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Counsel for Plaintiff and the Proposed Class

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

TANIA WARCHOL (f/k/a Tania Racha), on behalf of herself, all others similarly situated and the general public,

Plaintiff,

v.

LOVE HONEY, INC., a Delaware corporation; LOVEHONEY, LTD., a registered United Kingdom entity, form unknown; LOVEHONEY GROUP, LTD, a registered United Kingdom entity, form unknown; PHE, INC. d/b/a Adam and Eve Stores, a North Carolina corporation; and ERICA MITCHELL a/k/a E.L. JAMES,

Defendants.

Case No: **'15CV0238 DMS MDD**

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF:

- **CALIFORNIA UNFAIR COMPETITION LAW;**
- **CALIFORNIA FALSE ADVERTISING LAW;**
- **CALIFORNIA CONSUMERS LEGAL REMEDIES ACT;**

DEMAND FOR JURY TRIAL

Plaintiff Tania Warchol, on behalf of herself, all others similarly situated, and the general public, by and through her undersigned counsel, hereby sues Defendants LOVE HONEY, INC., a Delaware corporation; LOVEHONEY, LTD., a registered United Kingdom entity, form unknown; LOVEHONEY GROUP, LTD, a registered United Kingdom entity, form unknown; PHE, INC. d/b/a Adam and Eve Stores, a North Carolina corporation; and ERICA MITCHELL a/k/a E.L. JAMES ("Defendants"), and alleges the following upon her own knowledge, or where she lacks personal knowledge, upon information and belief and the investigation of her counsel.

INTRODUCTION

1. Defendants falsely market an over-the-counter product called "Fifty Shades of Grey Come Alive Pleasure Gel for Her" (the "Product") as having beneficial and aphrodisiac properties to increase pleasure and enhance orgasms, despite that none of the ingredients in the Product, individually or in combination, provide such benefits.

2. Further, Defendants advertise the Product as being a "Pleasure Gel" that is "Latex Compatible." Pursuant to 21 C.F.R. § 880.6375, Patient Lubricants, such as the Fifty Shades of Grey Come Alive Pleasure Gel, are defined as a Class I Medical Devices intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. Significantly, Patient lubricants are not exempt from Food and Drug Administration ("FDA") 510(K) pre-market clearance. When used as an accessory to a condom (a Class II medical device), the lubricant is considered, by the FDA as a Class II Medical Device requiring 510(k) clearance.

3. A search of the FDA's 510(k) public database reveals that the Fifty Shades of Grey Come Alive Pleasure Gel is neither registered as a Class I Medical Device nor a Class II Medical Device. Accordingly, the Product is being illegally marketed and sold as "latex compatible" lubricant despite the fact that YOU have not sought FDA pre-market clearance. See Cal. Health & Safety Code § 111550(a)(3).

4. Plaintiff read, believed, and relied upon Defendants' claims when purchasing the Product during the Class Period defined herein, and was damaged as a result.

5. Plaintiff brings this action challenging Defendants' claims relating to the Product on behalf of herself and all others similarly situated under California's Unfair Competition Law, False Advertising Law, and Consumer Legal Remedies Act.

6. Plaintiff seeks an order compelling Defendants to (1) cease marketing the Product using the misleading tactics complained of herein, (2) conduct a corrective advertising campaign, (3) restore the amounts by which Defendant has been unjustly enriched, and to (4) destroy all misleading and deceptive materials.

JURISDICTION & VENUE

7. The Court has original jurisdiction pursuant to 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 reside in states other than the state in which Defendants reside.

8. Defendants manufacture, market and sell the Product from Delaware, North Carolina, and Bath, England, United Kingdom to consumers in every state in the United States, both in brick-and-morter stores and via online means. Personal jurisdiction is derived from the fact that Defendants conducts business within the State of California and within this judicial district.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, including within the County of San Diego and within this judicial district. Moreover, Defendants are authorized to conduct business in this District, have intentionally availed itself of the laws and markets of this District and state through the promotion, marketing, distribution, and sale of the Product in this District and state; and is subject to personal jurisdiction in this District.

PARTIES

10. Plaintiff Tania Warchol is a resident of the City of San Diego, California.

11. Defendant Lovehoney, Inc. is Delaware corporation with its principal place of business located at 1209 Orange Street, Wilmington, Delaware.

12. Defendant Lovehoney, Ltd. is a registered British company, form unknown, who does business at 100 Locksbrook Road, Bath, England, United Kingdom.

13. Defendant PHE, Inc. d/b/a Adam and Eve Stores is a North Carolina company with its principal place of business at 302 Meadowland Drive, Hillsborough, N.C.

14. Defendant Erika Mitchel a/k/a E.L. James is a British individual, who resides in London, England, United Kingdom.

15. Members of the class reside in California and each of the other 49 states of the United States, with two-thirds or more than two-thirds of the class residing outside the State of California.

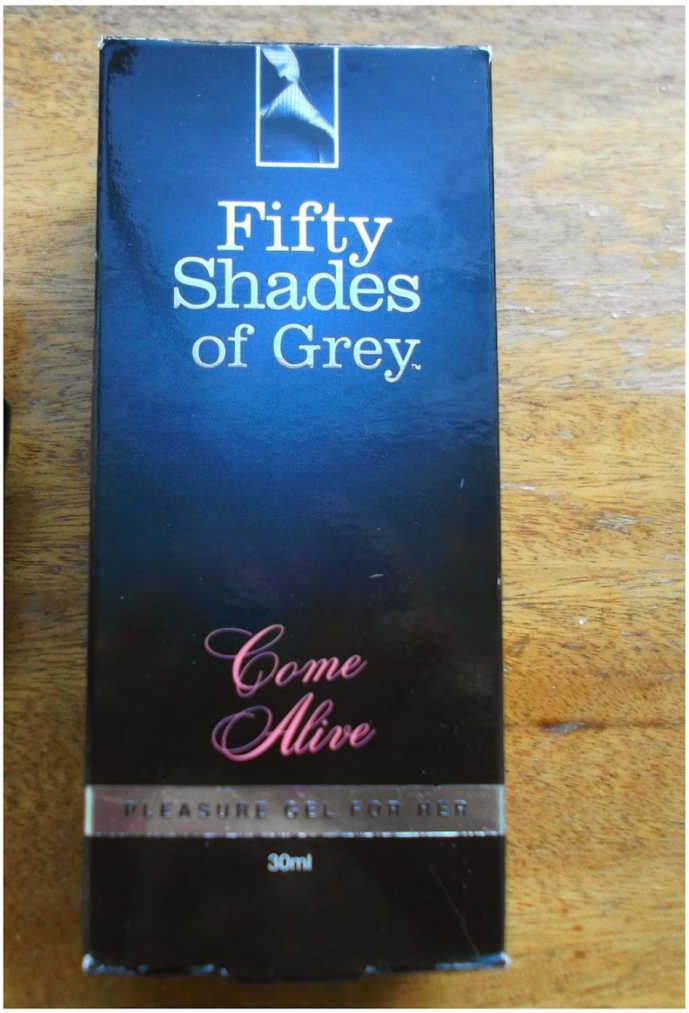
FACTUAL ALLEGATIONS

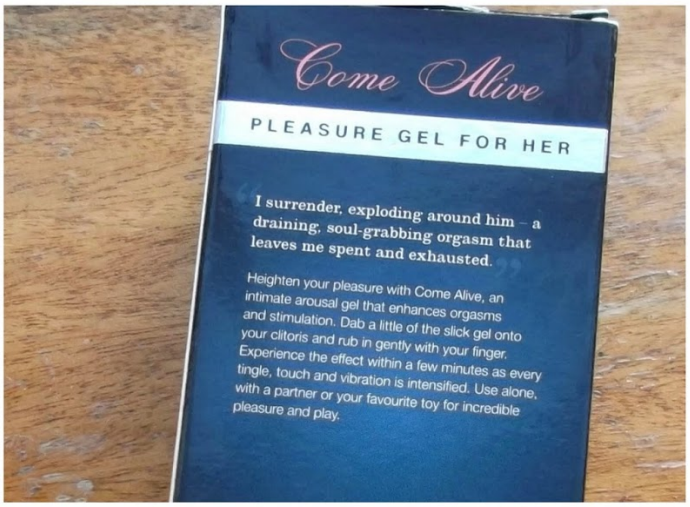
16. Defendants have distributed, marketed, and sold The Product on a nationwide basis, both online and at retail store locations. The Product retails for approximately $15.00.

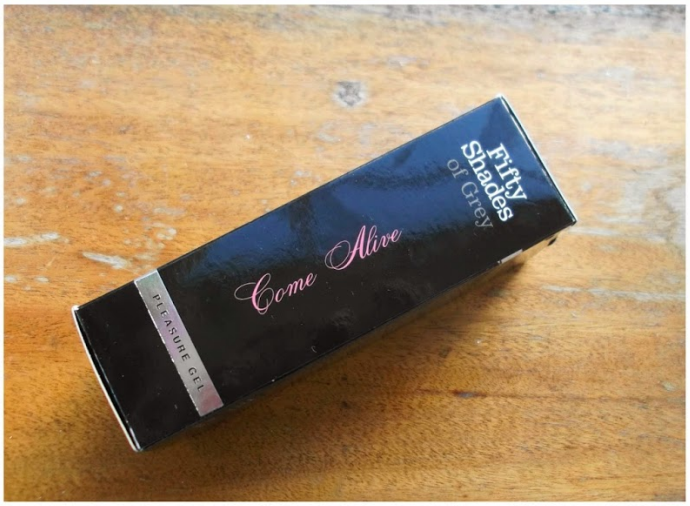
17. Defendants' Product is part of a larger group of products advertised and sold under the "Fifty Shades of Grey ™ The Official Pleasure Collection Approved by E.L. James."

18. The purpose of the Product's aforementioned marketing is to profit from the media hype surrounding Defendant E.L. James best-selling book, Fifty Shades of Grey, which according to its publisher "has become the best-selling book in Britain since records began." *See* www.telegraph.co.uk/culture/books/booknews/9459779/50-Shades-of-Grey-is-best-selling-book-of-all-time.html.

19. Defendants prominently label the Product as an "Intimate Arousal Gel," expressly and impliedly conveying to consumers that the Product's ingredients will help a user to experience heightened stimulation, pleasure, and orgasm, despite that the Product fails to be effective as an aphrodisiac.







20. Defendant further falsely advertises and markets Fifty Shades of Grey Come Alive Pleasure Gel for Her by putting false and misleading claims on the label, stating or suggesting that the Product is a "Pleasure Gel for Her" that "increase[s] sensual comfort and pleasure."

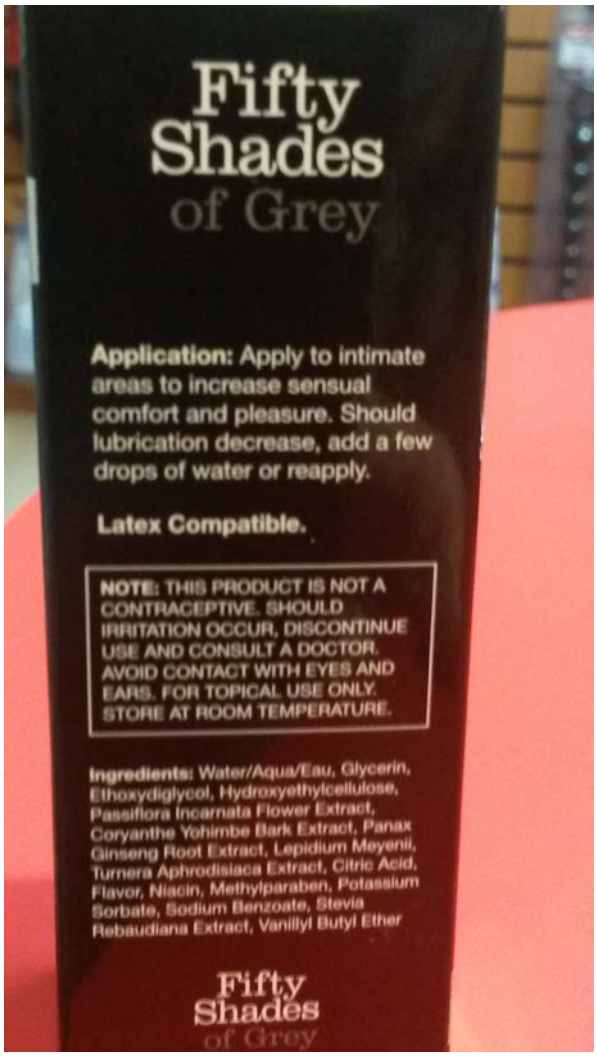
21. Defendants also use purported consumer endorsements or excerpts from E.L. James best-selling book, such as: "I surrender, exploding around him — a draining, soul-grabbing orgasm that leaves me spent and exhausted" to further induce consumers to buy the Product under false pretenses as described herein.

22. Defendants further claim that use of the Product will: "Heighten your pleasure with Come Alive, an intimate arousal gel that enhances orgasms and stimulation," "Experience enhanced orgasms and stimulation as every tingle, touch and vibration

intensifies," "Dab a little of the slick gel onto your clitoris and rub in gently with your finger," "Experience the effect within a few minutes as every tingle, touch and vibration is intensified," "Use alone, with a partner or your favourite toy for incredible pleasure and play."

23. Defendants also use the endorsement of a best-selling book author, through advertising to consumers that the Product is part of "[t]he official sensual care collection," "Approved by E.L. James."

24. The Product is further advertised as being "Latex Compatible."



25. However, under 21 C.F.R. § 880.6375, Patient lubricants, such as the Fifty Shades of Grey Come Alive Pleasure Gel for Her, are defined as a Class I Medical Devices intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. Significantly, Patient lubricants are not exempt from FDA

510(K) pre-market clearance. When used as an accessory to a condom (a Class II medical device), the lubricant is considered, by the FDA as a Class II Medical Device requiring 510(k) clearance.

26. A search of the FDA's 510(k) public database reveals that the Fifty Shades of Grey Come Alive Pleasure Gel is neither registered as a Class I Medical Device nor a Class II Medical Device.

27. Accordingly, the Product is being illegally marketed and sold as "Latex Compatible" lubricant despite the fact that Defendants have not sought FDA pre-market clearance. *See* Cal. Health & Safety Code § 111550(a)(3).

28. Other manufacturers have been warned that their topical stimulant lubricants for women were unlawful aphrodisiacs, and the Product is unlawful for the same reasons as indicated in those warning letters, which reflect FDA interpretation of their own implementing regulations. *See, e.g.*, Exhibit 1 attached hereto.

The Composition of The Product

29. The Product consists of a blend of small amounts of extracts from herbs, roots, and other organic substances, some of which are purported by Defendants to have an effect on the human body.

30. The exact ingredients in the Product, according to its label, are: Water, Glycerin, Ethoxydiglycol, Hydroxyethylcellulose, Passiflora Incarnata Flower Extract, Coryanthe Yohimbe Bark Extract, Panax Ginseng Root Extract, Lepidium Meyenii, Turnera Aphrodisiaca Extract, Citric Acid, Flavor, Niacin, Methylparaben, Potassium Sorbate, Sodium Benzoate, Stevia Rebaudiana Extract, Vanillyl Butyl Ether.

31. None of the ingredients in The Product, individually or in combination, however, are effective as an aphrodisiac, despite being advertised as such by Defendants.

32. Moreover, the California Sherman Law, which is identical to the federal Food, Drug and Cosmetic Act, prohibits the marketing and sale of aphrodisiac products, which the

Product is. *See* 21 C.F.R. § 310.528; Cal. Health & Safety Code §§ 110110-110111, 110115; 21 U.S.C. § 343-1.

33. In addition, application of heterogeneous herbs and herbal extracts to the genital areas, such the various botanicals and chemicals which are contained in the Product, presents a risk of an allergic or other adverse reaction without any offsetting benefit.

The Product is a Misbranded Drug

34. The labeling described above, including the listed ingredient of "Turnera Aphrodisiaca Extract," alone and in context with other labeling claims and packaging graphics, evidence the Product's intended use as an aphrodisiac, to arouse or increase sexual desire or energy, or improve sexual performance.

35. Pursuant to Title 21 of the Code of Federal Regulations, Part 310.528 (21 CFR § 310.528) any OTC drug product that is labeled, represented, or promoted for use as an aphrodisiac, like the Product, is regarded as a "new drug" within the meaning of section 201(p) of the United States Food, Drug and Cosmetic Act ("FDCA") (located at 21 U.S.C. § 355(p)).

36. The FDCA requires any new drug to have an application approved by the FDA before the drug can be marketed to the public, and further that the drug's label be approved by the FDA prior to marketing or selling the drug to the public. *See*, *generally*, *id.*; 21 U.S.C. §§ 355(a), (b) [New Drug Application], (j) [Abbreviated New Drug Application, for generic drugs].

37. Defendants' Product violates Section 505(a) of the FDCA since the adequacy of the labeled directions for its "aphrodisiac" uses has not been approved by the FDA prior to the Products being marketed to the public (*see* 21 U.S.C. § 355(a)).[1] Accordingly, the Product is misbranded under section 502(f)(1) of the FDCA (located at 21 U.S.C. § 352).

[1] In addition to proving effectiveness, the manufacturer of a new drug must also prove the drug's safety, sufficient to meet FDA standards. 21 U.S.C. § 355(d).

38. Further, the Product includes the ingredients, Yohimbe and Ginseng. However, neither of these ingredients are safe and effective for OTC use as an aphrodisiac. 21 C.F.R. § 310.528. The FDA bars these false, misleading, and unsupported by scientific data label claims. *Id.* Thus, based on the evidence currently available, *any* product containing ingredients for use as an aphrodisiac, including the Product, cannot be generally recognized as safe and effective, and instead are misbranded new drugs. *See id.*

39. California Health and Safety Code, Division 104, Part 5, contains the Sherman, Food, Drug, and Cosmetic Law ("Sherman Law," located at Cal. Health & Safety Code §§ 109875-111915). The Sherman Law imposes identical requirements to the federal FDCA: "All nonprescription drug regulations and regulations for new drug applications under the FDCA are the regulations of this State." Cal. Health & Safety Code §§ 110110-110111, 110115. The Sherman Law also defines a "drug" as "any article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal." Cal. Health & Safety Code § 109925(c).

40. The Sherman Law is explicitly authorized by the FDCA. 21 U.S.C. § 343-1.

41. Plaintiff and members of the Class would not have purchased the Product if it were known to them that the Product is misbranded pursuant to FDA regulations.

RELIANCE AND INJURY

42. Plaintiff purchased the Product on at least two occasions in August of 2014 from Defendant PHE's Adam and Eve store near her home in Hillcrest, California for approximately $30 total, not including sales tax.

43. When purchasing the Product, Plaintiff and the class were seeking a product that had the qualities described on the Product's label, namely, an effective and legal pleasure gel to heighten their arousal and pleasure during sexual activities.

44. When deciding to purchase the Product, Plaintiff read and relied on the deceptive claims contained on the packaging of the Product, as described herein in quotations. These

statements were made by Defendant directly on the packaging of the Product at the time Plaintiff purchased the Product.

45. Based on Defendants' representations, Plaintiff believed the Product had powerful aphrodisiac qualities and would increase her sexual pleasure as advertised.

46. Plaintiff believed the Product had the qualities he sought based on these deceptive labeling claims, but the Product was actually unsatisfactory to Plaintiff for the reasons described herein, *i.e.*, the Product did not deliver the purported benefits, there is no evidence the ingredients in the Product could provide the claimed benefits, the Product is an unlawful aphrodisiac whose claims are banned in the United States absent a new drug application, and the ingredients may actually impose an unreasonable risk of danger.

47. The Product costs more than similar products without misleading labeling, and would have cost less absent the false and misleading statements.

48. Plaintiff paid more for the Product, and would only have been willing to pay less or unwilling to purchase the Product at all, absent the false and misleading labeling complained of herein. Plaintiff would not have purchased the Product absent these claims and advertisements.

49. For these reasons, the Product was worth less than what Plaintiff and the class paid for it.

50. Instead of receiving a product that had actual and substantiated healthful or other beneficial qualities, the Product Plaintiff and the class received was one which does not provide the claimed benefits.

51. Plaintiff and the class lost money as a result of Defendants' deceptive claims and practices in that they did not receive what they paid for when purchasing the Product.

52. Plaintiff and the class altered their position to their detriment and suffered damages in an amount equal to the amount they paid for the Product.

53. The senior officers and directors of Defendants allowed the Product to be sold with full knowledge or reckless disregard that the challenged claims are fraudulent, unlawful, and misleading.

CLASS ACTION ALLEGATIONS

54. Pursuant to Rule 23, plaintiff seeks to represent a Class, provisionally defined as all persons in the United States (excluding officers, directors, and employees of Defendants) who purchased the Product primarily for personal, family, or household use, and not for resale within the four years prior to the filing of the current Complaint.

55. The members in the proposed class are so numerous that individual joinder of all members is impracticable, and the disposition of the claims of all class members in a single action will provide substantial benefits to the parties and Court.

56. Questions of law and fact common to plaintiff and the class include:

A. whether Defendants contributed to, committed, and/or are responsible for the conduct alleged herein;

B. Whether Defendants' conduct constitutes the violations of law alleged herein;

C. Whether Defendants acted willfully, recklessly, negligently, or with gross negligence in the violations of law alleged herein; and

D. Whether Class members are entitled to compensatory, injunctive, and other equitable relief.

57. Plaintiff's claims are typical of class members' claims in that they are based on the same underlying facts, events, and circumstances relating to Defendants' conduct.

58. Absent Defendants' deceptive claims, Plaintiff and the Class members would not have purchased the Product.

59. Plaintiff will fairly and adequate represent and protect the interests of the class, has no interests incompatible with the interests of the class, and has retained counsel competent and experienced in class action litigation.

60. The class is sufficiently numerous, as it contains at least hundreds of thousands of members who purchased the Product across the United States.

61. Class treatment is superior to other options for resolution of the controversy because the relief sought for each class member is small such that, absent representative litigation, it would be infeasible for class members to redress the wrongs done to them.

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

63. Defendants have acted on ground applicable to the Class, thereby making appropriate final injunctive and declaratory relief concerning the Class as a whole.

64. As a result of the foregoing, class treatment is appropriate under Fed. R. Civ. P. 23(a), (b)(2), and (b)(3).

FIRST CAUSE OF ACTION

Violations of the Unfair Competition Law, Unlawful Prong

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

65. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as set forth in full herein.

66. California Business and Professional Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."

67. 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 False Advertising Law and Consumer Legal Remedies Act.

68. Defendants' conduct is further "unlawful" because it violates the FDCA and its implementing regulations in the following ways:

a. Defendants' deceptive statements violate 21 U.S.C. §§ 343(a) and 352, which deem a food or drug (including nutritional supplements) misbranded when the label contains a statement that is "false or misleading in any particular";

b. Defendants' deceptive statements are *per se* false and misleading because the FDA has ruled there is a lack of adequate data to establish general recognition of the safety and effectiveness of any of the ingredients in the Product, or any other ingredient, for use as an aphrodisiac; and labeling claims for aphrodisiacs are "either false, misleading, or unsupported by scientific data." 21 C.F.R. § 310.528(a);

c. Defendants' deceptive statements violate 21 C.F.R § 310.528(b), which mandates that any OTC product that is labeled, represented, or promoted for use as an aphrodisiac, like the Product, is regarded as a "new drug" within the meaning of 21 U.S.C. § 355(p), but Defendants do not have new drug approval for the Product or its labeling, as required under the FDCA and its implementing regulations. Accordingly, Defendants' Product is misbranded under section 502(f)(1) of the FDCA;

d. Defendants' Product also violates the FDCA because, as an unapproved new drug and aphrodisiac, the Product cannot be generally recognized as safe and effective in the absence of a new drug application as set forth in the FDCA and its implementing regulations. 21 C.F.R. § 310.528(a).

e. Defendants' Product violates the FDCA, 21 C.F.R. § 880.6375, by advertising itself as being Latex Compatible when it is not registered as a Class I Medical Device nor a Class II Medical Device and does not have FDA pre-market clearance. *See also* Cal. Health & Safety Code § 111550(a)(3).

69. Defendants' conduct is further "unlawful" because it violates the California Sherman Food, Drug, and Cosmetic Law, *see* Cal. Health & Safety Code § 109875-111900, which incorporates all relevant provisions of the FDCA. *See id.* §§ 110110-110115.

70. Defendants profited from their sales of the falsely, deceptively, or unlawfully advertised Product to unwary consumers.

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

SECOND CAUSE OF ACTION

Violations of the Unfair Competition Law, Unfair and Fraudulent Prongs

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

72. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as set forth in full herein.

73. California Business and Professional Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."

74. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein also constitute "unfair" business acts and practices under the UCL in that Defendants' conduct is immoral, unscrupulous, and offends public policy by seeking to profit from female vulnerability to false or deceptive aphrodisiac claims. Further, the gravity of Defendants' conduct outweighs any conceivable benefit of such conduct.

75. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendants as alleged herein constitute "fraudulent" business acts and practices under the UCL in that Defendants' claims are false, misleading, and have a tendency to deceive the Class and the general public, as detailed herein.

76. Defendants profited from its sales of the fraudulently, falsely and deceptively advertised Product to unwary consumers.

77. In accordance with 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.

78. Plaintiff further seeks an order for the disgorgement and restitution of all profit earned from the sale of the Defendants' Product, which were acquired through acts of unlawful, unfair, and/or fraudulent competition by Defendants.

THIRD CAUSE OF ACTION

Violations of the False Advertising Law,

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

79. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as set forth in full herein.

80. In violation of California Business and Professional 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 the Product.

81. Defendant knew and reasonably should have known that the labels on Defendants' Product were untrue and/or misleading.

82. Defendant profited from its sales of the falsely and deceptively advertised Product to unwary consumers.

83. 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.

FOURTH CAUSE OF ACTION

Violations of the Consumer Legal Remedies Act,

Cal. Civ. Code § 1750, *et seq.*

84. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as set forth in full herein.

85. 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.

86. Plaintiff sent Defendants a CLRA letter, notifying them of the false, deceptive and unlawful business acts and practices as complained of herein. *See* Exhibit 2.

87. Defendants' false and misleading labeling and other policies, acts, and practices were designed to, and did, induce the purchase and use of Defendants' Product for personal,

family, or household purposes by Plaintiff and class members, and violated and continue to violate the following sections of the CLRA:

a. § 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have;

b. § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another;

c. § 1770(a)(9): advertising goods with intent not to sell them as advertised; and

d. § 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

88. Defendants profited from their sales of the falsely, deceptively and unlawfully advertised Product to unwary consumers.

89. As a result, Plaintiff and the Class have suffered irreparable harm and, should Defendants not remedy their practices as described herein (*see* Exhibit 2 hereto), will amend their complaint to seek actual damages in the amount of the total retail sales price of all Products sold throughout the class period to all class members, plus punitive damages in an amount sufficient to deter and punish.

90. Plaintiff and the Class presently seek injunctive relief in the form of modified advertising and a corrective advertising plan.

91. Defendants' wrongful business practices regarding the Product constituted, and constitute, a continuing course of conduct in violation of the CLRA since Defendant is still representing that the Product has characteristics, uses, benefits, and abilities which are false and misleading, and have injured Plaintiff and the Class. Therefore, prospective injunctive relief is proper because Plaintiff and the Class continued to be exposed to Defendants' unlawful, deceptive, misleading and fraudulent advertising because the Product remains on store shelves throughout the United States.

92. Plaintiff and the class seek equitable relief for their CLRA claims, and attorney's fees and costs, as allowed by statute.

PRAYER FOR RELIEF

98. Wherefore, Plaintiff, on behalf of herself, all others similarly situated and the general public, prays for judgment against Defendant as to each and every cause of action, and the following remedies:

A. An Order declaring this action to be a proper class action and appointing the undersigned counsel as class counsel;

B. An Order requiring Defendants to bear the cost of class notice;

C. An Order compelling Defendants to conduct a corrective advertising campaign;

D. An Order compelling Defendants to destroy all misleading and deceptive advertising materials and Product labels, and to conduct a recall;

E. An Order requiring Defendants to relabel the Product so that it complies with the law;

F. An Order requiring Defendants to pay Plaintiff and the Class' attorney's fees and costs.

G. Any other and further relief that Court deems necessary, just, or proper.

JURY DEMAND

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

Dated: February 5, 2015

/s/ Ronald A. Marron

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Attorneys for Plaintiff and the Proposed Class

I, Tania Warchol, declare as follows:

1. I am the Plaintiff in this action. I make this affidavit pursuant to California Civil Code Section 1780(d).

2. The Complaint in this action is filed in a proper place for the trial of this action because Defendant is doing business in this county.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: February 5, 2015

Tania Warchol

TANIA WARCHOL

TABLE OF EXHIBITS

EXHIBIT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 14 2001

WARNING LETTER

Jose I. Iparraguirre, MD
President
JIIM, L.L.C.
7700 N. Kendall Drive, Suite 604
Miami, Florida 33156

Ref: 01-HFD-312-02

Dear Dr. Iparragirre:

This letter concerns "Doctor's Lotion" marketed by your firm. Based on this product's labeling, it is intended for topical over-the-counter (OTC) use by women as an aphrodisiac to enhance arousal and improve the sexual experience. Thus, "Doctor's Lotion" is a "drug" under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The intended uses described above are conveyed through labeling, which includes statements such as, "Doctor's Lotion is the first stimulus enhancing lotion created for women to improve the sexual experience by enhancing arousal. The active ingredients in Doctor's Lotion have shown [sic] to increase the blood flow to the clitoris and surrounding area by gently and safely dilating blood vessels. The increase in blood flow improves the sensation of the nerve endings in the clitoris to enhance arousal and promote orgasm." In addition, you use similar statements in your current Internet promotion for "Doctor's Lotion" along with statements like "...aid[ ] women's sexual satisfaction...," "...aid women experiencing the significant problem of sexual dissatisfaction...," "...improving the quality of intimacy, and enhance their overall sexual experience...," and "...heightens the sensation of a woman's sexual organs...".

The immediate container label for "Doctor's Lotion" identifies "Aminophylline," "Ergoloid Mesylate," "Arginine," and "Isosorbide Dinitrite" as "active ingredients". A flyer distributed with the product identifies "Deionized Water," "Glycerin," "Vitamin E Gel," "Aminophylline," and "L-Arginine" as "active ingredients," while current Internet promotion identifies "Glycerin," "Vitamin E," "Theophylline," and "Arginine" as "active ingredients".

Regardless of the formulation, under Title 21 of the Code of Federal Regulations, Part 310.528 (21 CFR 310.528) (copy enclosed) any OTC drug product that is labeled, represented, or promoted for use as an aphrodisiac, like "Doctor's Lotion," is regarded as a "new drug" within the meaning of Section 201(p) of the Act. These regulations require that such drugs have an approved application under Section 505(b) of the Act before they

can be marketed. Thus, "Doctor's Lotion" violates Section 505(a) of the Act. Further, since the adequacy of the labeled directions for these "aphrodisiac" uses has not been established, this product is misbranded under section 502(f)(1) of the Act.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may consider this information when considering the award of contracts.

We request that you take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. It should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Address your reply to the Food and Drug Administration, Division of Labeling and Nonprescription Drug Compliance, OTC Compliance Team (HFD-312), 7520 Standish Place, Room 168, Rockville, MD 20855, Attention: Vesna V. Stanoyevitch, Compliance Officer. If you have any questions about this letter, you may contact Ms. Stanoyevitch by telephone at 1-301-827-7362.

Sincerely,

Melvin F. Szymanski
Acting Director
Division of Labeling and
Nonprescription Drug Compliance (HFD-310)
Office of Compliance
Center for Drug Evaluation and Research

Enclosure:
21 CFR 310.528

EXHIBIT 2

LAW OFFICES OF

RONALD A. MARRON

A PROFESSIONAL LAW CORPORATION

651 Arroyo Drive
San Diego, California 92103

Tel: 619.696.9006
Fax: 619.564.6665

January 30, 2015

Via: Certified Mail, (receipt acknowledgment with signature requested); International Registered Mail, (receipt acknowledgment with signature requested).

Love Honey, LTD.
Attn: LEGAL DEPARTMENT
100 Locksbrook Road Bath
BA1 3EN
UNITED KINGDOM

Love Honey, Inc.
c/o The Corporation Trust Company
As Agent for Service of Process
1209 Orange Street
Wilmington, DE 19801

Erika Mitchell a/k/a E.L. James
c/o Valerie Hoskins
Valarie Hoskins Associates Limited
20 Charlotte Street
London, W1T 2NA
UNITED KINGDOM

PHE, Inc. d/b/a Adam and Eve Stores
Attn: LEGAL DEPARTMENT
302 Meadowland Drive
Hillsborough, North Carolina 27278-8502

PHE, Inc. d/b/a Adam and Eve Stores
c/o Thomas D. Higgins, III
As Agent for Service of Process
1414 Raleigh Blvd. Suite 320
Chapel Hill, North Carolina 27516

RE: NOTICE: Violations of Consumer Protection Laws, Breach of Warranties, and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this letter constitutes notice under the California Consumer Legal Remedies Act, ("CLRA"), California Civil Code § 1750, *et seq.*, (the "ACT"), specifically, Civil Code § 1782, and the Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.* ("MMWA"), notifying **Love Honey, LTD., Love Honey, Inc., Erika Mitchell a/k/a E.L. James, and PHE, Inc. d/b/a Adam and**

Eve Stores (collectively "YOU" and "YOUR") of violations of the Act and the MMWA, and of our demand that YOU remedy such violations within thirty (30) days of your receipt of this letter.

This firm represents Ms. Tania Kacha. Ms. Kacha purchased Fifty Shades of Grey Come Alive Pleasure Gel for Her (the "Product") on at least two occasions from a Adam and Eve store in San Diego, California on or around August of 2014. Ms. Kacha was exposed to and saw YOUR claims about the Product, purchased the Product in reliance on those claims, and suffered injury in fact as a result of YOUR false and misleading advertising.

YOU falsely advertise and market Fifty Shades of Grey Come Alive Pleasure Gel for Her by putting false and misleading claims on the label, stating or suggesting that the Product is a "Pleasure Gel" that increases "sensual comfort and pleasure." YOU further make the following false and misleading claims on both of the Product's labels:

- "I surrender, exploding around him— a draining, soul-grabbing orgasm that leaves me spent and exhausted."
- "Heighten your pleasure with Come Alive, an intimate arousal gel that enhances orgasms and stimulation."
- "Dab a little of the slick gel onto your clitoris and rub in gently with your finger."
- "Experience the effect within a few minutes as every tingle, touch and vibration is intensified."
- "Use alone, with a partner or your favourite toy for incredible pleasure and play."
- "The official sensual care collection."
- "Approved by E.L. James."

Ms. Kacha purchased the Fifty Shades of Grey Come Alive Pleasure Gel in reliance on YOUR claims that, in general, the Product will enhance "orgasms and stimulation," among the other representations discussed in this letter and appearing on the Product's packaging. However, the truth is that Fifty Shades of Grey Come Alive Pleasure Gel do not enhance sexual performance, orgasms, or stimulation as the advertising states or suggests.

None of the ingredients in Fifty Shades of Grey Come Alive Pleasure Gel work as advertised. This is established by the fact that the California Sherman Law, which is identical to the federal Food, Drug and Cosmetic Act, prohibits the marketing and sale of aphrodisiac products, which the Product is. *See* 21 C.F.R. § 310.528; Cal. Health & Safety Code §§ 110110-110111, 110115; 21 U.S.C. § 343-1. Moreover, application of heterogeneous herbs and herbal extracts to the genital areas, such the various botanicals and chemicals which are contained in the Product, presents a risk of an allergic or other adverse reaction without any offsetting benefit.

Moreover, YOU market and advertise the Product as being a "Pleasure Gel" that is "Latex Compatible." Pursuant to 21 C.F.R. 880.6375, Patient lubricants, such as the Fifty Shades of Grey Come Alive Pleasure Gel, are defined as a Class I Medical Devices intended for medical purposes that is used

to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. Significantly, Patient lubricants are **not** exempt from FDA 510(K) pre-market clearance. When used as an accessory to a condom (a Class II medical device), the lubricant is considered, by the FDA as a Class II Medical Device requiring 510(k) clearance. A search of the FDA's 510(k) public database reveals that the Fifty Shades of Grey Come Alive Pleasure Gel is neither registered as a Class I Medical Device nor a Class II Medical Device. Accordingly, the Product is being illegally marketed and sold as "latex compatible" lubricant despite the fact that YOU have not sought FDA pre-market clearance. *See* Cal. Health & Safety Code § 111550(a)(3).

A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding YOUR products or services.

In conclusion, YOUR material misrepresentations are deceiving customers into purchasing YOUR Product under the representation that the Fifty Shades of Grey Come Alive Pleasure Gel provides enhanced sexual performance, orgasms, and stimulation when in fact it does not.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices in violation of the CLRA include, but are not necessarily limited to:

§ 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.

§ 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.

§ 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

YOU have failed to honor your consumer protection obligations. Based upon the above, demand is hereby made that YOU conduct a corrective advertising campaign and destroy all misleading and deceptive advertising materials and products.

Please be advised that your failure to comply with this request within thirty (30) days may subject you to the following remedies, available for violations of the CLRA and other consumer protection statutes, which will be requested in the class action complaint on behalf of our client, Ms. Kacha and all other similarly-situated U.S. residents:

(1) The actual damages suffered;

(2) An order enjoining you for such methods, acts or practices;

(3) Restitution of property (when applicable);

(4) Punitive damages;

(5) Any other relief which the court deems proper; and

(6) Court costs and attorneys' fees.

Additionally, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., *Convolve, Inc. v. Compaq Computer Corp.*, 223 F.R.D 162, 175 (S.D.N.Y 2004); *Computer Ass'n Int'l v. American Fundware, Inc.*, 133 F.R.D. 166, 168-69 (D. Colo. 1990). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that related to the formulation and marketing of YOUR products will be sought in the forthcoming discovery process. You therefore must inform any employees, contractors, and third-party agents (for example product consultants and advertising agencies handling your product account) to preserve all such relevant information.

In addition, California Civil Code Section 1780 (b) provides in part that: "Any consumer who is a **senior citizen or a disabled person**, as defined in subdivision (f) and (g) of Section 1761, as part of an action under subdivision (a), may seek and be awarded, in addition to the remedied specified therein, up to **five thousand dollars** ($5,000)… [emphasis added]".

This letter further serves to notify you that the Product's packaging claims as contained in quotes herein created express and implied warranties under the Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.* and other state laws. Those warranties formed part of the benefit of the bargain and when the Products were not as warranted by YOU, Ms. Kacha suffered economic loss.

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

Sincerely,

THE LAW OFFICES OF RONALD A. MARRON APLC

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Tania Kacha, all others similarly situated, and the general public