable or proper.

XVI. JURY DEMAND

Plaintiff requests a trial by jury.

DATED: September 3, 2021

Respectfully Submitted,

/s/ Gregory S. Weston

THE WESTON FIRM
GREGORY S. WESTON
1405 Morena Blvd., Suite 201
San Diego, CA 92110
Telephone: (619) 798-2006
Facsimile: (619) 343-2789

Counsel for Plaintiff

EXHIBIT 1

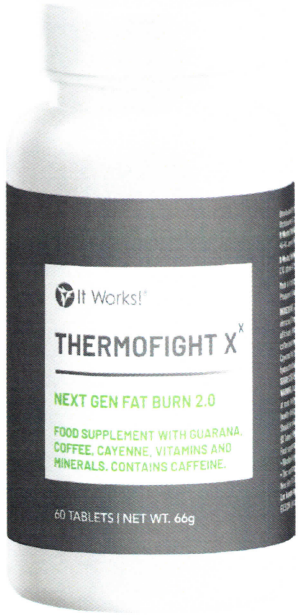
PRODUCT INFO

THERMOFIGHT X^{X}

NEXT GEN FAT BURN 2.0

60 Tablets

Introducing ThermoFight X^{X}. With world-renowned, metabolism-boosting ingredients***—including Magnesium, Chromium, and now with even more vitamins B1, B2, B6, and B12 — you can help get your body into burn mode while supporting your metabolism. We've enhanced our best-selling formula, ThermoFight X to bring you ThermoFight X^{X}, so you can help kickstart your body's metabolic rate and burn fat—no workout required! Take twice a day to ensure your sluggish metabolism doesn't prevent you from reaching your goals.



Features and Benefits:

- Boosts fat, carb, macronutrient, and stored energy metabolisms***
- Helps keep blood sugar under control and decreases sugar cravings****
- Supports energy levels and combats tiredness**
- Includes Green Tea, renowned for fat loss and nutritional properties
- Now contains even more B vitamins to support your metabolism

NON-GMO · NO ARTIFICIAL COLOURS OR FLAVOURS · KETO FRIENDLY · SOY-FREE · VEGAN

Nutrition Facts / Valeurs nutritionnelles / Información nutricional / Nährwertinformation / Ravintotietoa / Næringsindhold / Næringsinnholdsinformasjon / Voedingsinformatie / Näringsinnehåll		
	Per 2 Tablets / Pour 2 comprimés / Porc ada 2 pastillas / Pro 2 Tabletten / Per 2 tablettia / Pr. 2 tabletter / Per 2 tabletter / Per twee tabletten / Per 2 tabletter	% NRV* / VNR* / NBW* / VSVA* / RI* / ADH*
Thiamin / Thiamine / Tiamina / Tiamiini / Tiamin / Tiamin	2.75 mg	250%
Riboflavin / Riboflavine / Riboflavina / Riboflaviini / Riboflavine	3.50 mg	250%
Vitamin B6 / Vitamine B6 / Vitamina B6 / B6-vitamiinia	3.50 mg	250%
Vitamin B12 / Vitamine B12 / Vitamina B12 / B12-vitamiinia	6.25 µg	250%
Calcium / Calcio / Kalsium / Kalcium	120mg	15%
Magnesium / Magnésium / Magnesio	56mg	15%
Chromium / Chrome / Cromo / Chrom / Kromi / Krom / Chroom	40 µg	100%
Zinc / Zinc / Sinkkiä / Sink	5.0mg	50%
Caffeine / Caféine / Cafeína / Koffein / Kofeiini / Cafeine / Caffeina	200mg	
EGCG / EGCG (Epigallocatechingallat) / Epigallokatekiinigallaatti / Epigallocatechingallat / Epigallokatekingallat (EGCG)	26mg	
Chlorogenic acids / Acides chlorogéniques / Ácidos clorogénicos / Chlorogensäure / Klorogeenihappoja / Chlorogensyre / Klorogensyre / Chlorogeenzuren / Klorogensyror	6mg	
*NRV = Nutrition reference values / *VNR = valeurs nutritionnelles de référence / *VNR = Valores nutricionales de referencia / *NBW = Nährstoffbezugswerte / *VSVA = vuorokautisen saanti / *RI = referenceindtag for en voksen gennemsnitsperson (8400 kJ/2000 kcal) / *RI = referanseinntak for en voksen gjennomsnittsperson (8400 kJ/2000 kcal) / *RI = referensintag för en genomsnittlig vuxen (8400 kJ/2000 kcal) / *ADH = aanbevolen dagelijkse hoeveelheid		

SUGGESTED USE

Take 1 tablet twice daily with a meal.

WARNING: Do not exceed the recommended daily dose. Keep out of reach of young children. Protect from heat, light and moisture. Store at room temperature. Do not use if seal is broken or missing. Food supplements are not a substitute for a varied and balanced diet and a healthy lifestyle. Not recommended for children, adolescents and pregnant or breast feeding women. Do not take on an empty stomach. Should be taken during a meal.

INGREDIENTS : Guarana seed extract 20% (Paullinia cupana), Magnesium citrate, Calcium carbonate, Acai berry extract (Euterpe oleracea), Green tea extract (Camellia sinensis L.), Bulking agent (microcrystalline cellulose), Dandelion root extract (Taraxacum ocinale), Anti-caking agents (magnesium stearate, silicon dioxide), Caffeine, Cinnamon bark extract (Cinnamomum verum), Green coffee bean extract 3% (Coffea arabica L.), Glazing agents (hydroxypropyl methyl cellulose, microcrystalline cellulose, stearic acid), Cayenne fruit extract 2% (Capsicum annuum L.), Zinc citrate, Black pepper extract (Piper nigrum L.), Pyridoxine hydrochloride, Thiamin hydrochloride, Riboavin, Cyanocobalamin, Colour (Sodium copper chlorophyllin), Chromium picolinate. **Contains caffeine.**

It Works! INTERNATIONAL

Food supplements are not substitutes for a varied and balanced diet and a healthy lifestyle. Contains caffeine.
**Vitamin B6 and B12 contribute to normal energy-yielding metabolism*
***Riboflavin contributes to the reduction of tiredness and fatigue*
****Zinc contributes to normal macronutrient metabolism and the normal metabolism of fatty acids*
*****Chromium contributes to the maintenance of normal blood glucose levels*

EU pis ThermoFightX eu en 002

PRODUCT INFO

THERMOFIGHT X^X

NEXT GEN FAT BURN 2.0

FREQUENTLY ASKED QUESTIONS

Why should I take ThermoFight X^X?

ThermoFight X^X is a simple and convenient way to burn more fat***—even without exercise! By taking just two tablets each day, you're providing your body with ingredients scientifically proven to help boost metabolism* and drive energy**. Plus, ThermoFight X^X helps to balance blood glucose so your blood sugar stays in check and sugar cravings are reduced!****

Why is ThermoFight X^X noted as a next-generation fat burner?

While powering up your fat metabolism, ThermoFight X^X also helps boost carb, macronutrient, energy-yielding, and even glucose metabolism****. This next generation product puts your body into a multi-level burn mode!

What are the active ingredients in ThermoFight X^X?

ThermoFight X^X contains many globally-recognised ingredients to support metabolism and more:

- **Chromium** – Boosts metabolism
- **Magnesium** – Supports metabolism, normal muscle functions, and electrolyte balance
- **Green Tea** – Renowned for its benefits in nutrition and lifestyle, particularly with fat loss
- **Vitamin B** – Even more B Vitamins that help to support the reduction of tiredness and fatigue**, and support metabolism*

Why is it good to boost metabolism?

Your "metabolism" is a collective term that refers to how the energy you burn helps maintain functions in the body. It's putting stored energy to good use. By optimising your metabolism, you support good health practices.

How many ThermoFight X^{X}tablets should I take each day?

It is recommended that you take one tablet in the morning and a second tablet in the afternoon each day, with food. Since ThermoFight X^X can also support energy levels, we do not recommend taking your second tablet within four hours of your bedtime.

Can I use ThermoFight X^X if I am pregnant, nursing, or have ongoing medical conditions?

Before using any new product, we suggest that you consult your physician to find out if it is right for you. ThermoFight X^X is not recommended for children, adolescents and pregnant or breast-feeding women.

Can I give ThermoFight X^X to my children?

ThermoFight X^X is recommended only for adults, ages 18 years and older.

Food supplements are not substitutes for a varied and balanced diet and a healthy lifestyle. Contains caffeine.
**Vitamin B6 and B12 contribute to normal energy-yielding metabolism*
***Riboflavin contributes to the reduction of tiredness and fatigue*
****Zinc contributes to normal macronutrient metabolism and the normal metabolism of fatty acids*
*****Chromium contributes to the maintenance of normal blood glucose levels*

EXHIBIT 2

WARNING LETTER

Golean Detox US

MARCS-CMS 573404 — APRIL 29, 2019

Delivery Method: VIA UPS

Product: Drugs

Recipient:

Anh Thu Nguyen

Owner

Golean Detox US

4832 Central Ave
Charlotte, NC 28205-5844
United States

Issuing Office:

Division of Pharmaceutical Quality Operations II

4040 North Central Expressway, Suite 300
Dallas, TX 75204-3128
United States

April 29, 2019

CMS # 573404

WARNING LETTER

GoLean Detox US

Attn: Anh Thu Nguyen, Owner

4832 Central Ave

Charlotte, North Carolina 28205-5844

GoLean Detox US

Attn: Anh Thu Nguyen, Owner

10711 Reid Alexander Lane

Mint Hill, North Carolina 28227

Ms. Nguyen,

This letter is to advise you that the U.S. Food and Drug Administration (FDA) has reviewed the information on your Facebook page, https://www.facebook.com/GoLean-detox-US-1592137147568285/, and determined that you offer products for sale in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). More specifically, FDA has determined that the "Golean Detox" product you offer for sale is an unapproved new drug sold in violation of sections 505(a) and 301(d) of the FD&C Act [21 U.S.C. §§ 355(a) and 331(d)]. Furthermore, this product is a misbranded drug sold in violation of sections 502 and 301(a) of the FD&C Act [21 U.S.C. §§ 352 and 331(a)].

FDA confirmed through laboratory analysis that your "Golean Detox" contains undeclared sibutramine and phenolphthalein. Sibutramine is the active pharmaceutical ingredient in Meridia, a new drug approved by FDA for marketing in 1997 for prescription treatment of obesity and, subsequently, withdrawn from the United States market on December 21, 2010 after clinical data indicated sibutramine poses an increased risk of heart attack and stroke. Phenolphthalein is a chemical that is not an active ingredient in any approved drug in the United States. Studies have indicated that it presents a cancer-causing risk.

FDA has issued a warning to consumers not to use "Golean Detox" (see GoLean Detox Immediate Public Notification).

Unapproved New Drugs

You market "Golean Detox" as a dietary supplement. However, under section 201(ff)(3)(B)(ii) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)(ii)], a dietary supplement may not include an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was marketed as a dietary supplement or food before it was authorized for investigation as a new drug.

The investigational new drug (IND) application for Meridia (sibutramine) was received by FDA on December 24, 1985, and sibutramine became authorized for investigation as a new drug under an IND on January 23, 1986. When Meridia was approved for marketing as a new drug in the United States, the existence of substantial completed clinical investigations of sibutramine became public. Based on the information available to FDA, sibutramine was not marketed as a dietary supplement or as a food until after it was authorized for investigation as a new drug. Therefore, "Golean Detox," which contains sibutramine, is excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(ii) of the FD&C Act.

Your "Golean Detox," is an article (other than food) intended to affect the structure or function of the body and, thus, is a drug as defined by section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)]. Labeling statements documenting the intended uses include, but are not limited to, the following:

Product Label:

· "Enhanced metabolic support excessive fat, help lose weight, reduce the risk of obesity"

· "...incinerate fat..."

· "...lose body fat..."

· "...clear excess waste and transport toxins through the digestive system"

· "...helps suppress hunger, increase blood flow and even improves your immune system. In addition to a reduced appetite Golean Detox will help control how much you eat."

· "...more focused than ever while relishing an enhanced mood."

· "Jumpstart your metabolism and lower bad cholesterol levels known as LDL."

In addition, your "Golean Detox," is a new drug under section 201(p) of the FD&C Act [21 U.S.C. § 321(p)] because this product is not generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in its labeling. Under sections 301(d) and 505(a) of the FD&C Act, a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. There are no approved applications on file with FDA for your "Golean Detox." The distribution or sale of "Golean Detox" in interstate commerce without such approved application violates these provisions of the FD&C Act.

Misbranded Drugs

Your "Golean Detox" product is misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] in that the labeling for this drug fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended [21 CFR § 201.5]. It is impossible to write "adequate directions for use" for "Golean Detox" for at least two reasons: 1) prior to withdrawal of Meridia's approval, FDA approval of sibutramine was limited to use under the professional supervision of a practitioner licensed by law to administer such drugs and 2) FDA approval of Meridia was withdrawn because of serious safety risks. As such, the labeling of "Golean Detox" fails to bear adequate directions for its intended uses. "Golean Detox" is not exempt from the requirement that its labeling bears adequate directions for use under 21 CFR §§ 201.100(c)(2) and 201.115 because no FDA-approved application is in effect for this product.

Additionally, under section 502(a) of the FD&C Act [21 U.S.C. § 352(a)], a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act [21 U.S.C. § 321(n)] provides that, in determining whether an article's labeling or advertising "is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations . . .." Your product, "Golean Detox" is misbranded under section 502(a) of the FD&C Act because the labeling fails to reveal its sibutramine and phenolphthalein content, which are material facts with respect to consequences that may result from the use of this product. As described above, sibutramine and phenolphthalein may pose health risks to consumers which are only compounded by the fact that neither ingredient is declared on the label.

"Golean Detox" is also misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)], because the product labeling lacks adequate warnings for the protection of users. As noted, there is potential for adverse

events associated with the use of this product, particularly since someone who takes it would be unaware of the presence of the undeclared ingredients.

Likewise, "Golean Detox" is misbranded under section 502(j) of the FD&C Act [21 U.S.C. § 352(j)], because it is dangerous to health when used in the dosage or manner recommended in the labeling. As previously noted, sibutramine poses an increased risk of heart attack and stroke.

The introduction or delivery for introduction into interstate commerce of this misbranded drug product is a prohibited act under section 301(a) of the FD&C Act [21 U.S.C. §331(a)].

Conclusion

FDA acknowledges that you initiated a **voluntary nationwide recall** of all lots of "Golean Detox" on February 25, 2019.

A full list of all tainted products discovered by FDA can be found at http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder ([!--$wcmUrl('nodelink','2126')--]).

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist 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. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

Correct the violations cited in this letter promptly. Failure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction. Unresolved violations in this warning letter may also prevent other Federal agencies from awarding contracts.

Until these violations are corrected, we may withhold approval of pending drug applications listing your facility. We may re-inspect to verify that you have completed your corrective actions. We may also refuse your requests for export certificates.

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Your written notification should refer to the Warning Letter Number above (CMS # 573404). Please electronically submit your signed reply on your firm's letterhead to CDR John W. Diehl, M.S., Director, Compliance Branch, at john.diehl@fda.hhs.gov and orapharm2_responses@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact CDR Diehl, at 214-253-5288.

Sincerely,

/S/

Monica R. Maxwell

Program Division Director

Office of Pharmaceutical Quality Operations,

Division 2

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

Wave Miami LLC

MARCS-CMS 590422 — JANUARY 13, 2020

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Andres Rivera

Wave Miami LLC

1434 E. Hunting Park Avenue
Philadelphia, PA 19124
United States

Issuing Office:

Division of Pharmaceutical Quality Operations I

United States

WARNING LETTER
CMS #590422

January 13, 2020

Mr. Rivera,

This letter is to advise you that the U.S. Food and Drug Administration (FDA) has reviewed the information on your website, https://www.liprodietpill.com, and Facebook pages, https://www.facebook.com/Lipro-Diet-Pills-191157693096 and https://www.facebook.com/LiproDietPills, and determined that you market and offer a product for sale in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act). More specifically, FDA has determined that the "Lipro Dietary Capsule" product you offer for sale is an unapproved new drug sold in violation of sections 505(a) and 301(d) of the FD&C Act [21 U.S.C. §§ 355(a) and 331(d)]. Furthermore, this product is a misbranded drug sold in violation of sections 502 and 301(a) of the FD&C Act [21 U.S.C. §§ 352 and 331(a)].

FDA confirmed through laboratory analysis that your "Lipro Dietary Capsule" contains undeclared tadalafil,

which is a phosphodiesterase type-5 (PDE-5) inhibitor. Tadalafil is the active pharmaceutical ingredient in Cialis, used to treat erectile dysfunction (ED). This undeclared ingredient may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

FDA has issued a **warning to consumers** not to use "Lipro Dietary Capsule" (see Lipro Dietary Capsule Immediate Public Notification).

Although you engaged in communication with the Agency regarding a recall of "Lipro Dietary Capsule" on **(b)(4)**, to date your firm has not voluntarily recalled the product. We continue to recommend that the product be recalled from the market.

You market "Lipro Dietary Capsule" as a dietary supplement. However, under section 201(ff)(3)(B)(i) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)(i)], a dietary supplement may not include an article that is approved as a new drug under section 505 of the FD&C Act unless that article was marketed as a dietary supplement or food before its approval as a drug. FDA approved Cialis (containing tadalafil as the active ingredient) as a new drug on November 21, 2003. Given that tadalafil was not marketed as a dietary supplement or as a food before Cialis was approved, "Lipro Dietary Capsule," which contains tadalafil, is excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(i) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)(i)].

Unapproved New Drug

"Lipro Dietary Capsule" is a drug as defined by section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)] because it is intended to prevent, treat, or cure disease conditions and/or affect the structure or function of the body. Statements documenting the intended uses of your product include, but are not limited to, the following:

On the product webpage, https://www.liprodietpill.com:

- "Natural weight loss without starving."
- "Curbs appetite."
- "No crazy drugs, exercise or diet regimes"
- "Lipro diet pills come with a high promise of effective weight lose [sic]. They promise that the user will lose up to 30 pounds in a span of 30 days."

On the webpage, https://www.facebook.com/LiproDietPills:

- "Best Diet Pill for rapid weight loss"
- "Lose 15-30 pounds in one month"
- "Natural weight loss without starving"
- "Curbs appetite."
- "No crazy drugs, exercise or diet regimes"

In addition, your "Lipro Dietary Capsule," is a new drug under section 201(p) of the FD&C Act 21 U.S.C. 321(p), because this product is not generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in its labeling. Under sections 301(d) and 505(a) of the FD&C Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. There are no approved applications on file with FDA for

your "Lipro Dietary Capsule." Your marketing and distribution or sale of "Lipro Dietary Capsule" in interstate commerce without an approved application violates these provisions of the FD&C Act.

Misbranded Drug

Your "Lipro Dietary Capsule" product is also misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)] in that the labeling for this drug fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. [See 21 CFR § 201.5]. All PDE-5 inhibitors which have been approved for marketing by FDA are limited by an approved new drug application to use under the supervision of a practitioner licensed by law to administer such drugs. "Lipro Dietary Capsule" is a prescription drug as defined in section 503(b)(1)(A) of the FD&C Act [21 U.S.C. § 353(b)(1)(A)] because, in light of its toxicity or potentiality for harmful effect, the method of its use, or the collateral measures necessary for its use, it is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs; therefore adequate directions for use cannot be written so that a layperson can use your product safely. Under 21 CFR §§ 201.100(c)(2) and 201.115, FDA-approved prescription drugs that bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson. However, your "Lipro Dietary Capsule" is not exempt from the requirement that its labeling bear adequate directions for use because no FDA-approved application is in effect for this product.

Additionally, under section 502(a) of the FD&C Act [21 U.S.C. § 352(a)], a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act [21 U.S.C. § 321(n)] provides that, in determining whether an article's labeling or advertising "is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations . . .." The labeling for "Lipro Dietary Capsule" does not declare that it contains tadalafil. The failure to disclose the presence of tadalafil in the product's labeling renders "Lipro Dietary Capsule" misbranded under section 502(a) of the FD&C Act. As discussed earlier, the presence of an undeclared PDE-5 inhibitor contained in your product may pose serious health risks because consumers with underlying medical issues may take this product without knowing that it can cause serious harm or interact in dangerous ways with other drugs they may be taking. Those consumers who have been advised against taking PDE-5 inhibitors because of comorbidities or potential drug interactions may seek products like "Lipro Dietary Capsule" because it is marketed as a dietary supplement.

The undeclared tadalafil in "Lipro Dietary Capsule" also causes this product to be misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)], in that the product's labeling lacks adequate warnings for the protection of users. As previously noted, there is potential for adverse events associated with the use of PDE-5 inhibitors. Consumers who use "Lipro Dietary Capsule" would be unaware of the presence of the undeclared ingredient and unknowingly placed at risk for their associated adverse events.

The introduction or delivery for introduction into interstate commerce of this misbranded drug product is a prohibited act under section 301(a) of the FD&C Act [21 U.S.C. §331(a)].

Conclusion

A full list of all tainted products discovered by FDA can be found at http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder (http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder).

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist 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. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations, and to ensure that all products marketed or distributed by your firm comply with the FD&C Act and all its implementing regulations and all other requirements of federal law.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction.

You should notify this office in writing within fifteen (15) working days from your receipt of this letter of the current status of your corrective actions and the specific steps you have taken to correct the noted violations. In your response, please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Please send your electronic reply to orapharm1_responses@fda.hhs.gov. Your written notification should refer to the Warning Letter Number above (CMS #590422).

If you have any questions, contact Compliance Officer James Mason at james.mason@fda.hhs.gov or 570-262-0519.

Sincerely,
/S/

Diana Amador-Toro
Program Division Director/District Director
U.S. Food and Drug Administration
OPQO Division I/New Jersey District

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

The Health Management Group Inc.

MARCS-CMS 547614 — JUNE 06, 2018

Recipient:

Charles Sekeres

The Health Management Group Inc.

395 Springside Drive
Akron, OH 44333
United States

Issuing Office:

Cincinnati District Office

United States

U.S. FOOD & DRUG ADMINISTRATION

Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237
Telephone: (513) 679-2700
FAX: (513) 679-2772

June 6, 2018

Warning Letter 547614

VIA UPS

Charles Sekeres, Owner/CEO
Health Management Group Inc
395 Springside Drive
Akron, OH 44333

Dear Mr. Sekeres:

The Food and Drug Administration (FDA) conducted an inspection of your facility located at 1450 Firestone Parkway Suite H, Akron, OH 44301, from December 28, 2017, to January 26, 2018. During the inspection, our investigator identified a number of violations of the Current Good

Manufacturing Practice (CGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplement regulations, Title 21, Code of Federal Regulations, Part 111 (21 CFR 111). These violations cause your dietary supplements to be adulterated within the meaning of section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(g)(1)] in that they have been prepared, packed, or held under conditions that do not meet CGMP regulations for dietary supplements.

We also reviewed the labeling of your "AM/PM FAT BURNING & APPETITE SUPPRESSING WEIGHT CONTROL PATCHES," including your websites, www.24hourthermogenics.com, www.dietcenter.com, and www.pwlc.com, where you market and/or offer for sale the "AM/PM Weight Control Patches." Based on our review, we have determined that your "AM/PM Weight Control Patches" is an unapproved new drug in violation of sections 505(a) and 301(d) of the Act [21 U.S.C. §§ 331(d) and 355(a)].

In addition, we have reviewed the labeling for your Diet Center and the Advanced 24 Hour Thermogenics brand products, including product labels and your websites at www.dietcenter.com and www.24thermogenics.com. Based on our review, we have concluded that your products are misbranded under section 403 of the Act [21 U.S.C. § 343], and regulations implementing the dietary supplement labeling requirements of the Act, which are found in 21 CFR 101. You can find the Act and FDA regulations through links on FDA's website at www.fda.gov (http://www.fda.gov/).

Unapproved New Drug

Your product "AM/PM FAT BURNING & APPETITE SUPPRESSING WEIGHT CONTROL PATCHES" is a drug under section 201(g)(1)(C) of the Act [21 U.S.C. § 321(g)(1)(C)], because it is an article (other than food) intended to affect the structure or any function of the body. Claims on your product label, promotional labeling, and websites, www.24hourthermogenics.com, www.dietcenter.com, and www.pwlc.com, that document the intended use of your product include, but are not limited to, the following:

- "Fat Burning & Appetite Suppressing"
- "Burn the fat . . . Kill the hunger . . . Lose the weight . . ."
- "The AM Patch helps promote weight loss with ingredients that target fat burning, increased energy and enhanced metabolism . . ."
- "The PM Patch helps promote weight loss with ingredients that focus on evening appetite suppression . . ."

Moreover, the "AM/PM FAT BURNING & APPETITE SUPPRESSING WEIGHT CONTROL PATCHES" is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)], because it is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it.

Dietary Supplement CGMP Violations

The December 28, 2017, to January 26, 2018, inspection of your facility revealed the following significant violation of the CGMP requirements for dietary supplements: You failed to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing, as required by 21 CFR 111.103. Specifically, you have no written procedures for the responsibilities of the quality control operations.

We acknowledge receipt of your written response to the FDA 483 (Inspectional Observations), which we received on February 23, 2018. Your response states, "All our current bottles that are re-bottled for use in our online kits will now come prepackaged with expiration dates and specific lot numbers contained on the bottle labels," and "All our supplements will now be prepackaged by our manufacturer." This response does not address the requirements to establish and follow written procedures for the responsibilities of your quality control operations for approving for release, or rejecting, any packaged and labeled dietary supplements received at your firm for distribution. While we acknowledge that you now plan to contract out the manufacturing, packaging, and labeling of your dietary supplements, to the extent that another firm manufactures, packages, and/or labels your dietary supplements on your behalf that your firm releases for distribution under your firm's name, your firm has an obligation to know what and how manufacturing activities are performed so that your firm can make decisions related to whether the packaged and labeled dietary supplement products conform to established specifications and whether to approve and release the products for distribution [see 72 Fed. Reg. 34752, 34790 (June 25, 2007)]. Although a firm may contract out certain dietary supplement manufacturing, packaging, and/or labeling operations, it cannot contract out its ultimate responsibility to ensure that the dietary supplement it places into commerce (or causes to be placed into commerce) is not adulterated for failure to comply with dietary supplement CGMP

requirements (see United States v. Dotterweich, 320 U.S. 277, 284 (1943) (explaining that an offense can be committed under the Act by anyone who has "a responsible share in the furtherance of the transaction which the statute outlaws"); United States v. Park, 421 U.S. 658, 672 (1975) (holding that criminal liability under the Act does not turn on awareness of wrongdoing, and that "agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act" can be held accountable for violations of the Act). In particular, the Act prohibits a person from introducing or delivering for introduction, or causing the delivery or introduction, into interstate commerce a dietary supplement that is adulterated under section 402(g) for failure to comply with dietary supplement CGMP requirements (see 21 U.S.C. § 342(g) and 331(a)). Thus, a firm that contracts out some or all of its operations must establish a system of production and process controls to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record (21 CFR 111.55). Your firm's quality control personnel must ensure that the manufacturing, packaging, labeling, and holding operations ensure the quality of your dietary supplements and that the dietary supplements are packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.105. Further, your firm must have documentation of the quality control personnel review and approval for release of any packaged and labeled dietary supplement (21 CFR 111.127(h) and 21 CFR 111.140(b)(2)).

Once you have established your quality control written procedures, you must implement quality control operations in your holding operations, as required by 21 CFR 111.65.

Misbranded Dietary Supplements

In addition, we performed a review of the labeling for your dietary supplement products and found that they are misbranded under section 403 of the Act (21 U.S.C. § 343) in that the labeling for these products does not comply with the labeling requirements for dietary supplements, as follows:

1. Your Diet Center Cal-Mag 90 tablets and 28 tablets, Diet Center Vitamin & Mineral, and Diet Center Anti-Oxidant products are misbranded within the meaning of section 403(s)(2)(B) of the Act [21 U.S.C. § 343(s)(2)(B)] in that the labeling for each product fails to include a statement of identity as a "dietary supplement" as required by 21 CFR 101.3(g).

2. Your Diet Center Cal-Mag 28 tablets, Diet Center Vitamin & Mineral, and Diet Center Anti- Oxidant" products are misbranded within the meaning of section 403(q)(5)(F) of the Act [21 U.S.C.§ 343(q)(5)(F)] because the presentation of nutrition information is not in accordance with 21 CFR 101.36. For example:

- Your Diet Center Cal-Mag 28 Tablets product label does not indicate the number of servings, as required by 21 CFR 101.36(b) .
- Your Diet Center Cal-Mag 28 tablets, Vitamin & Mineral, and Anti-Oxidant" product labels do not use the required term Daily Value (DV), as required by 21 CFR 101.36(b)(2)(iii)(A); the labels incorrectly list the term "U.S. RDA".
- Your Diet Center Cal-Mag 28 tablets, Vitamin & Mineral, and Anti-Oxidant" product labels fail to indicate "Supplement Facts" and present the nutrition information in the appropriate format, as required by 21 CFR 101.36(e).
- Your Diet Center Cal-Mag 28 tablets product label fails to indicate the source of the calcium, as required by 21 CFR 101.36(d).
- Your 24 Hour Thermogenics Powerful Liquid Enhancing Concentrate product label fails to list (b)(3)-dietary ingredients within the Supplement Facts label, as required by 21 CFR 101.36(b)(3). Furthermore, we note that some of the botanical (b)(3)-dietary ingredients do not include the specific plant part. In particular, if the entire or whole plant is used, that information should be included in the listing of the dietary ingredient.

Your Diet Center Cal-Mag 28 Tablets product is misbranded within the meaning of section 403(q)(1)(A) of the Act [21 U.S.C. § 343(q)(1)(A)] because the product label fails to include a serving size in accordance with 21 CFR 101.36(b). The terms "serving" or "serving size" for a dietary supplement are defined in 21 CFR 101.9(b) and 21 CFR 101.12(b) Table 2, as the maximum amount recommended on the label for consumption per eating occasion.

3. Your 24 Hour Thermogenics Powerful Liquid Enhancing Concentrate and 24 Hour Thermogencis EFA's Essential Fatty Acid Supplement products, and Diet Center Cal-Mag 90 Tablets and 28 Tablets, Diet Center Vitamin & Mineral, and Diet Center Anti-oxidant product label(s) are misbranded within the meaning of section 403(y) of the Act [21 U.S.C. § 343(y)] in that each product label fails to bear a domestic address or domestic phone number through which the responsible person (as described in section 761) may receive a report of a serious adverse event with such dietary supplements. Specifically, each product label does not include a complete domestic address or domestic phone number.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. It is your responsibility to ensure that your products comply with all requirements of the Act and federal regulations. You should take prompt measures to correct all violations described in this letter. Failure to take appropriate corrective actions may subject your firm and products to

further actions, such as injunction or seizure.

Additionally, we have the following comments:

- Your 24 Hour Thermogenics EFA's Essential Fatty Acid Supplement and Powerful Liquid Enhancing Concentrate, Diet Center Cal-Mag, Diet Center Vitamin & Mineral and Diet Center Antioxidant products are misbranded under section 403(e)(1) [21 U.S.C. § 343(e)(1)] of the Act in that the labels fail to declare the place of business, including the ZIP code, in accordance with 21 CFR 101.5. You should verify all your product labels to make sure they meets this requirement.

- Your 24 Hour Thermogenics Powerful Liquid Enhancing Concentrate and 24 Hour Thermogenics EFA's Essential Fatty Acid Supplement products, and Diet Center Antioxidant product label(s) are misbranded under section 403(r)(6) in that the labels fail to make a declarative statement for the lack of evaluation of the product by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease in accordance with 21 CFR 101.93(c)(1). We note the terms "thermogenic" and "anti-oxidant" are structure function claims.

- Your 24 Hour Thermogenics Powerful Liquid Enhancing Concentrate product label declares chromium polynicotinate as a dietary ingredient. Chromium is a (b)(2)-dietary ingredient (see 21 CFR 101.36(b)(2)). If the serving size contains 2% or more of the RDI for chromium, the chromium should be declared in the supplement facts label section intended for (b)(2)-dietary ingredients. The source of the chromium may be declared either following the declaration of chromium and/or in the ingredients list" in accordance with 21 CFR 101.36(d) and 21 CFR 101.4(g).

- Your 24 Hour Thermogenics Powerful Liquid Enhancing Concentrate contains the statement "Percent Daily Value based on a 2,000 Calorie Diet." This statement is required when the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein in accordance with 21 CFR 101.9(c) and 21 CFR 101.36(b)(2)(iii)(D).

- Your 24 Hour Thermogenics Powerful Liquid Enhancing Concentrate contains the term "Vitamin B3" within the supplement facts label. The correct name should be only "niacin" in accordance with 21 CFR 101.9(c)(8)(iv).

- You told the FDA investigator that you intended to market "AM/PM Weight Control Patches" as a dietary supplement. However, it does not meet the definition of a dietary supplement under section 201(ff)(2)(A)(i) of the Act [21 U.S.C. § 321(ff)(2)(A)(i)], which defines a dietary supplement, among other things, as a product intended for ingestion. Topical patch products and other products that are not intended for ingestion are not dietary supplements.

If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. You should notify this office in writing within fifteen (15) business days from your receipt of this letter of the specific steps you have taken to correct the noted deviations, including an explanation of each step taken to prevent their recurrence. In your response, include documentation of your corrective actions, as well as copies of related documents. If you cannot complete all corrective actions before you respond, we expect that you will explain the reason for your delay and state when you will correct the remaining deficiencies.

Section 743 of the Act (21 U.S.C. 379j-31) authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of the reinspection and assessing and collecting the reinspection fees (21 U.S.C. 379j-31(a)(2)(B)). For a domestic facility, FDA will assess and collect fees for reinspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any reinspection-related costs.

Send your response to Stephen J. Rabe, Compliance Officer at the Food & Drug Administration, Cincinnati District Office, 6751 Steger Drive, Cincinnati, OH 45237. If you have questions regarding any issue in this letter, please contact Mr.Rabe at 513-679-2700 extension 2163 or at: Stephen.rabe@fda.hhs.gov.

Sincerely,
/S/
Steven B. Barber

Director, Division V

Office of Human and Animal Foods Operations - East

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

WARNING LETTER

Lose Fat Gain Life M&B

MARCS-CMS 594850 — APRIL 16, 2020

Delivery Method:

Via Overnight Delivery

Product:

Dietary Supplements
Food & Beverages

Recipient:

Mr. Bryaent Villalobos

Lose Fat Gain Life M&B

4102 Orange Ave Ste 118 & 119
Long Beach, CA 90807
United States

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

WARNING LETTER

April 16, 2020

Re: 594850

Dear Mr. Villalobos:

The United States Food and Drug Administration (FDA) conducted an inspection of your facility located at 4102 Orange Ave, Ste 118 & 119, Long Beach, CA 90807 on September 24 and 30, 2019. Based on laboratory analysis of your product and a review of your product labeling, we have identified serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. You can find the Act and FDA regulations through links on the FDA's home page at www.fda.gov. (www.fda.gov.)

Adulterated Dietary Supplements: Unsafe Food Additive

Your Skinny Pill product is adulterated under section 402(a)(2)(C)(i) of the Act [21 U.S.C. § 342(a)(2)(C)(i)] because it contains 1,3-dimethylamylamine (DMAA), an unsafe food additive under section 409(a) of the Act

[21 U.S.C. § 348(a)]. If a substance added to food is not generally recognized as safe (GRAS) by qualified experts for its intended use in food and does not qualify for any of the other exemptions from the food additive definition, it is a food additive.[1] Food additives require premarket approval based on data demonstrating safety. Any food additive that has not been approved for its intended use in food is deemed to be unsafe and causes the food to be adulterated under section 402(a)(2)(C)(i) of the Act [21 U.S.C. § 342(a)(C)(i)].

The definition of "food additive" in section 201(s) of the Act [21 U.S.C § 321(s)] does not include dietary ingredients used in dietary supplements as defined in section 201(ff)(1) of the Act [21 U.S.C § 321(ff)(1)] or substances that are GRAS under the conditions of intended use. DMAA does not qualify as a dietary ingredient under section 201(ff)(1) of the Act [21 U.S.C. § 321(ff)(1)] because it is not a vitamin, mineral, amino acid, herb or other botanical, dietary substance for use by man to supplement the diet by increasing the total dietary intake, or concentrate, metabolite, constituent, extract, or combination of any of the preceding dietary ingredient types. Neither is DMAA GRAS under its conditions of use in your dietary supplement product. Because DMAA does not qualify as a dietary ingredient and is not GRAS or otherwise exempt from the food additive definition, your Skinny Pill product is adulterated under section 402(a)(2)(C)(i) of the Act because it contains an unsafe food additive. The introduction or delivery for introduction into interstate commerce of any food that is adulterated is a prohibited act under section 301(a) of the Act [21 U.S.C. § 331(a)].

The FDA recognizes that your firm voluntarily destroyed your inventory of Skinny Pill on September 24, 2019, and the product is no longer listed for sale on your website, www.losefatgainlifemb.com. FDA has also issued a warning to consumers not to use Skinny Pill (see Skinny Pill Immediate Public Notification).

Unapproved New Drug and Misbranded Drugs

FDA reviewed your website at www.losefatgainlifemb.com in March 2020 and has determined that you take order there for the products Reishi Coffee, Sugar Control, Blood Pressure Support, Fat Burner, Hear Clear Ear Health Formula, Hemp Oil, Liquid Gold, Omega 3, and Ovary Care. FDA also reviewed your Facebook page at www.facebook.com/LoseFatMB/ and your Instagram page at www.instagram.com/losefatgainlifembofficial in March 2020, which sites link to your website at www.losefatgainlifemb.com. The claims on your website, Facebook page, and Instagram page establish that your Reishi Coffee, Sugar Control, Blood Pressure Support, Fat Burner, Hear Clear Ear Health Formula, Hemp Oil, Liquid Gold, Omega 3, and Ovary Care are drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. 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 claims from your website at www.losefatgainlifemb.com that provide evidence that your products are intended for use as drugs include:

Reishi Coffee

- "Helps: ... Diabetes ... Cancer cells ... Urinary tract infections ... Tumors"

Sugar Control

- "Helps with: High blood sugar ... Excess glucose in blood ... Diabetic foot"

Blood Pressure Support

- "Helps: ... Control High Blood Pressure ... Varicose veins ... Hemorrhoids"

Fat Burner

- "... [B]alancing blood sugar levels."
- "It also helps with ... obesity, high blood pressure, chronic tiredness, and fatigue."

Hear Clear Ear Health Formula

- "Ayuda evitar infecciones y dolor" (English translation: "It helps prevent infections and pain"
- "Ayuda a reducir el daño causado por la exposición al ruido" (English translation: "It helps reduce the damage caused by exposure to noise")

Hemp Oil

- "Helps Fight Cancer"
- "Lower Risk of Diabetes"
- "OCD"
- "PTSD"
- "Neurological disorders Such as schizophrenia"

Liquid Gold

- "Asthma"
- "Bronchitis"

Omega 3

- "Helps with: Protecting against alzheimer's [sic] disease[,] Rheumatoid arthritis[,] Cardiovascular diseases[,] High cholesterol[,] Decreasing inflammation[,] Reducing risk of stroke and heart attack"

An example of a claim on your Facebook page that establish that your products are intended for use as drugs includes:

- On June 25, 2019, your company posted an image of your Hemp Oil product surrounded by the following language: "Benefits of Hemp Cannabidiol (CBD) ...ANTIPSYCHOTIC Combats Psychosis Disorders[,] ANTI-OXIDANT Combats Neurodegenerative Disorders[,] ANXIOLYTIC/ANTIDEPRESSANT Combats Anxiety and Depression Disorders ... ANTI-TUMOR/ANTI-CANCER Combats Tumor and Cancer Cells." You caption this photo post with "Hemp Oil" and provide a link to your website where you offer this product for sale.

Examples of some of the claims on your Instagram page that establish that your products are intended for use as drugs include:

- On September 28, 2019: "Ovary Care... Helps ... Prevent ovarian cancer, Cysts in the ovaries, Polycystic ovary syndrome ...Swelling in lower abdomen, Has anti-pasmodic action [sic]"
- Your Instagram page also contains evidence of intended use in the form of the following personal testimonial recommending or describing the use of your Sugar Control for the cure, mitigation, treatment, or prevention of disease. On July 4, 2019: "Le doy gracias a Dios Porke [sic] me ciento [sic] bien con mis productos después de tanto tiempo con esta condición de la diabetes de tenerla a 580 y

antes de tomar sugar control la tenia 480 y ahora la tengo 344" (English translation: "I thank God because I feel good with my products after being with diabetes for a long time having it was at 580 and before taking sugar control, I had 480 and now I have 344")

Your Reishi Coffee, Sugar Control, Blood Pressure Support, Fat Burner, Hear Clear Ear Health Formula, Hemp Oil, Liquid Gold, Omega 3, and Ovary Care products are not generally recognized as safe and effective for the above referenced uses and, therefore, these 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.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 C.F.R. § 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your products Reishi Coffee, Sugar Control, Blood Pressure Support, Fat Burner, Hemp Oil, Liquid Gold, Omega 3, and Ovary Care are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, Reishi Coffee, Sugar Control, Blood Pressure Support, Fat Burner, Hemp Oil, Liquid Gold, Omega 3, and Ovary Care fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist 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. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your written reply should be directed to Aaron Dotson, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Aaron Dotson at aaron.dotson@fda.hss.gov.

Sincerely,
/S/

William A. Correll
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

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1 Under section 201(s) of the Act [21 U.S.C. § 321(s)], the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food; (2) pesticide chemicals; (3) color additives; (4) substances used in accordance with a "prior sanction" (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the Act, the Poultry Products Inspection Act, or the Meat Inspection Act; (5) new animal drugs; and (6) dietary ingredients in or intended for use in a dietary supplement.

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

EXHIBIT 3

ReviewMeta

Copy & Paste an Amazon Product Page URL

https://www.amazon.com/Infinite-Growth-Hair-Regrowth-Treatment/dp/B00OI4ANG0

RUN REPORT

CATEGORIES PHONE APPS BROWSER EXTENSIONS FAQS HOW IT WORKS BLOG SELLER TOOLS

Thermofight XX Next Gen Fat Burn 2.0- Even More Fat Burning Properties

More product info

From It works!

View product on Amazon.com

amazon Rating:

3.8

289 *Ratings*

15 *Reviews*

("Ratings" vs. "Reviews")

0% of potentially unnatural reviews removed (why?)

View/Edit Adjustment

Jump to Report Card

Adjusted Rating:

2.6

15 Reviews

See Product Details

Our extension is available for your browser!

See our Adjusted Rating without having to leave Amazon.

ADD TO CHROME

Report Card

FAIL Overall Grade

WARN	Suspicious Reviewers
PASS	Rating Trend
PASS	Unverified Purchases
PASS	Word Count Comparison
PASS	Phrase Repetition
PASS	Overlapping Review History
PASS	Reviewer Participation
PASS	Reviewer Ease
PASS	Brand Repeats
PASS	Incentivized Reviews
PASS	Deleted Reviews

Report inaccurate data

Analysis Details

WARN

Suspicious Reviewers

Take-Back Reviewers

27% Have Previously Deleted Reviews

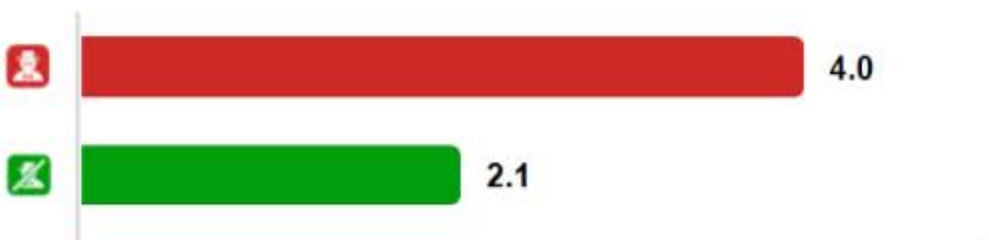
4 of the 15 reviewers have had at least one of their past reviews for another product deleted. While this is more Take-Back Reviewers than we'd expect to see, the discrepancy in ratings between the Take-Back Reviewers and reviewers who don't have any deleted reviews in their history isn't significant enough to rule out the possibility of it being due to random chance.

4.0 /5

From Take-Back Reviewers

2.1 /5

From Reviewers Without Previously Deleted Reviews



Read more about our Suspicious Reviewers test.

EXHIBIT 4

It Works!
908 Riverside Dr. · Palmetto, FL 34221

IT WORKS! LOYAL CUSTOMER AGREEMENT
TERMS & CONDITIONS
UNITED STATES

It Works Marketing, Inc. shall be referred to as "It Works!" or "the Company" thoughout this Agreement. Where a customer has elected to become an It Works! Loyal Customer, they agree to the following terms and conditions:

I. GENERAL TERMS

1. The It Works! Loyal Customer Agreement allows a customer to enjoy Loyal Customer pricing on all orders.
2. There are two ways to become a Loyal Customer. (1) You can make a three (3) consecutive month minimum commitment to a monthly autoshipment order; or (2) You can enroll by making a $50 Membership Fee payment and placing a single order for product.
3. A Loyal Customer must be at least 18 years of age as our products are intended for use by adults only.
4. The autoshipment order or initial order under the $50 Membership Fee option must consist of any It Works! products that contain Bonus Volume (BV). Autoshipment orders may be changed online by using the Customer ID and password or by calling Customer Support (see below) at least two (2) business days prior to the Loyal Customer's next autoshipment.
5. The Loyal Customer may order products in addition to their autoshipment order at any time and receive Loyal Customer pricing.
6. The Loyal Customer may cancel the autoship program at any time after the three (3) month commitment has been fulfilled. The Loyal Customer is still considered a member of the It Works! Loyal Customer Agreement and will receive Loyal Customer pricing on future orders, subject to paragraph 9, below. The autoshipment will continue to run every month until the Loyal Customer contacts It Works! to change or end their autoshipment. To end participation in the It Works! Loyal Customer Agreement after the three (3) month commitment has been fulfilled, Loyal Customer can cancel online by logging into their account at www.itworks.com or they can contact Customer Support at the numbers listed below.
7. Loyal Customers who cancel their autoshipment prior to completing the three (3) month minimum commitment will be charged a $50 Membership Fee. Payment of this $50 Membership Fee does complete the Loyal Customer Agreement.
8. If a Loyal Customer wishes to upgrade to a Distributor and has completed the Loyal Customer Agreement or the Loyal Customer has paid the $50 Membership fee, then the Loyal Customer is free to enroll as a Distributor under whomever they choose. If a Loyal Customer wishes to upgrade to a Distributor and has NOT completed the Loyal Customer Agreement and they want the Membership Fee to be waived, the Loyal Customer must enroll under their enrolling Distributor.
9. The accounts of Loyal Customers who do not place an order for two (2) years (twenty-four (24) consecutive months) will be cancelled and purged from the It Works! system. Orders placed after the Loyal Customer has been removed from the system following two years of inactivity will require entering into a new It Works! Loyal Customer Agreement pursuant to paragraph 2, above.
10. It Works!, including but not limited to any of its affiliates and/or subsidiaries, may transfer or assign this Agreement in its sole discretion. In the case that the Loyal Customer does not accept the transfer or assignment, they may provide written notice that they wish to terminate this Agreement. In the event of such notice being provided, the termination will become effective immediately.

II. IT WORKS! PRODUCT REFUNDS AND RETURNS POLICY

1. As It Works! products produce different results for different people, It Works! does not guarantee specific results nor offer a money back guarantee. Loyal Customers should follow the directions with each product received.

It Works!
908 Riverside Dr. · Palmetto, FL 34221

2. The Loyal Customer can utilize the Self Service Returns process located in the Loyal Customer portal to generate a shipping label.
3. The Loyal Customer is responsible for all return shipping costs.
4. To receive a refund, all products must be post-marked within thirty (30) days of the ship date and all items must be in an unopened, "new" condition. When making a return, the Loyal Customer must use a traceable shipping method. It Works! is not liable for the shipping costs of returned products or any return shipments that may be lost in the return shipping process.
5. To receive a replacement product or a refund on incomplete or defective product, the Loyal Customer must report the matter within sixty (60) days from the date of delivery and the incomplete or defective product must be made available for inspection at the Returns Processing Center.
6. Refused orders are defined as orders that are refused upon delivery, marked return to sender, are undeliverable, or that have an insufficient address. A refused order is assigned a $15 refusal fee that is deducted from the refund. Refusal fees are applied to orders to offset return shipping costs and return processing charges. Refused orders could take up to ninety (90) days to reach the Returns Processing Center and are not guaranteed a refund.
7. Loyal Customers that select the autoshipment membership option at enrollment must complete the Loyal Customer Agreement. If an order is returned at any time causing the total completed orders on the account to be less than three, It Works! will deduct a $50 Membership Fee from the refund on the returned order. If the full amount of the Membership Fee cannot be deducted from the return, the Loyal Customer account will be canceled. Loyal Customers that select the $50 Membership Fee option at enrollment will never incur a Membership Fee for returning an order.
8. Returning an order to It Works! will not automatically cancel the Loyal Customer's monthly autoshipment. To cancel an autoshipment the Loyal Customer can call the Customer Support number listed below or submit a support ticket in the Loyal Customer portal. All autoshipment cancellation requests must be completed at least two (2) business days prior to the autoshipment process date.
9. If only a portion of a stocked package (several products grouped under one item name/number) is returned, the full value of the item(s) kept will be deducted from the refund on the return order.
10. Once a returned order is received and inspected at the Returns Processing Center (usually within 10 business days), a refund will be processed to the credit card used to purchase the order. Depending on the credit card company, it may take an additional 2-10 business days after a refund is applied for monies to post to the Loyal Customer's account.
11. All returns must be accompanied with the original, or a copy of the original, packing slip.
12. To exchange products, Loyal Customers can submit a support ticket in their Loyal Customer portal within thirty (30) days of delivery to specify which product they would like to return and which products they would like to purchase in exchange. Exchange orders should be placed prior to Loyal Customer's returning their original items for refund to avoid interruption of their autoshipment services.

PRODUCTS MUST BE RETURNED TO:

IT WORKS MARKETING, INC.
4005 Newpoint Place
Suite 200
Lawrenceville, GA 30043

Customer Support:
https://itworks.com/contactus

EXHIBIT 5

Not BBB Accredited

Business Profile

IT Works! Global

Home Based Business Marketing

Headquarters Multi Location Business Find locations

CURRENT ALERTS FOR THIS BUSINESS

Pattern of Complaints:
BBB has received a pattern of complaints from consumers alleging that after trying to cancel with the business, they continue to receive additional products. Consumers also state that they have found additional charges being taken that the business has not informed them would be occurring. Complaints also allege ...
Read More

Custom Rating Text:
On April 24, 2020 FTC sent It Works Marketing, Inc. ("It Works!") a Warning letter Regarding Earnings Claims Related to Coronavirus Disease 2019 (COVID-19). Per the FTC on the business social media website at https://www.facebook.com/TheOfficialItWorks/, and by It Works! business opportunity participants or ...
Read More

ADDITIONAL BUSINESS INFORMATION

See all additional business information

Additional Information: Loyal Customer Agreement

The Loyal Customer Agreement states that in order the get wholesale (discounted) pricing for life a Loyal Customer agrees to "fulfill the three-month minimum purchase agreement." By completing your enrollment, you agree to the following: 1) Your credit card will be billed for the initial order and any subsequent orders. 2) B.. Read More

Contact Information

908 Riverside Dr
Palmetto, FL 34221-5035

Get Directions

http://www.itworks.com

(941) 348-6650

6:30 AM - 8:00 PM

Customer Reviews

1.72/5

Average of 520 Customer Reviews

Read Reviews Start a Review

Customer Complaints

687 complaints closed in last 3 years
190 complaints closed in last 12 months

Read Complaints File a Complaint

BBB Rating & Accreditation

C+

THIS BUSINESS IS NOT BBB ACCREDITED

Years in Business: 20

Customer Reviews are not used in the calculation of BBB Rating

Reasons for BBB Rating

Business Details

This is a multi-location business. Need to find a different location?

Headquarters
908 Riverside Dr, Palmetto, FL 34221-5035

BBB File Opened: 4/25/2011
Years in Business: 20
Business Started: 4/12/2001
Business Incorporated: 2/1/2011 in MI, USA
Type of Entity: Corporation

Alternate Business Name
IT Works Marketing, Inc.

Hours of Operation
Primary
M: 6:30 AM - 8:00 PM
T: 6:30 AM - 8:00 PM
W: 6:30 AM - 8:00 PM
Th: **6:30 AM - 8:00 PM**
F: 6:30 AM - 8:00 PM
Sa: 8:30 AM - 5:00 PM
Su: 8:30 AM - 5:00 PM

Contact Information

Principal
Ms. Beth McDonald, Compliance Specialist

Other Contacts
Mr. Tim Seat, General Counsel
Mr. Mark B. Pentecost, President/CEO
Mr. Douglas Nooney, Chief Compliance Officer
Ms. Cindy Pentecost, Secretary/Treasurer
Mr. Jerry Ogle, CFO

Read More Business Details and See Alerts

Customer Complaints

687 Customer Complaints

Need to file a complaint? BBB is here to help. We'll guide you through the process. How BBB Processes Complaints and Reviews

File a Complaint

Most Recent Customer Complaint
Complaint Type: Billing/Collection Issues **Status:** Resolved

08/23/2021

I purchased a weight loss supplement from ItWorks. There's a three month supply requirement, or else no one has to pay a $50 subscription service, so I paid $70.43 for one month on 12 Aug (incl. shipping & handling). I've used the product for 6 days. Each day I've been on it, I've been extremely tired & hungry, which has caused me to GAIN 6.4 lbs in six days. If I stay on this for 90 days, I'll be HEAVIER! I told the "friend" this evening that I want to cancel the autoship, & she said that I have to pay $50 to cancel the autoship or order some other product from the company. I've already tried the coffees they sell, and they're repugnant, so I definitely don't want those. Nothing else they have interests me. I'm not trying to get a refund for the $70.43. I tried the product & had the intention of following through on all three months, but it doesn't work for me, & I do not want any more of it. I'm giving lots of notice. Please allow me to cancel without penalty... Read More

Desired Outcome
Allow me to cancel without any further charges.

Read 686 More Complaints

Customer Reviews

520 Customer Reviews

What do you think? Share your review. How BBB Processes Complaints and Reviews

Start a Review

Most Recent Customer Review
Jessica W
(1 star)

08/31/2021

I couldn't cancel my auto ship because it said I would be charged 50$. So I got charged the 40$ for the package and it's going to an address that I no longer live at and have no access to the mail there. They won't do anything to help me and are saying I'm out the money unless the item is returned. How am I supposed to return an item I will never receive

IT Works! Global Response 09/01/2021

Hello *******, We are sorry to hear about this matter. Our records show you contacted customer service on August 31, 2021, and they cancelled the autoship. Please be advised there is no membership fee as you completed the loyal customer agreement. Regarding your last order, please fill out the Lost Order Claim Form for customer service to review at https://lostorderclaim.myitworks.com/ . Sincerely, It Works!

Read 519 More Customer Reviews

Business Categories

Home Based Business Marketing

Local BBB

BBB of West Florida

More Info on Local BBB

BBB Reports On

BBB reports on known marketplace practices.

See What BBB Reports On

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When considering complaint information, please take into account the company's size and volume of transactions, and understand that the nature of complaints and a firm's responses to them are often more important than the number of complaints.

BBB Business Profiles generally cover a three-year reporting period. BBB Business Profiles are subject to change at any time. If you choose to do business with this business, please let the business know that you contacted BBB for a BBB Business Profile.

As a matter of policy, BBB does not endorse any product, service or business.

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When considering complaint information, please take into account the company's size and volume of transactions, and understand that the nature of complaints and a firm's responses to them are often more important than the number of complaints.

BBB Business Profiles generally cover a three-year reporting period. BBB Business Profiles are subject to change at any time. If you choose to do business with this business, please let the business know that you contacted BBB for a BBB Business Profile.

As a matter of policy, BBB does not endorse any product, service or business.

BBB Start With Trust

For Consumers
Search for a Business
Get a Quote
Start a Review
File a Complaint
BBB Scam Tracker
File an Auto Warranty Complaint
BBB Ad Truth
Sign up for Scam Alerts
Frequently Asked Questions (FAQ)

For Businesses
Search Business Profiles
Get Accredited
BBB EU Privacy Shield
Get Your Business Listed

About BBB
BBB Directory
Give.org
BBB Institute for Marketplace Trust
International Association of Better Business Bureaus
Contact
BBB Business Partner Code
Mission & Vision
BBB National Programs

This website uses cookies to analyze traffic, assist with navigation, and improve your experience. You can learn more about our cookies in our Privacy Policy.

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: Class Action Alleges Thermofight Supplement Is Unsafe, Ineffective at Rapid Weight Loss, Fat Burning

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