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Attorney for Plaintiffs

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MARIO ORTEGA and KAMILLE FAYE VINLUAN-JULARBAL, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

SIMILASAN CORPORATION,

Defendant.

No. 5:23-cv-01984

CLASS ACTION COMPLAINT

JURY DEMAND

Table of Contents

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I. Introduction.

1. Defendant markets, distributes, and sells eye drops. Defendant's eye drops are intended for use in the eye, and purport to relieve symptoms for a variety of eye ailments, such as pink eye, dry eye, and allergies.

2. Defendant's eye drops include: Similasan Dry Eye Relief, Similasan Complete Eye Relief, Similasan Allergy Eye Relief, Similasan Kids Allergy Eye Relief, Similasan Red Eye Relief, Similasan Pink Eye Relief, Similasan Kids Pink Eye Relief, Similasan Aging Eye Relief, Similasan Computer Eye Relief, Similasan Stye Eye Relief, Similasan Pink Eye Nighttime Gel, and Similasan Dry Eye Nighttime Gel (the "Eye Drops" or "Products").

3. But Defendant's Eye Drops are dangerously defective, for several reasons. First, they are unapproved drugs, and thus illegal to sell. Second, they are labeled "sterile," when in fact they are not manufactured using processes sufficiently designed to prevent contamination. Third, they contain silver sulfate, a substance that can decrease night vision and cause irreversible eye and skin discoloration. The Products, however, fail to warn of any of these risks.

4. Defendant's Products are particularly troublesome from a public health perspective, because eye products, "in general pose a greater risk of harm to users because the route of administration for these products bypasses some of the body's natural defenses."[1] Contaminated eye drops can result in blindness and even death.[2]

5. Plaintiffs Mario Ortega and Kamille Faye Vinluan-Jularbal purchased and used Defendant's Eye Drops. They did not know that the Eye Drops were unapproved drugs. They did not know that the Eye Drops were unsafe and

[1] FDA Notice letter, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/similasan-ag-658878-09112023.

[2] https://www.scientificamerican.com/article/eye-drops-recalled-after-deaths-and-blindness-heres-what-to-know/

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adulterated, that they were made using faulty processes, or that they contained a preservative that could harm their eyes or skin. Had they known the truth, they would not have purchased the eye drops. And if other consumers knew the truth, they would immediately stop using the Eye Drops. Plaintiffs bring this case to force Defendant to recall its products and issue full refunds to consumers who used them.

II. Parties.

6. Plaintiff Mario Ortega is a citizen of California, domiciled in San Bernadino County. Mr. Ortega purchased Similasan Stye Eye Relief Eye Drops.

7. Plaintiff Kamille Faye Vinluan-Jularbal is a citizen of California, domiciled in Sacramento County. Ms. Vinluan-Jularbal purchased Similasan Pink Eye Relief Eye Drops.

8. The proposed class and subclasses (identified below) include citizens of all states.

9. Defendant Similasan Corporation is a Colorado corporation with its principal place of business in Highlands Ranch, Colorado.

10. Defendant markets, sells, and distributes the Eye Drop products.

III. Jurisdiction and Venue.

11. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d)(2). The amount in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and the matter is a class action in which one or more members of the proposed class are citizens of a state different from Defendant.

12. This Court has personal jurisdiction over Defendant. Defendant does business in California. They advertise and sell their Products in California, and serve a market for their Products in California. Due to Defendant's actions, their Products have been marketed and sold to consumers in California, and harmed consumers in California. Plaintiffs' claims arise out of Defendant's contacts with this forum. Due to Defendant's actions, Plaintiffs purchased Defendant's Products in California, and

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were harmed in California.

13. Venue is proper under 28 U.S.C. § 1391(b)(1) and 28 U.S.C. § 1391(d) because Defendant would be subject to personal jurisdiction in this District if this District were a separate state. Defendant advertises and sells its Products to customers in this District, serves a market for their Products in this District, and Plaintiffs' claims arise out of Defendant's contacts in this forum.

IV. Facts.

A. Defendant's Products.

14. Defendant markets, distributes, and sells its Eye Drop products nationwide.

15. The Eye Drops include Similasan Dry Eye Relief, Similasan Complete Eye Relief, Similasan Allergy Eye Relief, Similasan Kids Allergy Eye Relief, Similasan Red Eye Relief, Similasan Pink Eye Relief, Similasan Kids Pink Eye Relief, Similasan Aging Eye Relief, Similasan Computer Eye Relief, Similasan Stye Eye Relief, Similasan Pink Eye Nighttime Gel, and Similasan Dry Eye Nighttime Gel" (the "Eye Drops" or "Products").

16. For purposes of the claims asserted in this action, each of Defendant's Eye Drops are substantially similar to the other, in that: (1) each Eye Drop is a product intended for use in the eyes that is distributed, marketed, and sold by Defendant; (2) each Eye Drop is an unapproved drug that makes drug claims; (3) each Eye Drop is labeled "STERILE," when in fact the Product is not sufficiently designed to prevent contamination; (4) each Eye Drop contains silver sulfate, but fails to warn of the risks of silver sulfate.

17. Each Eye Drop is intended for use in the eyes, and contains instructions for use in the eyes. For example:

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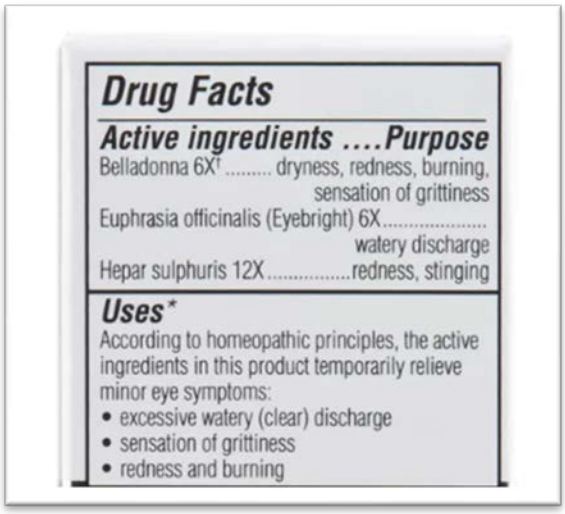

Drug Facts

Active ingredients ....Purpose

Belladonna 6X† ..... dryness, redness, burning, sensation of grittiness

Euphrasia officinalis (Eyebright) 6X..... watery discharge

Hepar sulphuris 12X.....redness, stinging

Uses*

According to homeopathic principles, the active ingredients in this product temporarily relieve minor eye symptoms:

- excessive watery (clear) discharge
- sensation of grittiness
- redness and burning

Drug Facts

Active Ingredients .... Purpose

Conium maculatum 6X ..... redness

Graphites 12X ..... eyelid redness

Sulphur 12X.....tearing, burning

Uses*

According to homeopathic principles, the active ingredients in this product temporarily relieve minor symptoms such as:

- redness
- burning
- eyelid redness
- tearing

Warnings

Drug Facts

Active Ingredients .... Purpose

Apis mellifica 6X.....burning, itching, stinging

Euphrasia officinalis (Eyebright) 6X ..... redness, swelling, watering

Sabadilla 6X.....watering, redness of lids

Uses:

According to homeopathic principles, the active ingredients in this product temporarily relieve minor eye allergy symptoms such as:

- itching
- burning
- excessive watering
- redness of eyes and lids

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18. In addition, each Eye Drop product makes substantially similar claims regarding its use in diagnosis, cure, mitigation, or treatment of eye disease and symptoms. For example:

Product	Claims
Similasan Dry Eye Relief	• Use As Often As Needed For • Dryness • Redness • Soothes • Moisturizes • temporarily relieve minor symptoms such as: • dry eye • redness of eyes and lids • reflex watering secondary to dry eye
Similasan Complete Eye Relief	• Use As Often As Needed For • Redness • Burning • Watering • Grittiness • Dryness • Irritation • temporarily relieve minor symptoms such as: • redness of eyes and eye lids • dry eye • reflex watering secondary to dry eye • sensation of grittiness • sensation of burning
Similasan Allergy Eye Relief	• Use As Often As Needed For • Itching • Burning • Watering • Redness • temporarily relieve minor eye allergy symptoms such as: • itching • burning • excessive watering • redness of eyes and lids

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Similasan Kids Allergy Eye Relief	• Use As Often As Needed For • Itching • Burning • Watering • Redness • temporarily relieve minor eye allergy symptoms such as: • itching • burning • excessive watering • redness of eyes and lids
Similasan Red Eye Relief	• Use As Often As Needed For • Redness • Stinging • Irritation • Watering • temporarily relieve minor eye symptoms such as: • itching • burning • redness of eyes and lids • stinging • excessive watering • irritation
Similasan Pink Eye Relief	• Use as often as needed for • Redness • Burning • Watery Discharge • Sensation of Grittiness • temporarily relieve minor eye symptoms such as: • excessive watery (clear) discharge • sensation of grittiness • redness and burning
Similasan Kids Pink Eye Relief	• Use As Often As Needed For •Redness •Burning •Dryness •Stinging •Grittiness •Watering • temporarily relieve minor symptoms such as: •redness of the eyes •irritation, dryness, and burning •sensation of grittiness, stinging •excessive watering (clear)
Similasan Aging Eye Relief	• Multi-Symptom Relief •Blurred Vision • Eyestrain • Tearing due to Dryness • temporarily relieve minor symptoms such as: • Blurred vision • Eye Strain • Tearing due to dryness"
Similasan Computer Eye Relief	• Use As Often As Needed For • Aching Eyes • Eye Strain • Burning • Redness • temporarily relieve minor symptoms such as: • aching eyes • burning • redness • strained eyes (Computer, TV, reading, driving)
Similasan Stye Eye Relief	• Multi-Symptom Relief • Redness • Burning • Tearing

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	• temporarily relieve minor symptoms such as: • redness • burning • eyelid redness • tearing
Similasan Pink Eye Nighttime Gel Relief	• Use As Often As Needed For • Redness • Burning • Watery Discharge •Sensation of Grittiness • temporarily relieve minor eye symptoms: • excessive watery (clear) discharge • sensation of grittiness • redness and burning
Similasan Dry Eye Nighttime Gel	• Use As Often As Needed For • Dryness • Redness • temporarily relieve minor eye symptoms such as: • dry eye • redness of eyes and lids •reflex watering secondary to dry eye

B. Defendant's Products are unapproved new drugs.

19. Both Federal and state regulations apply to the sale of drugs.

20. The federal Food, Drug, and Cosmetics Act ("FDCA") (21 U.S.C. §§ 301 et. seq.) defines drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 § U.S.C. 321(g)(1)(B). Products that qualify as drugs must comply with the regulations for drugs. Under federal law, a new drug generally cannot be introduced or delivered into interstate commerce without an approved FDA application in effect.[3] 21 U.S.C. §§355(a), 331(d). Sale of unapproved new drugs is illegal.

21. The California Sherman Food, Drug, and Cosmetics Law mirrors the federal regulations. Under the California Sherman Act, a drug includes "An article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or any other animal." Cal. Health & Safety Code § 109925(a). And, under California's Sherman Act, new drugs generally cannot be sold unless a new drug application has been approved. Cal Health & Safety Code §111550.

22. As explained in greater detail above, each of Defendant's Eye Drops claims to cure, mitigate, or treat eye diseases in humans. For example, the packaging

[3] Subject to some exceptions, which do not apply here.

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on the Eye Drops makes claims that the products soothe pink eye, provide allergy relief, provide dry eye relief, and relieve eye symptoms. Thus, each of the Eye Drop products are drugs under both the FD&C Act, and the California Sherman Act. 21 § U.S.C. 321(g)(1)(B); Cal. Health & Safety Code § 109925(a).

23. In addition, none of the Eye Drops have been approved as new drugs. Thus, they are unapproved new drugs that are illegal both under federal and state law.

24. Further, the FDA agrees that Defendant's Eye Drops are unapproved drugs. On September 11, 2023, the FDA sent Similasin AG (Defendant's related company) a letter stating that the Eye Drops were "unapproved new drugs under section 505(a)" of the FD&C Act. Thus, the FDA explained, "introducing or delivering these products for introduction into interstate commerce violates sections 301(d) and 505(a) of the FD&C Act, 21U.S.C. 331(d) and 355(a)," and is thus illegal.[4]

C. Defendant's use of the word "STERILE" in its packaging is misleading.

25. Each of Defendant's Eye Drops contain the words "STERILE EYE DROPS" on the packaging.

26. As one example:

[4] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/similasan-ag-658878-09112023

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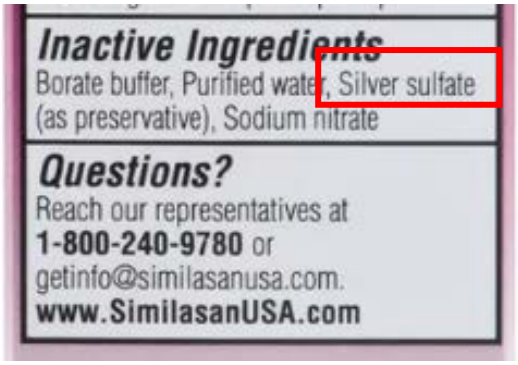
27. Each of the other Eye Drops have the same representation on the front of their packages.

28. The representation that the Products are sterile, however, is false and misleading, because Defendant fails to ensure that the Products are actually sterile.

29. In its September 2023 letter, the FDA stated that Defendant's Products were manufactured without establishing and following "procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes."[5] This increases the risk of contamination, and fails to ensure sterility. Because Defendants fail to use processes designed to prevent microbiological contamination, Defendant's claim that its Eye Products are "sterile" is false and misleading.

D. Defendant's use of silver sulfate makes the Products defective, and Defendant fails to disclose these risks.

30. Defendant's Eye Drops are also defective for an additional reason. Each Eye Drop product uses silver sulfate as a preservative. For example:



31. Silver sulfate, however, is not safe for use as an eye drop preservative, because deposits of silver in the conjunctiva and cornea may cause decreased night vision, and silver can cause irreversible eye and skin discoloration. Thus, the use of

[5] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/similasan-ag-658878-09112023

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silver sulfate as a preservative violates 21 C.F.R. 200.50(b)(1), which requires that preservative for eye products be "safe and harmless."[6] Defendant fails to warn of these risks. Defendant's packaging fails to warn that silver sulfate can cause decreased night vision, eye discoloration, or skin discoloration. Defendant further failed to warn that the use of silver sulfate as a preservative is neither suitable nor harmless.

32. Moreover, the use of silver sulfate is unnecessary. Other eye drop makers can, and do, make eye drops that do not contain silver sulfate. As one example, Visine makes eye drops that do not list silver sulfate as an ingredient. Similarly, Alcon's Opti-Free line of eye drops does not list silver sulfate as an ingredient. This shows that it is possible to make eye drops that do not use silver sulfate.

E. Defendant knew of the defects.

33. Companies that manufacture ophthalmologic products, such as Defendant, are aware of the FDA regulations regarding drugs. Defendant is also aware that its labels contain claims intended for the use in diagnosis, cure, mitigation, or treatment of disease.

34. Defendant was also on notice that its practices violated the FDCA regulations, because the FDA inspected the manufacturing facilities for the Eye Drop products and warned its related company, Similasin AG, about the conditions.

35. From March 27, 2023, to April 4, 2023, the FDA inspected the drug facility that manufactures the Eye Products at issue here. After the inspection, the FDA warned Similasin AG about the conditions. Thus, at least as of April 2023, after the FDA inspection, Defendant was aware that its manufacturing processes did not meet FDA standards. Defendant's website also acknowledges that it received an

[6] *Id* at n. 1.

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FDA warning letter after a facility inspection.[7]

36. Similarly, Defendant is aware that each of its Products make a "STERILE" representation. Defendant is further aware that its products are not manufactured using procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile.

37. Finally, Defendant is aware that it uses silver sulfate as a preservative, and aware of the risks. As a manufacturer of eye products, Defendant is aware of research regarding the risks of various ingredients in the eye. Defendant is aware that silver sulfate can affect vision and discolor the eye and surrounding area.

F. Plaintiffs suffered injury.

38. In fall 2022, Plaintiff Ortega purchased Similasan Stye Eye Relief Eye Drops at a Walmart store in Ontario, CA.

39. Plaintiff Ortega purchased the product for personal use.

40. In purchasing the item, Plaintiff Ortega relied on Defendant's position as a maker of eye products, and believed that the products would be safe for use in the eye. The packaging did not disclose that the Products were unapproved drugs that were illegal. If Plaintiff had known that the Products were unapproved drugs, he would not have purchased the Product.

41. In addition, Plaintiff Ortega saw and relied on the representations on the front of the packaging that the products were "sterile." If Defendant had disclosed that the products were not in fact sterile, or made in manufacturing conditions that risked contamination, Plaintiff would not have purchased the Product.

42. Finally, Plaintiff Ortega was unaware that the Products contained a preservative that could decrease night vision, and risked eye and skin discoloration. If he knew of this risk, he would not have purchased the Product.

[7] Similasan Statement regarding FDA Warning Letter: https://www.similasanusa.com/similasan-statement-regarding-fda-warning-letter

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43. Thus, Plaintiff Ortega suffered economic injury as a result of Defendant's actions. Plaintiff would purchase additional Eye Drops if they were redesigned to be FDA approved, sterile, and did not contain any harmful preservatives. Plaintiff, however, faces an imminent threat of harm because he will not be able to rely on the representations of the package and the comprehensiveness of warnings in the future, and thus will not be able to purchase the Product.

44. On August 31, 2023, Plaintiff Vinluan-Jularbal purchased Similasan Pink Eye Relief Eye Drops at a Walmart store in Elk Grove, CA.

45. Plaintiff Vinluan-Jularbal purchased the product for personal use.

46. In purchasing the item, Plaintiff Vinluan-Jularbal relied on Defendant's position as a maker of eye products, and believed that the products would be safe for use in the eye. The packaging did not disclose that the Products were unapproved drugs that were illegal. If Plaintiff had known that the Products were unapproved drugs, she would not have purchased the Product.

47. In addition, Plaintiff Vinluan-Jularbal saw and relied on the representations on the front of the packaging that the products were "sterile." If Defendant had disclosed that the products were not in fact sterile, or made in manufacturing conditions that risked contamination, Plaintiff would not have purchased the Product.

48. Finally, Plaintiff Vinluan-Jularbal was unaware that the Products contained a preservative that could decrease night vision, and risked eye and skin discoloration. If she knew of this risk, she would not have purchased the Product.

49. Thus, Plaintiff Vinluan-Jularbal suffered economic injury as a result of Defendant's actions. Plaintiff would purchase additional Eye Drops if they were redesigned to be FDA approved, sterile, and did not contain any harmful preservatives. Plaintiff, however, faces an imminent threat of harm because she will not be able to rely on the representations of the package and the comprehensiveness

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of warnings in the future, and thus will not be able to purchase the product.

G. Defendant's actions injured Plaintiffs and class members.

50. Defendant's sale of unapproved drugs, false and misleading representations of sterility, and failure to warn of the dangers of silver sulfate allowed it to charge more for the Eye Drops than it otherwise would have been able to.

51. Because the Eye Drops are unapproved drugs, the sale of the Products is illegal. If consumers knew the truth, the Products would not be on the market, and consumers would not have purchased the Products.

52. In addition, if consumers had known that the Eye Drops were not sterile, consumers would not have purchased the products.

53. If consumers had been warned of the risks of silver sulfate, consumers would not have purchased the products, or, at a minimum, would have paid substantially less for it.

54. Thus, as a result of Defendant's sale of unapproved drugs, misrepresentations, and omissions, Plaintiffs and class members were charged a price premium and sustained economic injuries.

55. The who, what, when, where, and how are as follows.

56. Who: Defendant Similasan Corporation USA.

57. What: Defendant made misrepresentations on the packaging of the Eye Drops by stating that the Products were "STERILE," "Eye Drops," for "Eye Relief." These representations led consumers to believe that the Eye Drops were sterile, and safe to use in the eyes for eye relief. In addition, Defendant made misrepresentations by: (a) selling its Products at retail, which was a representation that the products were of merchantable quality and were safe for their ordinary use; (b) marketing the Products to consumers for use as eye drops; and (c) making partial representations that are misleading because they warned of some risks of the Product, but failed to warn of others— specifically, that the Products were unapproved drugs, that they

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were made with unsafe manufacturing processes, and that they contained a preservative that can decrease vision and discolor eyes and skin. Defendant also made fraudulent omissions by failing to disclose that its products were unapproved drugs, that they were made with unsafe manufacturing processes, and that they contained a preservative that risks decreasing vision and discoloring eyes and skin.

58. When: In fall 2022, Plaintiff Ortega purchased Similasan Stye Eye Relief Eye Drops at a Walmart store in Ontario, CA. On August 31, 2023, Plaintiff Vinluan-Jularbal purchased Similasan Pink Eye Relief Eye Drops at a Walmart store in Elk Grove, CA.

59. Where: Plaintiff Ortega purchased Similasan Stye Eye Relief Eye Drops at a Walmart store in Ontario, CA. Plaintiff Vinluan-Jularbal purchased Similasan Pink Eye Relief Eye Drops at a Walmart store in Elk Grove, CA. Defendant should and could have included the omitted warnings on its marketing materials including on its website; on the product packaging, such as the box of the Products; and/or on the Products themselves. But, as described above, no such warnings were included on any of these materials. The misrepresentations were made on the product packaging and on the website.

60. How: Defendant's representations and omissions led Plaintiffs and other reasonable consumers to believe that Defendant's Products were safe for use as eye drops. They led consumers to believe that the Products were sterile. In fact, as described in greater detail above, Defendant's Products are not safe for use as eye drops, and not made in a way to ensure sterility. Defendant knew this, but did not warn of it.

61. Plaintiffs seek damages and, in the alternative, restitution. Plaintiffs are permitted to seek equitable remedies in the alternative because she has no adequate remedy at law.

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V. No Adequate Remedy at Law.

62. A legal remedy is not adequate if it is not as certain as an equitable remedy. To obtain a full refund as damages, Plaintiffs must show that the Product they received has essentially no market value. In contrast, Plaintiffs can seek restitution without making this showing. This is because Plaintiffs purchased a Product that they would not otherwise have purchased, but for Defendant's misrepresentations and omissions. Obtaining a full refund at law is less certain that obtaining a refund in equity.

63. In addition, the elements of Plaintiffs' equitable claims are different and do not require the same showings as Plaintiffs' legal claims. For example, to obtain damages under the CLRA, a plaintiff must show that they complied with the CLRA's notice requirement for damages. No such requirements exist to obtain restitution. Obtaining damages under the CLRA requires Plaintiffs to show that Defendant made negligent or fraudulent misrepresentations. No such requirement exists for Plaintiffs to obtain equitable relief, for example under the "unfair" or "unlawful" prong of the UCL. Because a plaintiff must make this additional showing to obtain damages, rather than restitution, the legal remedies are more uncertain.

64. Finally, the remedies at law available to Plaintiffs are not equally prompt or otherwise efficient. The need to schedule a jury trial may result in delay. And a jury trial will take longer, and be more expensive, than a bench trial. Plaintiffs seek damages and, in the alternative, restitution. Plaintiffs are permitted to seek equitable remedies in the alternative because they have no adequate remedy at law.

VI. Class Action Allegations.

65. Plaintiffs bring claims on behalf of themselves as well as (a) a nationwide class of consumers who purchased the Eye Drops during the applicable statute of limitations (the "Nationwide Class"); (b) for certain claims, a subclass of consumers who purchased the Products in California (the "California Subclass"), and (c) for

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certain claims, a subclass of consumers who, while living in California, Connecticut, Illinois, Maryland, Missouri, and New York, purchased the Eye Drops during the applicable statute of limitations (the "Consumer Protection Subclass").

66. The following people are excluded from the class and the subclasses: (1) any Judge or Magistrate Judge presiding over this action and the members of their family; (2) Defendant, Defendant's subsidiaries, parents, successors, predecessors, and any entity in which the Defendant or its parents have a controlling interest and their current employees, officers and directors; (3) persons who properly execute and file a timely request for exclusion from the class; (4) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (5) Plaintiffs' counsel and Defendant's counsel, and their experts and consultants; and (6) the legal representatives, successors, and assigns of any such excluded persons.

Numerosity

67. The proposed class(es) contain members so numerous that separate joinder of each member of the class is impractical. Based on the pervasive distribution of Defendant's Products, there are tens of thousands of proposed class members (or more).

Commonality

68. There are questions of law and fact common to the proposed class. Common questions of law and fact include, without limitation:

(1) Whether the Eye Drops are unapproved drugs,

(2) Whether the Eye Drops are fit for their ordinary and intended use;

(3) Whether Defendant engaged in an unlawful deceptive practice in marketing and selling the Products as is;

(4) Whether Defendant was unjustly enriched by the sale of the Products;

(5) Whether Plaintiffs suffered ascertainable loss as a result of Defendant's conduct;

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(6) Whether Defendant should be enjoined from further sales of the seats;

(7) What damages are needed to compensate Plaintiffs and the proposed class(es).

Typicality

69. Plaintiffs' claims are typical of the proposed class. Like the proposed class, Plaintiffs purchased the Products.

Adequacy

70. The interests of the members of the proposed class and subclass will be adequately protected by Plaintiffs and their counsel. Plaintiffs' interests are aligned with, and do not conflict with, the interests of the members of the proposed class or subclasses that they seek to represent. Moreover, Plaintiffs have retained experienced and competent counsel to prosecute the class and subclasses' claims.

Predominance and Superiority

71. The prosecution of separate actions by individual members of the proposed class would create a risk of inconsistent or varying adjudication with respect to individual members, which would establish incompatible standards for the parties opposing the class. For example, individual adjudication would create a risk that the same product is found unfit for its ordinary use for some proposed class members, but not for others. Common questions of law and fact predominate over any questions affecting only individual members of the proposed class. These common legal and factual questions arise from certain central issues which do not vary from class member to class member, and which may be determined without reference to the individual circumstances of any particular class member. For example, a core liability question is common: whether Defendant has made and marketed an unapproved drug.

72. A class action is superior to all other available methods for the fair and efficient adjudication of this litigation because individual litigation of each claim is

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impractical. It would be unduly burdensome to have individual litigation of millions of individual claims in separate lawsuits, every one of which would present the issues presented in this lawsuit.

VII. Claims.

Count I: Violation of California's Unfair Competition Law (UCL)

(on behalf of Plaintiffs and the California Subclass)

73. Plaintiffs incorporate by reference and re-allege each and every factual allegation set forth above as though fully set forth herein.

74. Plaintiffs bring this cause of action on behalf of themselves and members of the California Subclass.

75. Defendant has violated California's Unfair Competition Law (UCL) by engaging in unlawful, fraudulent, and unfair conduct (i.e., violating each of the three prongs of the UCL).

The Unlawful Prong

76. As alleged in detail above, Defendants have violated the unlawful prong by virtue of their violations of the Sherman Food Drug & Cosmetics Laws, California's Health & Safety Code §§ 109875 et seq., and selling unapproved drugs.

77. In addition, Defendant engaged in unlawful conduct by violating the CLRA and FAL, as alleged above and below and incorporated here.

The Fraudulent Prong

78. As alleged in detail above, Defendant has violated the fraudulent prong of section 17200 because (1) their sale of unapproved drugs; (2) their misrepresentations that the Eye Drops were sterile and suitable for use as eye drops for eye relief; and (3) their material omissions about the unapproved drugs, sterility of their products, and dangers of silver sulfate were likely to deceive a reasonable consumer, and did deceive Plaintiffs and reasonable consumers. The true facts were material to Plaintiffs, and would be material to a reasonable consumer.

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The Unfair Prong

79. Defendant has violated the unfair prong of section 17200 because the acts and practices set forth in the Complaint—including the sale of unapproved drugs, the sale of eye drops that have not been manufactured using sterile conditions, and the use of silver sulfate as an eye drop preservative—offends established public policy. The challenged conduct is substantially injurious to consumers. The harm that these acts and practices cause to consumers greatly outweighs any benefits associated with them. Reasonable consumers are not in a position to know and understand the safety concerns posed by unapproved drugs. Reasonable consumers do not know what the manufacturing practices of an eye drop maker are, and whether the practices are sufficient to ensure sterility. In addition, reasonable consumers do not research eye drop preservatives, and do not know the dangers of silver sulfate as an eye drop preservative.

80. Defendants' conduct also impairs competition within the market for eye care products, and stops Plaintiffs and Class members from making fully informed decisions about the kind of eye drops to purchase, or the price to pay for such products.

81. Defendant's conduct caused substantial injury to Plaintiffs and subclass members. The harm to Plaintiffs and the subclass greatly outweighs the public utility of Defendant's conduct (which is none). Distributing or selling unsafe, unapproved drugs has no public utility at all. There is no public utility in distributing or eye drops that are unsafe and not sterile. This injury was not outweighed by any countervailing benefits to consumers or competition. Selling products unsafe and unfit for their intended purposes only injures healthy competition and harms consumers.

82. Plaintiffs and the subclass could not have reasonably avoided this injury. As alleged above, Defendant's false representations and omissions were deceiving to reasonable consumers.

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83. Defendant's conduct, as alleged above, was immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

84. For all prongs, Plaintiffs saw and reasonably relied on Defendant's false representations and omissions when purchasing the Eye Drops.

85. Defendant failed to tell consumers that the Eye Drops were unapproved drugs.

86. Defendant also falsely represented that the Eye Drops were sterile.

87. Defendant further failed to warn consumers that the preservative used in the Eye Drops could be harmful to the eyes.

88. Defendant knew of these defects, but actively concealed them.

89. The warnings could have been included on the packaging for the product. But Defendant did not include any such warning. Instead, as further alleged above, the packaging instead represents that the Eye Drops are safe for use in the eyes, and that they are sterile.

90. Defendant had a duty to warn of the defects. The defects were central to the Eye Drops' function, and because consumers could not reasonably know the product was defective, Defendant had exclusive knowledge of the defect. Still, Defendant actively concealed the defect from consumers by failing to disclose it on the product's packaging.

91. Defendant's false representations and omissions were material. Plaintiffs and other reasonable consumers would not have purchased the product had they known the product was an unapproved drug, that it was not sterile, and that it could harm eyes. Thus, subclass-wide reliance can be inferred. Defendant's false representations and omissions were a substantial factor in Plaintiff's purchase decision and the purchase decisions of class members.

92. Plaintiffs and subclass members were injured as a direct and proximate result of Defendant's conduct because: (a) they would not have purchased the Eye

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Drops if they had known it was dangerous for young children; (b) they overpaid for the product because the product is sold at a price premium due to Defendant's false representations and omissions; or (c) they received a product that is worthless for its intended purpose.

Count II: Violation of California's Legal Remedies Act (CLRA)

(on behalf of Plaintiffs and the California Subclass)

93. Plaintiffs incorporate by reference and re-alleges each and every allegation set forth above as though fully set forth herein.

94. Plaintiffs bring this cause of action on behalf of themselves and members of the California Subclass.

95. Plaintiffs and the other members of the California Subclass are "consumers," as the term is defined by California Civil Code § 1761(d).

96. Plaintiffs, the other members of the California Subclass, and Defendant have engaged in "transactions," as that term is defined by California Civil Code § 1761(e).

97. The conduct alleged in this Complaint constitutes unfair methods of competition and unfair and deceptive acts and practices for the purpose of the CLRA, and the conduct was undertaken by Defendant in transactions intended to result in, and which did result in, the sale of goods to consumers.

98. As alleged more fully above, Defendant has violated the CLRA by falsely representing to Plaintiffs and other members of the California Subclass that the Eye Drops are safe and fit for ordinary use, when in fact, the Eye Drops are dangerous for use in the eyes and can cause injury. As described in greater detail above, the Eye Drops (1) are unapproved drugs, (2) are made with unsafe and faulty manufacturing processes, and (3) contain silver sulfate.

99. In addition, the packages prominently state that the Eye Drops are "STERILE," when in fact they are made using unsafe manufacturing processes that

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do not ensure sterility.

100. As a result of engaging in such conduct, Defendant has violated California Civil Code §§ 1770(a)(2), (a)(5), (a)(7), and (a)(9).

101. Defendant's conduct was likely to deceive, and did deceive, Plaintiffs and reasonable consumers. Defendant knew, or should have known through the exercise of reasonable care, that Products were unsafe and that presenting it as fit for use as eye drops for eye relief was deceptive.

102. Defendant's false representations were intended to induce reliance, and Plaintiffs saw and reasonably relied on them when purchasing the Eye Drops. Defendant's false representations of safety and fitness for use as eye drops were a substantial factor in Plaintiffs' purchase decision.

103. In addition, class-wide reliance can be inferred because Defendant's false representations were material, i.e., a reasonable consumer would consider them important in deciding whether to buy the Eye Drops.

104. Defendant's false representations were a substantial factor and proximate cause in causing damages and losses to Plaintiffs and Subclass members.

105. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendant's conduct because (a) they would not have purchased the product if they had known it was unsafe and unfit for use in the eye; (b) they overpaid for the product because it is sold at a price premium due to Defendant's false representations; or (c) they received a product that is worthless for its intended purpose.

106. Accordingly, pursuant to California Civil Code § 1780(a)(2), Plaintiffs, on behalf of themselves and all other members of the California Subclass, seek injunctive relief.

107. CLRA § 1782 NOTICE. On September 20, 2023, a CLRA demand letter was sent to Defendant's headquarters and California registered agent, via certified mail (return receipt requested). This letter provided notice of Defendant's violation of the

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CLRA and demanded that Defendant correct the unlawful, unfair, false and/or deceptive practices alleged here. If Defendant does not fully correct the problem for Plaintiffs and for each member of the class within 30 days of receipt, Plaintiffs and the class will seek all monetary relief allowed under the CLRA.

Count III: Violation of California's False Advertising Law (FAL)

(on behalf of Plaintiffs and the California Sublass)

108. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

109. Plaintiffs bring this cause of action on behalf of themselves and members of the California Subclass.

110. As alleged more fully above, Defendant has falsely advertised the Eye Drops by falsely representing that the Products are safe and fit for use as Eye Drops. As detailed above, Defendant's Products prominently state "Eye Drops" and "Eye Relief" on the front of each package. The packages also prominently state that the Eye Drops are "STERILE." This led consumers to believe that the Eye Drops were sterile and safe and fit for use as eye drops.

111. Defendant's false representations were likely to deceive, and did deceive, Plaintiffs and reasonable consumers. Defendant knew, or should have known through the exercise of reasonable care, that their representations were inaccurate and misleading.

112. Defendant's false representations were intended to induce reliance, and Plaintiffs saw and reasonably relied on them when purchasing the Eye Drops. Defendant's false representations were a substantial factor in Plaintiff's purchase decision.

113. In addition, class-wide reliance can be inferred because Defendant's false representations were material, i.e., a reasonable consumer would consider them important in deciding whether to buy Eye Drops.

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114. Defendant's false representations were a substantial factor and proximate cause in causing damages and losses to Plaintiffs and Subclass members.

115. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendant's conduct because (a) they would not have purchased the Products if they had known the Products were unsafe and unfit for use in the eye; (b) they overpaid for the Products because the Products were sold at a price premium due to Defendant's false representations; or (c) they received a Product that is worthless for its intended purpose.

Count IV: Violations of State Consumer Protection Statutes

(on behalf of Plaintiffs and the Consumer Protection Class)

116. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

117. This count is brought on behalf of Plaintiffs and the Consumer Protection Subclass for violations of the following state consumer protection statutes:

State	Statute
California	Cal. Bus. & Prof. Code § 17200, and the following; *Id.* §17500, and the following; Cal. Civ. Code §1750 and the following.
Connecticut	Conn. Gen Stat. Ann. § 42- 110, and the following.
Illinois	815 ILCS § 501/1, and the following.
Maryland	Md. Code Ann. Com. Law, § 13-301, and the following.
Missouri	Mo. Rev. Stat. § 407, and the following.
New York	N.Y. Gen. Bus. Law § 349, and the following.

118. Each of these consumer protection statutes prohibits unfair, unconscionable, and/or deceptive acts or practices in the course of trade or commerce or in connection with the sales of goods or services to consumers.

119. As alleged in detail above, Defendant's conduct, including the marketing

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and sale of its Products to consumers, violates each statute's prohibitions.

120. As further alleged above, Defendant's misrepresentations and omissions were a substantial factor in Plaintiffs' purchase decisions and the purchase decisions of subclass members. Defendant's misrepresentations and omissions were misleading to a reasonable consumer, and Plaintiffs and subclass members reasonably relied on Defendant's misrepresentations.

121. Plaintiffs and subclass members were injured as a direct and proximate result of Defendant's conduct because (a) they would not and could not have purchased the Defendant's Products if they had known the truth, (b) they overpaid for the Products because the Products were sold at a price premium due to the illegality, misrepresentation, and omissions, and/or (c) they received a Product that was defective and thus less valuable than what they paid for.

122. In this way, Plaintiffs and the members of the proposed Subclass have suffered an ascertainable loss, in an amount to be determined at trial.

Count V: Breach of Implied Warranties

(on behalf of Plaintiffs and the Nationwide Class)

123. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

124. Plaintiffs bring this count individually and for the Nationwide Class.

Implied Warranty of Merchantability

125. The Uniform Commercial Code § 2-314 states that "a warranty that [] goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." "Merchantable" goods must be "fit for the ordinary purposes for which the goods are used."

126. Defendant is and was, at all relevant times, a merchant with respect to eye drop products. The Eye Drops constitutes a "good" under the UCC.

127. Plaintiffs and Class Members purchased the Eye Drops.

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128. As the manufacturer of the Eye Drops, Defendant impliedly warranted to Plaintiffs and the Class that the Eye Drops were of merchantable quality and were safe for their ordinary use.

129. In fact, when sold and at all times thereafter, the Eye Drops were not in merchantable condition and were not fit for the ordinary purpose. Specifically, as described in greater detail above, the Products are not safe for use as eye drops because (1) they are unapproved drugs, (2) they are made with faulty and unsafe manufacturing processes, and (3) they contain silver sulfate. The defective design makes them unfit for ordinary purposes even when used correctly.

130. Thus, Defendant breached the implied warranty of merchantability in connection with the sale and distribution of the Eye Drops.

131. Plaintiff Ortega provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

132. Plaintiff Vinluan-Jularbel provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

133. Plaintiffs and the Class were foreseeable third-party beneficiaries of Defendant's sale of the Eye Drops. Defendant sells Eye Drops to retailers for distribution and sale to consumers such as Plaintiffs and Class Members.

134. Defendant's breach directly caused Plaintiffs and class members harm. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendant's conduct because (a) they would not have purchased the Defendant's Products if they had known the truth, (b) they overpaid for the Products because the Products are sold at a price premium due to the misrepresentation and omissions, and/or (c) they received a product that was defective and thus worthless for its intended purpose.

Implied Warranty of Fitness

135. The Uniform Commercial Code § 2-315 states that where a seller "has

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reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose."

136. Plaintiffs and Class Members purchased the Eye Drops for the purpose of using them as eye drops for eye relief.

137. Defendant knew, or had reason to know, that Plaintiffs and Class Members were purchasing the Products for this particular purpose. Defendant directs consumers to use the Products as eye drops, for eye relief. And, as detailed above, Defendant's Products prominently state "Eye Drops" and "Eye Relief" on the front of each package. Defendant is aware that consumers purchase Products for use as eye drops.

138. Defendant markets itself as a knowledgeable and effective developer and purveyor eye drop products.

139. Defendant knew, or had reason to know, that Plaintiffs and Class Members would justifiably rely on Defendant's particular skill and knowledge of eye drops in selecting or furnishing products suitable for use as eye drops.

140. Plaintiffs and Class Members did justifiably rely on Defendant's judgement and skill.

141. The Eye Drops were not suitable for their intended purpose. The Products are not safe for use as eye drops because, as described in greater detail above, (1) they are unapproved drugs, (2) they are made with faulty and unsafe manufacturing processes, and (3) they contain silver sulfate.

142. Thus, Defendant breached its implied warranty of fitness concerning the Eye Drops.

143. Plaintiff Ortega provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

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144. Plaintiff Vinluan-Jularbel provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

145. Plaintiffs and the Class were foreseeable third-party beneficiaries of Defendant's sale of the Eye Drops. Defendant sells Eye Drops to retailers for distribution and sale to consumers such as Plaintiffs and Class Members.

146. Defendant's breach directly caused Plaintiffs and class members harm. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendant's conduct because (a) they would not have purchased the Defendant's Products if they had known the truth, (b) they overpaid for the Products because the Products are sold at a price premium due to the misrepresentation and omissions, and/or (c) they received a product that was defective and thus worthless for its intended purpose.

Count VI: Breach of Express Warranty

(on behalf of Plaintiffs and the Nationwide Class)

147. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

148. Plaintiffs bring this count individually and for the Nationwide Class.

149. As detailed above, Defendant makes, markets, and sells the Eye Drops.

150. As detailed above, Defendant markets the product as Eye Drops for "Eye Relief." Each Product has a statement on the front of the packaging stating that they are "Eye Drops" for "Eye Relief." These statements are an affirmation of fact about the Eye Drops (i.e. a representation that the Products are safe for use in the eye as eye drops) and a promise relating to the goods.

151. In fact, the Products do not conform to this express representation. The Products are not safe for use as eye drops because (1) they are unapproved drugs, (2) they are not made with faulty manufacturing processes, and (3) they contain silver sulfate.

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152. Defendant further warrants that the products are sterile. As detailed above, Defendant expressly states on the product packaging that the Products are "STERILE." This is an affirmation of fact that the Eye Drops are sterile, and made in a way to ensure sterility. As described in further detail above, the manufacturing processes used to make the Eye Drops, however, are flawed, and do not ensure sterility.

153. Each of these warranties were part of the basis of the bargain, and Plaintiffs and Class Members saw and relied on each of these warranties.

154. Plaintiff Ortega provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

155. Plaintiff Vinluan-Jularbel provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

156. Defendant's breach directly caused Plaintiffs and class members harm. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendant's conduct because (a) they would not have purchased the Defendant's Products if they had known the truth, (b) they overpaid for the Products because the Products are sold at a price premium due to the misrepresentation and omissions, and/or (c) they received a product that was defective and thus less valuable than what they paid for.

Count VII: Fraudulent Omission

(on behalf of Plaintiffs and the Nationwide Class)

157. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

158. Plaintiffs bring this count individually and for the Nationwide Class. In the alternative, Plaintiffs bring this cause of action on behalf of themselves and the California Subclass.

159. As alleged in detail above, Defendant made materially misleading

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omissions concerning the safety of its Products.

160. In deciding to purchase Eye Drops products from Defendant, Plaintiffs and the class reasonably relied on Defendant's omissions to form the mistaken belief that the Products were safe for use as eye drops.

161. As alleged in detail above, Defendant's fraudulent conduct was knowing and intentional. The omissions made by Defendant were intended to induce and actually induced Plaintiffs and class members to purchase the Products. Plaintiffs would not have purchased the products had they known of the defects. Class-wide reliance can be inferred because Defendant's omissions were material, i.e., a reasonable consumer would consider them important to their purchase decision.

162. As alleged in detail above, Defendant had a duty to disclose the defect.

163. Plaintiffs and class members were injured as a direct and proximate result of Defendant's fraudulent omissions because (a) they would not have purchased the Products if they had known the truth; (b) they overpaid for the Products because the Products are sold at a price premium due to Defendant's misleading representations and omissions, or (c) they received a Product that was defective and thus worthless.

164. Defendant's acts were done maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiffs' rights and well-being to enrich Defendant. Defendant's conduct warrants an assessment of punitive damages in an amount sufficient to deter such conduct in the future, which amount is to be determined according to proof.

Count VIII: Unjust Enrichment

(on behalf of Plaintiffs and the Nationwide Class)

165. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

166. Plaintiffs bring this count individually and for the Nationwide Class.

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167. Plaintiffs and Class Members purchased Eye Drops. They reasonably believed that the Products would function as advertised, and would be fit for their expected ordinary purpose. Plaintiffs and Class Members did not, and could not, have known that the Eye Drops were defective.

168. Plaintiffs and Class Members conferred a tangible and material economic benefit upon Defendant by purchasing defective eye drops.

169. In exchange for the purchase price, Defendant provided products with inherent defects, which make the products unfit and unsafe for their ordinary use. Defendants knew and appreciated the benefit they incurred from consumers purchasing their Eye Drops.

170. Thus, Defendant is aware of, and has retained, the unjust benefit conferred upon them by Plaintiffs and the Class Members.

171. Defendant received a direct and unjust benefit, at the Plaintiffs' expense.

172. Plaintiffs and the Nationwide Class seek restitution.

VIII. Jury Demand

173. Plaintiffs demand a jury trial on all issues so triable.

IX. Prayer for Relief

174. Plaintiffs seek the following relief individually and for the proposed class and subclasses:

- An order certifying the asserted claims, or issues raised, as a class action;
- An order appointing Plaintiffs as representatives for the Nationwide Class and the California Subclass, and appointing their counsel as lead counsel for the classes;
- An order awarding Plaintiffs and all other class members damages in an amount to be determined at trial for the wrongful acts of Defendant;
- A declaration that the Eye Drops are unfit for ordinary purposes and pose a serious safety risk to consumers;

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- An order enjoining Defendant from engaging in or continuing to engage in the manufacture, marketing, and sale of unapproved new drugs; requiring Defendant to issue corrective actions including notification and recall of the Eye Drops;
- Nominal damages as authorized by law;
- Restitution as authorized by law;
- Pre- and post-judgment interest;
- Reasonable attorneys' fees and costs, as allowed by law; and
- Any additional relief that the Court deems reasonable and just.

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Dated: September 27, 2023

Respectfully submitted,

By: */s/ Christin Cho*

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Mario Ortega and Kamille Faye Vinluan-Jularbal, each individually and on behalf of all others similarly situated,

Plaintiffs,

v.

Similasan Corporation,

Defendant.

Case No. 5:23-cv-01984

CLRA VENUE DECLARATION

I, Mario Ortega, declare as follows:

1. I am a named Plaintiff in this action.

2. In fall 2022, I purchased Similasan Stye Eye Relief Eye Drops from a Walmart store, while living in Ontario, California.

3. I understand that, because I purchased the products in Ontario, California, the transaction occurred within the Central District of California, and this is a proper place to bring my California Consumer Legal Remedies Act claim.

I declare under penalty of perjury, under the laws of the United States and the State of California, that the foregoing is true and correct to the best of my knowledge.

Signature: DocuSigned by: Mario Ortega B1753A89627243E...

Mario Ortega

Dated: Septmember 27, 2023

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Attorney for Plaintiffs

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Mario Ortega and Kamille Faye Vinluan-Jularbal, each individually and on behalf of all others similarly situated,

Plaintiffs,

v.

Similasan Corporation,

Defendant.

Case No. 5:23-cv-01984

CLRA VENUE DECLARATION

I, Kamille Faye Vinluan-Julardal, declare as follows:

1. I am a named Plaintiff in this action.

2. On August 31, 2023, I purchased Similasan Pink Eye Relief Eye Drops from a Walmart store, while living in Elk Grove, California.

3. I understand that, because Similasan Corporation conducts business within the Central District of California by sellings its products there, this is a proper place to bring my California Consumer Legal Remedies Act claim.

I declare under penalty of perjury, under the laws of the United States and the State of California, that the foregoing is true and correct to the best of my knowledge.

Signature: DocuSigned by: 9842BB5B823F465... Kamille Faye Vinluan-Julardal

Dated: Septmember 27, 2023