UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

MAYA HEREDIA and EMMANUEL VEGA, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

ROHTO-MENTHOLATUM CO., LTD., ROHTO PHARMACEUTICAL CO., LTD., and THE MENTHOLATUM COMPANY,

Defendants.

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

INTRODUCTION

Plaintiffs Maya Heredia and Emmanuel Vega (collectively, the "Plaintiffs"), by and through their undersigned counsel, on behalf of themselves and all others similarly situated (the "Class"), bring this Class Action Complaint against Defendants Rohto-Mentholatum Co., Ltd., Rohto Pharmaceutical Co., Ltd., and The Mentholatum Company (collectively, the "Defendants"), based upon personal knowledge as to themselves and their own acts and experiences, and as to all other matters, upon information and belief, including investigation of counsel.

NATURE OF THIS ACTION

1. This is a class action brought individually by Plaintiffs on behalf of consumers who purchased Defendants' Rohto Cooling Eye Drops ALL-IN-ONE, Rohto Cooling Eye Drops Max Strength, Rohto Cooling Eye Drops Optic Glow, Rohto Cooling Eye Drops Digi Eye, Rohto Cooling Eye Drops Dry Aid, and Rohto Cooling Eye Drops Cool Relief (collectively, the "Product(s)").

2. The Products' labeling consistently and uniformly states that the Products are "Sterile" and each Product is marketed to relieve a number of eye symptoms.

3. However, on July 14, 2026, Defendants initiated a nationwide voluntary recall in conjunction with the United States Food and Drug Administration ("FDA") because of a "Lack of Assurance Sterility"[1], meaning the Products were not sterile as promised, and as required by the FDA for lawful sale.

4. The Recall was initiated by Defendants and involves nearly 12 million cartons of the Products.

5. The FDA designated the Recall as a Class II Recall, meaning the use of the Products may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

6. Pursuant to the Recall, consumers were instructed to discontinue use of the Products. However, Defendants failed to provide adequate notice of the Recall to ensure maximum reach to consumers of the Products, or adequate instructions to consumers to participate in the Recall. In fact, on the Rohto website, there is no mention of the Recall. Instead, when clicking on the Products, they simply say "sold out."[2]

7. As the designers, manufacturers, marketers, distributors, and sellers of the Products, Defendants knew or should have known that they lacked assurance sterility.

[1] *See* https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=99440 (the "Recall") (last accessed Aug. 11, 2026).

[2] *See e.g.*, https://rohtoeyedrops.com/products/rohto-all-in-one-multi-symptom-eye-drops (last accessed Aug. 11, 2026).

8. Defendants' design and formulation of the Products are not reasonably fit, suitable, or safe for their intended purpose and therefore Defendants breached their reasonable care and duties owed to Plaintiffs.

9. Had Plaintiffs and Class Members known about the true nature of the Products, including their lack of sterility at the time of purchase, they would not have purchased them. Indeed, had the lack of sterility been disclosed, the Products would not have been able to be lawfully retailed, distributed, and sold.

10. Plaintiffs, on behalf of themselves and Class Members, seek actual and statutory damages, costs of suit, reasonable attorneys' fees, and all other relief available under law and equity from Defendants, including punitive damages for their misconduct. Plaintiffs also seek class wide injunctive relief including: (i) a state-of-the-art notice program for the wide dissemination of a factually accurate and fully informative recall notice for the Products; and/or (ii) an offer of full refund to all Class Members, including those who no longer have the Products.

JURISDICTION AND VENUE

11. This Court has original jurisdiction over this controversy pursuant to 28 U.S.C. § 1332(d). The amount in controversy in this class action exceeds $5,000,000.00, exclusive of interest and costs, there are tens of thousands of Class Members, and there are numerous Class Members who are citizens of states other than Defendants' states of citizenship.

12. This Court has personal jurisdiction over Defendant, The Mentholatum Company, in this matter because Defendant is a resident of New York, and further the acts and omissions of Defendants giving rise to this action occurred in the state of New York.

13. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)(2) and (c) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District

and because Defendant, The Mentholatum Company, is headquartered within this District and Defendants transact business and/or have agents within this District; hence, Defendants have intentionally availed themselves of the laws and markets within this District.

PARTIES

Plaintiff Maya Heredia

14. Plaintiff Maya Heredia is a resident and citizen of California and, at all times relevant to this action, resided in Anaheim, California. Plaintiff Heredia purchased Defendants' Rohto All-in-One Cooling and Redness Reliever Multi-Symptom Relief Eye Drops several times, including in March 2026, and again on May 17, 2026, for $6.36 from Walmart in Anaheim, California.

15. Prior to purchasing the Product, Plaintiff Heredia saw and relied on Defendants' statements that the Product was "Sterile," and provided "Relief from Stinging, Red, Gritty, Watery, Irritated, Burning, Dry, Itchy Eyes." As a result, Plaintiff Heredia believed that the Product was sterile and safe for its stated use.

16. Plaintiff Heredia used the Rohto All-in-One Cooling and Redness Reliever Multi-Symptom Relief Eye Drops that she purchased as instructed.

17. The Rohto All-in-One Cooling and Redness Reliever Multi-Symptom Relief Eye Drops Plaintiff Heredia purchased were part of the Recall.

18. Plaintiff Heredia did not receive notice of the Recall from Defendants or Walmart. There is no notice of the Recall on Defendants' or Walmart's website. Accordingly, there are no instructions provided by Defendants or their retailers on how to seek a refund.

19. Plaintiff Heredia would not have purchased the Rohto All-in-One Cooling and Redness Reliever Multi-Symptom Relief Eye Drops had she known the Product was not sterile or safe for its stated use.

20. In making her purchases, Plaintiff Heredia paid a price premium due to Defendants' false and misleading marketing of the Rohto All-in-One Cooling and Redness Reliever Multi-Symptom Relief Eye Drops as sterile and safe for its stated use.

21. Plaintiff Heredia is not opposed to purchasing the Rohto All-in-One Cooling and Redness Reliever Multi-Symptom Relief Eye Drops or any of the Products in the future if they are properly marketed, using approved or generally recognized as safe and effective ingredients, and are not adulterated.

Plaintiff Emmanuel Vega

22. Plaintiff Emmanuel Vega is a resident and citizen of Illinois and, at all times relevant to this action, resided in Moline, Illinois. Plaintiff Vega purchased Defendants' Rohto Max Strength Redness Reliever Eye Drops, Rohto Ice All-in-One Multi-Symptom Relief Cooling Eye Drops and Rohto Digi-Eye Cooling Eye Drops several times, including in February and April 2023, April 20245 and January 16, 2026, for $5.51 from Amazon.com.

23. Prior to purchasing the Products, Plaintiff Vega saw and relied on Defendants' statements that the Products were "Sterile," and provided "Fast, Cooling Relief for Red, Dry, Itchy Eyes, Redness and Dryness Symptom Relief." As a result, Plaintiff Vega believed that the Products were sterile and safe for their stated use.

24. The Products Plaintiff Vega purchased were part of the Recall.

25. Plaintiff Vega did not receive notice of the Recall from Defendants or Amazon.com. There is no notice of the Recall on Defendants' or Amazon.com's website.

Accordingly, there are no instructions provided by Defendants or their retailers on how to seek a refund.

26. Plaintiff Vega would not have purchased the Rohto Max Strength Redness Reliever Eye Drops, Rohto Ice All-in-One Multi-Symptom Relief Cooling Eye Drops or Rohto Digi-Eye Cooling Eye Drops had he known the Products were not sterile or safe for their stated use.

27. In making his purchases, Plaintiff Vega paid a price premium due to Defendants' false and misleading marketing of the Rohto Max Strength Redness Reliever Eye Drops, Rohto Ice All-in-One Multi-Symptom Relief Cooling Eye Drops and Rohto Digi-Eye Cooling Eye Drops as sterile and safe for their stated use.

28. Plaintiff Vega is not opposed to purchasing the Rohto Max Strength Redness Reliever Eye Drops, Rohto Ice All-in-One Multi-Symptom Relief Cooling Eye Drops, Rohto Digi-Eye Cooling Eye Drops or any of the Products in the future if they are properly marketed, using approved or generally recognized as safe and effective ingredients, and are not adulterated.

Defendants

29. Defendant Rohto-Mentholatum Co., Ltd. is a corporation headquartered at No. 16, Street No. 5, Vietnam-Singapore Industrial Park (VSIP), Thuan Giao Ward, Thuan An City, Binh Duong Province, Vietnam.

30. Defendant Rohto Pharmaceutical Co., Ltd. is a corporation headquartered at Rohto Pharmaceutical Co., Ltd., 1-8-1 Tatsuminishi, Ikuno-ku, Osaka 544-8666, Japan.

31. Defendant The Mentholatum Company is a corporation existing under the laws of the State of Delaware with its principal place of business in Orchard Park, New York.

32. The Products were manufactured by Rohto-Mentholatum in Vietnam and distributed by The Mentholatum Company of Orchard Park, New York.

FACTUAL ALLEGATIONS

33. Shown below, each Product promises that it is Sterile on the front of the label, where it cannot be missed by consumers. Further, depending on the Product, this could include red, dry, itchy, irritated, burning, gritty, watery, stinging eyes or redness.


ROHTO®
Cooling Eye Drops
MAX STRENGTH
Redness Reliever, Lubricant Eye Drops
MAXIMUM
REDNESS
RELIEF
ROHTO®
MAX
STRENGTH
Redness Reliever,
Lubricant Eye Drops
soothes up to 8 hrs.
with CoolSense™ Technology
Fast Acting
STERILE


ROHTO®
Cooling Eye Drops
OPTIC GLOW™
Redness Reliever, Lubricant Eye Drops
Soothes, Brightens and Hydrates
ROHTO®
OPTIC
GLOW™
Redness Reliever,
Lubricant Eye Drops
Fast Acting
Redness Relief
Dual Lubricants


ROHTO®
Cooling Eye Drops
DIGI-EYE®
Lubricant, Redness Reliever Eye Drops
ROHTO®
DIGI-EYE®
Lubricant/Redness Reliever Eye Drops
See back for opening instruction
0.4 FL OZ (13 mL) Sterile
STERILE
0.4 FL OZ (13mL)
soothes up to 8 hrs.
Relieves Symptoms of Digital Eye Strain


ROHTO®
Cooling Eye Drops
DRY AID®
Lubricant Eye Drops
ADVANCED DRY EYE TREATMENT
LIQUID SHIELD™ TECHNOLOGY
ROHTO®
DRY AID®
Lubricant Eye Drops
0.34 FL OZ (10 mL)
Sterile
STERILE
0.34 FL OZ (10mL)
Soothes up to 12 HRS Long-Lasting
Fast Acting
Repairs Natural Tear Film
Superior Comfort
Non-blurring

34. Defendants market the Products in response to consumer demand for "safe" treatment of common health concerns for eye irritation and redness.

35. However, on July 14, 2026, Defendants initiated a nationwide voluntary Recall in conjunction with the FDA because of a "Lack of Assurance Sterility"[3], meaning the Products were not sterile as promised, and as required by the FDA for lawful sale. Sterility in ophthalmic drugs is particularly important because contamination of these drugs pose a potential heightened risk of harm to users because such drugs are applied to the eyes and bypass some of the body's natural defenses. Accordingly, under the law, any drug used in the eyes must be sterile to reduce the risk of infection. *See* 21 C.F.R. § 200.50. Thus, if an ophthalmic drug is not sterile, it is regarded as adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act

[3] *See* https://www.accessdata.fda.gov/scripts/ires/index.cfm?Event=99440 ("Recall") (last accessed Aug. 11, 2026).

("FDCA"), and, further, deemed misbranded within the meaning of section 502(j) of the FDCA. *Id.* This includes over-the-counter drugs such as the Products. *See* 21 C.F.R. §§ 349.1 & 349.3(a) & (f).

36. The Recall was initiated by Defendants and involves nearly 12 million cartons of the Products.

37. The FDA designated the Recall as a Class II Recall, meaning that using the Products may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. Because they are adulterated under the FDCA, and parallel state laws, they are not able to be distributed or sold. 21 U.S.C. § 331; *see also* CAL. HEALTH & SAFETY CODE §§ 111295, 111300.

38. Pursuant to the Recall, consumers were instructed to discontinue use of the Products. However, Defendants failed to provide adequate notice of the Recall to ensure maximum reach to consumers of the Products, or adequate instructions to consumers to participate in the Recall. In fact, on the Rohto website, there is no mention of the Recall. Instead, when clicking on the Products, they simply say "sold out" yet the webpage continues to market the Products for their intended use.[4]

[4] *See e.g.*, https://rohtoeyedrops.com/products/rohto-all-in-one-multi-symptom-eye-drops. (last accessed Aug. 11, 2026).

ROHTO® Cooling Eye Drops

HOME SHOP ABOUT US WHERE TO BUY Search Account Cart - 0

Rohto® All-In-One Multi-Symptom Eye Drops

Sold out

Relieve up to 8 symptoms with Rohto® All-In-One cooling eye irritation drops.

Intense cooling – Rohto® All-In-One Multi-Symptom Eye Drops soothes up to 8 indoor and outdoor eye symptoms! Just 1 or 2 drops relieves redness, dryness, itching, burning, gritty, irritated, stinging and watery eyes, AND soothes for up to 8 hours. With CoolSense™ Technology, experience instant cooling and long-lasting comfort. Rohto® All-In-One Multi-Symptom Eye Drops clear away symptoms fast!

- Rohto® All-In-One Multi-Symptom Eye Drops delivers cooling comfort to irritated eyes due to late nights, eye strain, and environmental conditions.
- Cooling lubricant dry eye drops that soothe itch and burn, relieve redness, and hydrate dry eyes.
- **CoolSense™ Technology** brings instant cooling and long-lasting comfort.
- Compact single drop dispenser for convenient use.

Sold out

Ingredients +

Directions +

Free Shipping on All Orders Over $50

Use as directed.

Rohto® All-In-One is safety tested and meets FDA requirements

Read how Rohto® is committed to your safety.

5

You ma

Rohto® Cool Relief Cooling Eye Drops

Sold out

Rohto® Digi Eye® Digital Eye Strain Eye Drops

Sold out

[5] *Id.*

6

Rohto® Max Strength Redness Relief Eye Drops

Sold out

Rohto® Dry Aid® Eye Drops for Dry Eyes

Sold out

7

[6] *Id.*

[7] *Id.*

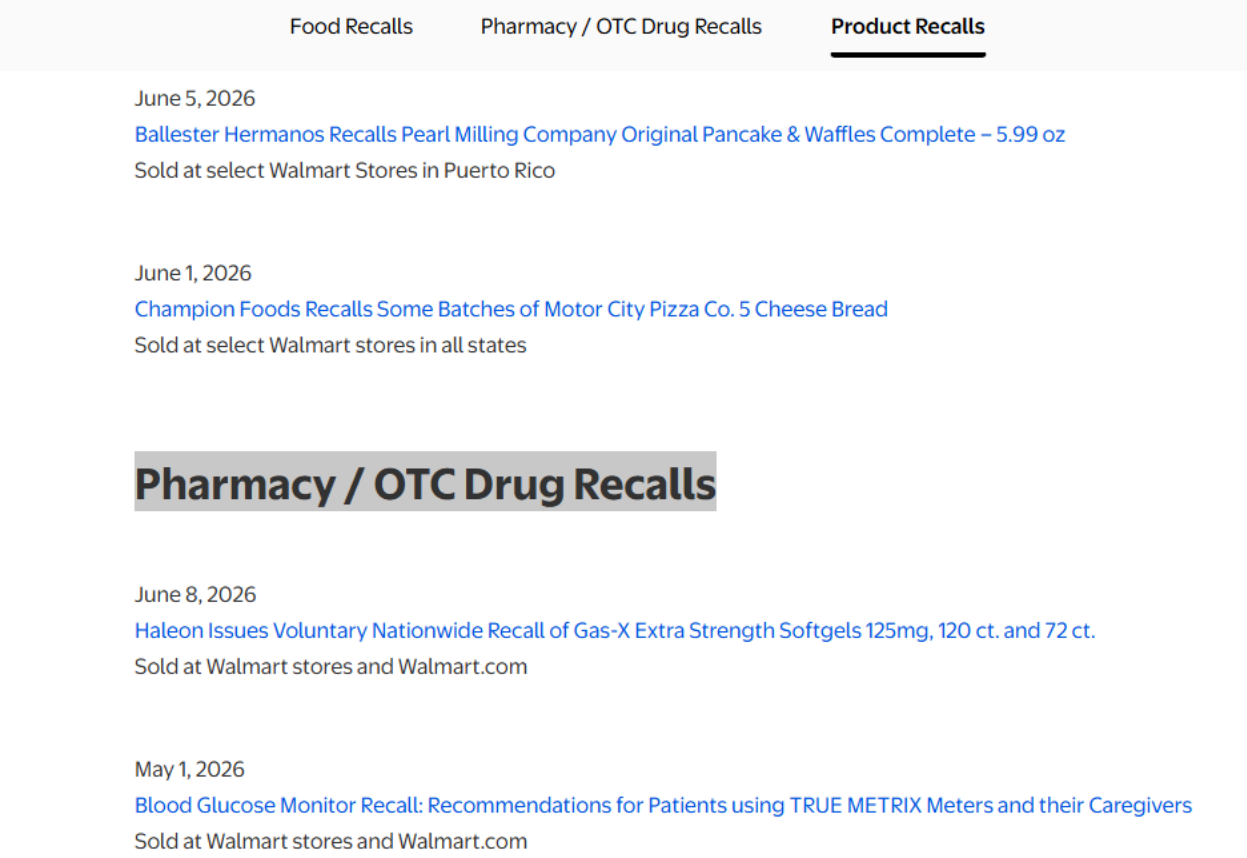
[8]

39. Even more, links to the Products' Facebook and Instagram pages do not include information about the Recall.[9] The same is true of Defendants' retailers. For example, Plaintiff Heredia purchased the Product from Walmart. However, the Walmart website's recall webpage has no mention of the Recall in the appropriate "Pharmacy / OTC Drug Recalls" section:[10]

[8] *Id.*

[9] *See* https://www.facebook.com/rohtoeyedrops/ and https://www.instagram.com/rohtoeyedrops/ (last accessed Aug 11, 2026)

[10] *See* https://corporate.walmart.com/recalls (last accessed Aug 26, 2026).



Food Recalls Pharmacy / OTC Drug Recalls **Product Recalls**

June 5, 2026
Ballester Hermanos Recalls Pearl Milling Company Original Pancake & Waffles Complete – 5.99 oz
Sold at select Walmart Stores in Puerto Rico

June 1, 2026
Champion Foods Recalls Some Batches of Motor City Pizza Co. 5 Cheese Bread
Sold at select Walmart stores in all states

Pharmacy / OTC Drug Recalls

June 8, 2026
Haleon Issues Voluntary Nationwide Recall of Gas-X Extra Strength Softgels 125mg, 120 ct. and 72 ct.
Sold at Walmart stores and Walmart.com

May 1, 2026
Blood Glucose Monitor Recall: Recommendations for Patients using TRUE METRIX Meters and their Caregivers
Sold at Walmart stores and Walmart.com

40. Similarly, Amazon.com, where Plaintiff Vega made his Product purchases, fails to identify the Recall associated with the Products.[11]

41. Indeed, even a Google search regarding the Recall shows a number of news stories regarding the Recall, but no official notice from Defendants or their retailers with instructions on how to seek compensation. In the first three pages of results, no information regarding how to seek compensation under the Recall can be found. This is because Defendants fail to provide adequate notice of the Recall and do not provide any specific means of seeking compensation thereunder. Instead, consumers are left to seek compensation from the retailers of the Products (if at all) which

[11] *See* https://www.amazon.com/product-safety-alerts?search=Rohto (last accessed Sept. 8, 2026).

may be difficult, if not impossible, because these are low cost, consumable items. Consumers are unlikely to keep receipts for such Products and will likely discard the packaging after the item is consumed. Without some direct compensation mechanism from Defendants, and adequate notice of such mechanism, any claimed benefits under the Recall are illusory.

42. Thus, it is unreasonably difficult for consumers to learn about the Recall, how to participate in the Recall, or whether and how to obtain remuneration relating to the Recall.

TOLLING AND ESTOPPEL OF STATUTE OF LIMITATIONS

43. Defendants continuously manufactured, marketed and sold the Products to unsuspecting customers. At all times relevant, it continuously represented that the Pools were sterile and fit for their intended use.

44. By continuously repeating these false representations and failing to disclose that the Products were not sterile as promised, Defendants engaged in a continuing wrong sufficient to render inapplicable any statute of limitations that Defendants might seek to apply.

45. As the designers, manufacturers, marketers, distributors, and sellers of the Products, Defendants knew or should have known that they lacked assurance sterility.

46. Defendants' knowledge of lack of sterility is evidenced by, amongst other things, the Recall.

47. Thus, at all relevant times, Defendants indisputably possessed continuous knowledge of the lack of sterility, and yet Defendants knowingly continued to allow the sale of the Products. Plaintiffs' and other Class Members' claims are therefore not time barred.

48. Moreover, even after the Recall, there is no evidence that news of the Defendants' Recall or lack of sterility reached all purchasers of the Products.

49. Plaintiffs and other Class Members could not reasonably discover and could not know facts that would cause a reasonable person to suspect that Defendants knowingly misrepresented and failed to disclose material information within their knowledge about the Products' lack of sterility to consumers in the United States and elsewhere. Therefore, no potentially relevant statute of limitations applies.

50. Throughout the time period relevant to this action, Defendants misrepresented and concealed from, and failed to disclose to, Plaintiffs and the other Class Members vital information about the Products' lack of sterility described herein.

51. Defendants kept Plaintiffs and the other Class Members ignorant of vital information essential to pursue their claims. As a result, neither Plaintiffs nor the other Class Members could have discovered the Products' lack of sterility, even upon reasonable exercise of due diligence.

52. Defendants had a duty to disclose to Plaintiffs and the Class Members the true quality and nature of the Products and that the Products were not sterile.

53. Instead, Defendants continued to market the Products as sterile and suitable for their intended purpose to further profit from the sale of its popular Products and prevent Plaintiffs and other Class Members from seeking redress.

54. Plaintiffs and the other Class Members justifiably relied on Defendants to disclose the true nature of the Products they purchased and/or owned because the sterility of the Products was not discoverable by Plaintiffs and the other Class Members through reasonable efforts.

55. Defendants' affirmative acts of concealment, including their continued marketing of the Products as reasonably fit, suitable or safe for their intended purpose while possessing

knowledge of the Products' lack of sterility, further support estoppel and tolling of any applicable limitations period.

FED. R. CIV. P. 9(b) ALLEGATIONS

56. Although Defendants are in the best position to know information about the design, manufacture, distribution, and sale of the Products as well as the facts surrounding the Products' lack of sterility during the relevant timeframe, to the extent necessary, Plaintiffs satisfy the requirements of Rule 9(b) by alleging the following facts with particularity:

57. **WHO**: Defendants made material misrepresentations and/or omissions of fact through their marketing, on their website, product packaging, warranties, and labeling, which include statements such that the Products are sterile and are safe and suitable for their intended use.

58. **WHAT**: Defendants' conduct here was, and continues to be, fraudulent because they affirmatively misrepresented and omitted and concealed that the Products are defective, unsafe, and unsuitable for their intended use in that the Products are not sterile. Defendants' employees and representatives made affirmative misrepresentations as a part of Defendants' marketing and labeling of the Products to Plaintiffs and Class Members at the time of purchase regarding the same qualities. Defendants failed to adequately warn Plaintiffs and Class Members that the Products were not sterile, were not suitable for their intended use, and the Products' lack of sterility presented a risk of harm. Further, Defendants' conduct has the effect of deceiving Plaintiffs and Class Members into believing that the Products are not defective, and instead, are suitable for their intended use. Defendants knew, or should have known, the sterility of the Products is material to the reasonable consumer, including Plaintiffs and Class Members, and

impacts their purchasing decisions, and yet Defendants affirmatively label the Products as Sterile and are unsafe and unsuitable for their intended use.

59. **WHEN**: Defendants made material misrepresentations and/or omissions during the putative class periods and at the time Plaintiffs and Class Members purchased the Products, prior to and at the time Plaintiffs and Class Members made claims after realizing the Products were not sterile and continuously throughout the applicable class periods.

60. **WHERE**: Defendants' marketing message and omissions were uniform and pervasive, carried through material misrepresentations and omissions on the Products' labeling and packaging, their website(s) and the websites of authorized retailers.

61. **HOW**: Defendants made material misrepresentations of material facts regarding the Products, including, but not limited to, the Products' sterility as well as the associated risks.

62. **WHY**: Defendants made the material misrepresentations and/or omissions detailed herein for the express purpose of inducing Plaintiffs, Class Members, and all reasonable consumers to purchase and/or pay a premium price for the Products, the effect of which was Defendants profited by selling the Products to many thousands of consumers.

63. **INJURY**: Plaintiffs and Class Members purchased, paid a premium, or otherwise paid more for the Products when they otherwise would not have absent Defendants' misrepresentations and omissions.

CLASS ACTION ALLEGATIONS

64. Plaintiffs bring this action individually and as representatives of all those similarly situated, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3) on behalf of following Nationwide Class:

> During the fullest period allowed by law, all persons who purchased the Products in the United States for personal use and not resale, until the date notice is

disseminated.

65. Plaintiffs bring this action individually and as representatives of all those similarly situated, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3) on behalf of following Multi-State Consumer Protection Class:

> During the fullest period allowed by law, all persons who purchased a Product in the state of California, Florida, Illinois, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, and Washington,[12] for personal use and not resale, until the date notice is disseminated.

66. Plaintiff Heredia further brings this action individually and as a representative of all those similarly situated, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3) on behalf of the following California Class:

> During the fullest period allowed by law, all persons who purchased the Products in the State of California for personal use and not resale, until the date notice is disseminated.

67. Plaintiff Vega further brings this action individually and as a representative of all those similarly situated, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3) on behalf of the following Illinois Class:

> During the fullest period allowed by law, all persons who purchased the Products in the State of Illinois for personal use and not resale, until the date notice is disseminated.

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[12] While discovery may alter the following, Plaintiffs seek to certify a Multi-State Consumer Protection Class consisting of persons in the following states (and implicating the following statutes): California (Cal. Bus. & Prof. Code §§ 17200, *et seq*.); Florida (Fla. Stat. §§ 501.201, *et seq*.); Illinois (815 Ill. Comp. Stat. 502/1, et seq.); Massachusetts (Mass. Gen. Laws Ch. 93A, *et seq*.); Michigan (Mich. Comp. Laws §§ 445.901, *et seq*.); Minnesota (Minn. Stat. §§ 325F.67, *et seq*.); Missouri (Mo. Rev. Stat. §§ 407.010, *et seq*.); New Jersey (N.J. Stat. §§ 56:8-1, *et seq*.); New York (N.Y. Gen. Bus. Law §§ 349, *et seq*.); and Washington (Wash. Rev. Code §§ 19.86.010, *et seq*.). *See Langan v. Johnson & Johnson Consumer Cos., Inc*., 897 F.3d 88, 96 (2d Cir. 2018); *Mancuso v. RFA Brands, LLC*, 454 F. Supp. 3d 197, 201, 204 (W.D.N.Y. 2020); *see also Benson v. Newell Brands, Inc.*, No. 19 C 6836, 2021 WL 5321510, at *9-10 (N.D. Ill. Nov. 16, 2021) (certifying a similar multi-state consumer protection class), *id*. at ECF No. 337 (Dec. 1, 2025) (denying motion to decertify the multi-state consumer protection class).

68. Specifically excluded from these definitions are: (1) Defendants, any entity in which Defendants have a controlling interest, and their legal representatives, officers, directors, employees, assigns and successors; (2) the Judge to whom this case is assigned and any member of the Judge's staff or immediate family; and (3) Class Counsel. Plaintiffs reserve the right to amend the Class definitions as necessary.

69. The Nationwide Class, Multi-State Consumer Protection Class, California Class and Illinois Class are referred to collectively throughout the Complaint as the "Class." Members of the Class are referred to as "Class Members."

70. Certification of Plaintiffs' claims for class-wide treatment are appropriate because Plaintiffs can prove the elements of the claims on a class-wide basis using the same evidence that individual Class Members would use to prove those elements in individual actions alleging the same claims.

71. **Numerosity**: The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class Members is presently unknown, it likely consists of thousands or hundreds of thousands of consumers as the Recall includes nearly 12,000,000 cartons of the Products. The number of Class Members can be further determined by sales information and other records. Moreover, joinder of all potential Class Members is not practicable given their numbers and geographic diversity. The Class is readily identifiable from information and records in the possession of Defendants and their authorized retailers.

72. **Typicality**: The claims of the representative Plaintiffs are typical in that Plaintiffs, like all Class Members, purchased the Products that were manufactured, marketed, advertised, distributed, and sold by Defendants. Furthermore, the factual basis of Defendants' misconduct is common to all Class Members. By advancing their claims, Plaintiffs will also advance the claims

of all Class Members because Defendants' unlawful conduct caused and continues to cause Class Members to suffer similar harm.

73. **Commonality**: Common questions of law and fact exist as to all members of the Class. These questions predominate over questions that may affect only individual Class Members because Defendants acted on grounds generally applicable to the Class. Such common legal or factual questions include, *inter alia*:

a. Whether the Products were manufactured are being sold in violation of the FDCA and similar state laws;

b. Whether Defendants' course of conduct alleged herein violates the statutory and common law claims pled in this Complaint;

c. Whether Defendants' representations regarding their Products are misleading and deceptive;

d. Whether Defendants omitted or failed to disclose material information to Plaintiffs and Class Members regarding the Products;

e. Whether Defendants' representations and omissions concerning their Products involved representations and omissions of material facts;

f. Whether Defendants knew or should have known their representations regarding their Products are misleading and deceptive;

g. Whether Defendants engaged in false, deceptive, or misleading conduct in the marketing, advertising, labeling, and sale of the Products;

h. Whether Defendants were unjustly enriched by retaining monies from the sale of the Products;

i. Whether certification of each Class is appropriate under Rule 23;

j. Whether Plaintiffs and Class Members have been injured by Defendants' misconduct, and the proper measure of their losses as a result of those injuries;

k. Whether Plaintiffs and Class Members are entitled to damages, including compensatory, exemplary, and statutory damages, and the amount and nature of such damages; and

l. Whether Plaintiffs and the members of each Class are entitled to declaratory, equitable or injunctive relief, and/or other relief, and the scope of such relief.

74. **Adequacy**: Plaintiffs will fairly and adequately protect the interests of the proposed Class as their interests do not conflict with the interests of the members of the proposed Classes they seek to represent, and they retained counsel competent and experienced in class action litigation. Thus, the interests of the members of the Class will be fairly and adequately protected by Plaintiffs and their counsel.

75. **Predominance**: Pursuant to Rule 23(b)(3), the common issues of law and fact identified in this Complaint predominate over any individual issues. No inquiry into individual conduct is necessary; all that is required is a narrow focus on Defendants' misconduct detailed at length in this Complaint.

76. **Superiority**: 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 impractical. It would be unduly burdensome to have individual litigation of thousands of individual claims in separate lawsuits, every one of which would present the issues presented in the Complaint. Further, because the damages suffered by any individual Class Member may be relatively modest in relation to the cost of litigation, the expense and burden of individual litigation make it difficult, if not impossible. In addition, many of the Class Members may be unaware that

claims exist against Defendants. Class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would entail. Individualized litigation creates potential for inconsistent or contradictory judgments and increases the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court. Furthermore, Defendants transact substantial business in New York and will not be prejudiced or inconvenienced by the maintenance of this class action in this forum.

77. **Declaratory and Injunctive Relief**: Pursuant to Rule 23(b)(2), declaratory and injunctive relief is appropriate in this matter. Defendants acted, or refused to act, on grounds generally applicable to Plaintiffs and Class Members, thereby making appropriate final injunctive relief and declaratory relief, as described below, with respect to Class Members as a whole. Unless a class-wide injunction is issued, consumers will continue to remain uninformed about the Recall and how to receive remuneration under the Recall, if at all. Members of the Class will continue to be misled, harmed and denied their rights under the law. Plaintiffs and the Class do not have an adequate remedy at law because damages alone will not stop Defendants' unlawful conduct. Additionally, Plaintiffs seek restitution if monetary damages are not available. But even if damages were available, such relief would not be adequate to address the injury suffered by Plaintiffs and the Class.

CAUSES OF ACTION

78. Plaintiffs do not plead, and hereby disclaim, causes of action under the FDCA and regulations promulgated thereunder by the FDA. Plaintiffs rely on the FDCA and FDA regulations

only to the extent such laws and regulations are separately enacted as state law or regulation or provide a predicate basis of liability under the state and common laws cited in the following causes of action:

COUNT I

California Consumers Legal Remedies Act
Violation of California Civil Code §§ 1750, *et seq*. ("CLRA")
(On Behalf of Plaintiff Heredia and the California Class)

79. Plaintiff Heredia incorporates by reference the allegations contained in paragraphs 1 through 78 as if fully set forth herein.

80. Plaintiff Heredia brings this cause of action on behalf of herself, and the California Class members, all of whom are similarly situated consumers within the meaning of CAL. CIV. CODE § 1781.

81. Defendants' acts violated the CLRA, which was enacted to protect consumers from being victimized and deceived by advertisers, distributors, and sellers like Defendants. Defendants regularly transact business in California and engaged in misconduct that had a direct, substantial, foreseeable, and intended effect of injuring people in California.

82. The CLRA prohibits unfair methods of competition and unfair or deceptive acts or practices in connection with the sale of consumer goods. Defendants violated several prohibitions of the CLRA.

83. Defendants violated CAL. CIV. CODE § 1750(a)(2), (5), and (9) by representing the source, sponsorship, and approval, of the Products by representing that Defendants met their obligations to ensure that the Products are "STERILE" as advertised and that the Products were not adulterated, therefore legal to sell.

84. Defendants violated CAL. CIV. CODE § 1750(a)(6) and (7) by representing the Products were not deteriorated unreasonably or altered (*e.g.*, that the Products were sterile), when they were deteriorated unreasonably or altered.

85. Defendants' acts, omissions, and concealment of material health and safety information are ongoing and continue to cause harm. Defendants continue to market, advertise, and sell the Products to the public, even though they are adulterated. Further, Defendants continue to market themselves as responsible drug manufacturers and sellers who sells safe and legal products when they do not.

86. Defendants also failed to provide adequate notice of their Recall or a reasonable mechanism for consumers to receive compensation thereunder.

87. Defendants engaged in these deceptive practices for significant financial gain, which is unfair, unreasonably dangerous to Plaintiff Heredia and the California Class, and not outweighed by any benefit. Omitting and/or concealing material human health and safety information and that the Products are adulterated (and therefore cannot be legally sold) is unethical, unscrupulous, and offensive.

88. Plaintiff Heredia and the California Class suffered ascertainable economic loss as a result of Defendants' misconduct because they bought Products they would not have otherwise bought, or paid less for them. Indeed, it was unlikely that the Products would have been sold, as they were adulterated, that the truth been known.

89. Pursuant to the provisions of Cal. Civ. Code § 1782(a), concurrently with the filing of this Complaint, Plaintiff Heredia, through counsel, mailed Defendants a letter by certified mail addressed to their headquarters, providing notice of Defendants' alleged violations of the CLRA, demanding that Defendants correct such violations, and providing Defendants with the opportunity

to correct their business practices. Plaintiff Heredia specifically identified which provisions of Cal. Civ. Code § 1770 Defendants are alleged to have violated.

90. Pursuant to California Civil Code § 1780, Plaintiff Heredia seeks injunctive relief, her reasonable attorneys' fees and costs, and any other relief that the Court deems proper. Should Defendants not response to Plaintiff Heredia's CLRA demand letter, Plaintiff Heredia will amend her Complaint to seek additional monetary relief, which may include statutory damages.

COUNT II

California Unfair Competition Law
Violation of California Business & Professions Code §§ 17200, *et seq.* ("UCL")
(On Behalf of Plaintiff Heredia and the California Class)

91. Plaintiff Heredia incorporates by reference the allegations contained in paragraphs 1 through 78 as if fully set forth herein.

92. Plaintiff Heredia brings this cause of action on behalf of herself, and all members of the California Class, all of whom are similarly situated consumers.

93. California's Unfair Competition Law, CAL. BUS. & PROF. CODE §§ 17200, *et seq*., prohibits "unlawful, unfair, or fraudulent business act or practices" and "unfair, deceptive, untrue or misleading advertising." Defendants regularly transact business in California and engaged in misconduct that had a direct, substantial, foreseeable, and intended effect of injuring people in California.

94. Defendants misrepresented their Products in advertising, labels, and containers and misled Plaintiff Heredia, the California Class, and the public about the characteristics, purity, quality, approval, and safety of the Products. Defendants led Plaintiff Heredia and the California Class, and the public to believe the Products were "STERILE" and safe, legal to sell, and had characteristics, purity, and quality that the Products did not have.

95. Defendants' advertising, online representations, labeling, and packaging of the Products were misleading, fraudulent, and deceptive. Defendants knew through the Products' development, formulation, manufacturing, and quality control that, the Products were not "STERILE."

96. Defendants omitted material health and safety information when misrepresenting that the Products were legal to sell as Over-the-Counter ("OTC") drugs, when they were actually adulterated.

97. Defendants' acts and omissions were likely to deceive reasonable consumers and the public. Reasonable consumers expect that Defendants' Products are "STERILE," legally sold as OTC drugs, and are not adulterated.

98. Had Defendants been truthful in their advertising, labeling, packaging, and online statements about the Products, including that the Products were not "STERILE" rendering the Products adulterated, and illegal to sell, Plaintiff Heredia and the California Class would not have bought the Products, or paid less for them.

99. Defendants' acts, omissions, and concealment of material health and safety information are ongoing and continue to cause harm. Defendants continue to market, advertise, and sell the Products to the public, even though they are adulterated. Further, Defendants continue to market themselves as responsible drug manufacturers and sellers who sells safe and legal products when they are not.

100. Defendants also failed to provide adequate notice of their Recall or a reasonable mechanism for consumers to receive compensation thereunder.

101. Plaintiff Heredia seeks an order enjoining Defendants from continuing to conduct business through or unlawful acts and practices.

102. Defendants' conduct is ongoing and continuing, such that prospective injunctive relief is necessary, especially given Plaintiff Heredia's desire to purchase the Products in the future if she can be assured that the Products are sterile.

103. Plaintiff Heredia seeks restitution if monetary damages are not available. Indeed, restitution under the UCL can be awarded in situations where the entitlement to damages may prove difficult. But even if damages were available, such relief would not be adequate to address the injury suffered by Plaintiff Heredia and the California Class. Unlike damages, the Court's discretion in fashioning equitable relief is very broad. Thus, restitution would allow recovery even when normal consideration associated with damages would not.

"Unfair Prong"

104. Under the UCL, a challenged activity is "unfair" when any injury it causes outweighs any benefits provided to consumers and the injury is one that the consumers themselves could not reasonably avoid.

105. Defendants' practice of marketing and selling the Products as sterile, safe, and suitable for their intended purpose and failing to effectively disclose to consumers that Products were adulterated provides no benefit to consumers; rather, it harms them. By concealing this material information, Defendants cause consumers to purchase Products that fail to meet their reasonable expectations, overpay for Products they believed were fit for their marketed use, and receive Products that pose a greater risk than what they were led to believe. Consumers are deprived of the ability to make informed decisions and cannot avoid the injuries caused by Defendants' deceptive labeling and advertising. Accordingly, the injuries resulting from Defendants' deceptive conduct far outweigh any purported benefits.

106. Defendants engaged in these illegal practices for significant financial gain, which are unlawful and violate state and federal drug laws, are unreasonably dangerous to Plaintiff Heredia and the California Class, and not outweighed by any benefit. Marketing adulterated drugs, and failing to comply with FDCA regulations in a systematic manner, is unethical, unscrupulous, and offensive.

107. Some courts conduct a balancing test to decide if a challenged activity amounts to unfair conduct under California Business and Professions Code Section 17200. They weigh the utility of the defendant's conduct against the gravity of the harm to the alleged victim.

108. Here, Defendants' conduct with regard to its uniformly mislabeled Products has no legitimate utility and financially harms consumers. Any potential utility from Defendants' conduct is vastly outweighed by the gravity of the harm caused to consumers, who are unknowingly exposed to the adulterated Products and unjustly pay a premium for Products that fail to meet their reasonable expectations.

109. Some courts require that unfairness must be tethered to some legislative declared policy or proof of some actual or threatened impact on competition.

110. Defendants' conduct constitutes "unfair" business acts and practices within the meaning of the UCL, in that their conduct was injurious to consumers, offended public policy, and was unethical and unscrupulous.

111. Defendants' labeling and advertising of the Products, as alleged herein, is deceptive, misleading, and unreasonable, and constitutes unfair conduct. Further, Defendants' conduct was unfair because they sold adulterated Products and now, seek to protect their bottom line by refusing to adequately provide refunds for those Products.

112. Defendants knew, or should have known, of their unfair conduct. Defendants' material representations and omissions constitute unfair business practices within the meaning of California Business and Professions Code Section 17200.

113. Reasonably available alternatives existed that would have allowed Defendants to further their legitimate business interests without engaging in the deceptive conduct described herein. Defendants could have refrained from falsely representing their Products or could have provided clear warnings on the Products' labels to inform consumers of their adulteration.

114. Plaintiff Heredia and California Class Members suffered injury in fact, lost money and were exposed to the safety hazards associated with the adulterated Products as a result of Defendants' unfair conduct. Plaintiff Heredia and California Class Members paid an unwarranted premium for the Products, believing they were fit for their marketed purpose and sterile. Specifically, Plaintiff Heredia and California Class Members paid for Products they reasonably believed were sterile, safe, and suitable for their intended purpose. Had they known the truth, Plaintiff Heredia and California Class Members would not have purchased the Products or would have paid substantially less for them. Accordingly, Plaintiff Heredia and California Class Members seek damages, restitution, and/or disgorgement of ill-gotten gains pursuant to the UCL.

"Fraudulent" Prong

115. The UCL considers conduct fraudulent (and prohibits said conduct) if it is likely to deceive members of the public.

116. Defendants employed their material omissions, partial representations, and affirmative misrepresentations concerning the adulterated Products with the intent to sell the Products to consumers, including Plaintiff Heredia and California Class Members. Defendants' omissions and affirmative misrepresentations were deceptive, and Defendants knew, or should

have known, of their deceptive nature. By marketing and labeling the Products as sterile, safe, and suitable for their intended purpose while failing to disclose to consumers that Products were adulterated, Defendants misled consumers into believing the Products are fit for their intended use. Both Defendants' omissions, partial representations, and affirmative misrepresentations are likely to mislead reasonable consumers, as they pertain to fitness for the marketed use, which is material to the purchasing decisions of the average, ordinary, and reasonable consumer.

117. As alleged herein, the omissions, partial representations, and affirmative misrepresentations by Defendants constitute a fraudulent business practice in violation of California Business & Professions Code Section 17200.

118. Plaintiff Heredia and California Class Members reasonably and detrimentally relied on Defendants' omissions, partial representations, and affirmative misrepresentations to their detriment in that they purchased the Products.

119. Reasonably available alternatives existed that would have allowed Defendants to further their legitimate business interests without engaging in the deceptive conduct described herein. Defendants could have provided clear warnings on the Products' labels to inform consumers of Products' adulterated nature, or they could have manufactured the Products in accordance with their sterile representations.

120. The conduct alleged herein occurred in Defendants' business. Defendants' wrongful conduct was part of a pattern or generalized course of conduct.

121. Plaintiff Heredia and California Class Members suffered injury-in-fact, lost money and were exposed to increased risks as a result of Defendants' fraudulent conduct. Plaintiff Heredia and California Class Members paid an unwarranted premium for the Products, believing they were not adulterated. Specifically, Plaintiff Heredia and California Class Members paid for Products

they reasonably believed were sterile. Had they known the truth, Plaintiff Heredia and California Class Members would not have purchased the Products or would have paid substantially less for them. Accordingly, Plaintiff Heredia and California Class Members seek damages, restitution and/or disgorgement of ill-gotten gains pursuant to the UCL.

"Unlawful Prong"

122. The UCL identifies violations of other laws as unlawful practices that the unfair competition law makes independently actionable.

123. Defendants' labeling of the Products, as alleged herein, violates the Sherman law, the FDCA, the CLRA, the FAL and the Song-Beverly Consumer Warranty Act, as set forth herein in the sections regarding those causes of action.

124. Defendants' conduct in making the omissions, partial representations, and affirmative misrepresentations described herein constitute a knowing failure to adopt policies in accordance with and/or adherence to applicable laws, as set forth herein, all of which are binding upon and burdensome to its competitors. This conduct engenders an unfair competitive advantage for Defendants, thereby constituting an unfair, fraudulent, and/or unlawful business practice under California Business & Professions Code sections 17200-208. Additionally, Defendants' omission of material facts, as set forth herein, violates California Civil Code sections 1572, 1573, 1709, 1710, 1711 and 1770, as well as the common law.

125. Defendants' packaging, labeling, and advertising of the Products, as alleged herein, are deceptive, misleading, and unreasonable, and constitute unlawful conduct. Defendants knew, or should have known, of their unlawful conduct.

126. Defendants had reasonably available alternatives to further their legitimate business interests, other than the conduct described herein. Defendants could have manufactured the

Products in compliance with applicable regulations and/or in compliance with the Products' representation of sterile.

127. All of the conduct alleged herein occurred in Defendants' business. Defendants' wrongful conduct is part of a pattern or generalized course of conduct.

128. Plaintiff Heredia and California Class Members suffered injury-in-fact, lost money and were exposed to increased risks as a result of Defendants' unlawful conduct. Plaintiff Heredia and California Class Members paid an unwarranted premium for the Products, believing they were fit for their marketed use and were not adulterated. Specifically, Plaintiff Heredia and California Class Members paid for Products they reasonably believed were sterile. Had they known the truth, Plaintiff Heredia and California Class Members would not have purchased the Products or would have paid substantially less for them. Accordingly, Plaintiff Heredia and California Class Members seek damages, restitution and/or disgorgement of ill-gotten gains pursuant to the UCL.

129. Plaintiff Heredia and California Class Members seek all monetary relief allowed by law, including restitution stemming from Defendants' unfair, fraudulent, and unlawful business practices; reasonable attorneys' fees and costs under California Code of Civil Procedure § 1021.5.

130. On behalf of herself and the California Class, Plaintiff Heredia also seeks an order for the restitution of all monies from the sale of the Products, which were unjustly acquired through acts of fraudulent, unfair, or unlawful competition.

COUNT III

California False Advertisement Law
Violation of California Business & Professions Code §§ 17500, *et seq*. ("FAL")
(On Behalf of Plaintiff Heredia and the California Class)

131. Plaintiff Heredia incorporates by reference the allegations contained in paragraphs 1 through 78 as if fully set forth herein.

132. Plaintiff Heredia brings this cause of action on behalf of herself, and all members of the California Class, all of whom are similarly situated consumers.

133. California's Unfair Competition Law, CAL. BUS. & PROF. CODE §§ 17500, *et seq*., prohibits "unfair, deceptive, untrue or misleading advertising." Defendants regularly transact business in California and engaged in misconduct that had a direct, substantial, foreseeable, and intended effect of injuring people in California.

134. Defendants misrepresented their Products in advertising, labels, and containers and misled Plaintiff, the California Class, and the public about the characteristics, purity, quality, approval, and safety of the Products. Defendants led Plaintiff and the California Class, and the public to believe the Products were "STERILE" and safe, legal to sell, and had characteristics, purity, and quality that the Products did not have.

135. Defendants' advertising, online representations, labeling, and packaging of the Products were misleading, fraudulent, and deceptive. Defendants knew through the Products' development, formulation, manufacturing, and quality control that, the Products were not "STERILE."

136. Defendants omitted material health and safety information when misrepresenting that the Products were legal to sell as OTC drugs, when they were actually adulterated.

137. Defendants' acts and omissions were likely to deceive reasonable consumers and the public. Reasonable consumers expect that Defendants' Products are "STERILE," legally sold as OTC drugs, and are not adulterated.

138. Had Defendants been truthful in their advertising, labeling, packaging, and online statements about the Products, including that the Products were not "STERILE" rendering the

Products adulterated, and illegal to sell, Plaintiff and the California Class members would not have bought the Products, or paid less for them.

139. Defendants' acts, omissions, and concealment of material health and safety information are ongoing and continue to cause harm. Defendants continue to market, advertise, and sell the Products to the public, even though they are adulterated. Further, Defendants continue to market themselves as responsible drug manufacturers and sellers who sell safe and legal products when they are not.

140. Defendants also failed to provide adequate notice of their Recall or a reasonable mechanism for consumers to receive compensation thereunder.

141. As a direct and proximate result of Defendants' misconduct, in violation of the FAL, Plaintiff and California Class Members were harmed in the amount of the purchase price they paid for the Products. Additionally, Plaintiff and California Class Members suffered, and continue to suffer, economic losses and other damages, including but not limited to, the amounts paid for the Products and any interest that would have accrued on those monies, in an amount to be proven at trial. Accordingly, Plaintiff seeks a monetary award for violation of the FAL in the form of damages, restitution, and/or disgorgement of ill-gotten gains to compensate Plaintiff and California Class Members.

COUNT IV

Illinois Consumer Fraud and Deceptive Trade Practices Act Violations of 815 ILCS 505/1, *et seq.* *(By Plaintiff Vega and on behalf of the Illinois Class)*

142. Plaintiff Vega incorporates by reference the allegations contained in paragraphs 1 through 78 as if fully set forth herein.

143. Plaintiff Vega and other Illinois Class Members are persons within the context of the Illinois Consumer Fraud and Deceptive Trade Practices Act ("ICFA"), 815 ILCS 505/1(c).

144. Defendants are persons within the context of the ICFA, 815 ILCS 505/1(c).

145. At all times relevant hereto, Defendants were engaged in trade or commerce as defined under the ICFA, 815 ILCS 505/1(f).

146. Plaintiff Vega and the proposed Illinois Class are "consumers" who purchased the Products for personal, family, or household use within the meaning of the ICFA, 815 ILCS 505/1(e).

147. The ICFA prohibits engaging in any "unfair or deceptive acts or practices … in the conduct of any trade or commerce…." *See* ICFA, 815 ILCS 505/2.

148. The ICFA prohibits any deceptive, unlawful, unfair, or fraudulent business acts or practices including using deception, fraud, false pretenses, false promises, false advertising, misrepresentation, or the concealment, suppression, or omission of any material fact, or the use or employment of any practice described in Section 2 of the Uniform Deceptive Trade Practices Act. *See* 815 ILCS § 505/2.

149. Plaintiff Vega and the other Illinois Class Members reasonably relied upon Defendants' representation that the Products were sterile and did not present associated hazards. Additionally, Defendants concealed the Products' adulterated nature.

150. Defendants' conduct, as described herein, took place within the State of Illinois and constitutes unfair or deceptive acts or practices in trade and commerce, violating 815 ICFA 505/1, *et seq.*

151. Defendants violated the ICFA by representing the Products have characteristics or benefits that they do not have. *See* 815 ILCS § 505/2; 815 ILCS § 510/2(7).

152. Defendants did not intend to sell the Products as advertised, in violation of 815 ILCS § 505/2 and 815 ILCS § 510/2(9).

153. Defendants engaged in fraudulent and/or deceptive conduct which creates a likelihood of confusion or misunderstanding in violation of 815 ILCS § 505/2; 815 ILCS § 510/2(3).

154. Prior to placing the Products into the stream of commerce and the hands of consumers, Defendants knew, or should have known, that the Products were not sterile. Still, Defendants failed to ensure the Products were manufactured in accordance with the Products' on-label representations and further misrepresented, omitted, and concealed this fact to consumers, including Plaintiff Vega and Illinois Class Members, by not warning about the Products' adulteration and associated risks.

155. Plaintiff Vega and Class Members were damaged economically as a proximate result of Defendants' violations of the ICFA and suffered damages as a direct and proximate result of purchasing the Products.

156. As a direct and proximate result of Defendants' violations of the ICFA, as set forth *supra*, Plaintiff Vega and the Illinois Class Members suffered ascertainable losses of money caused by Defendants' misrepresentations and material omissions regarding the sterility of the Products.

157. Had they been aware of the adulterated nature of the Products, Plaintiff Vega and Illinois Class Members either would have paid less for the Products or would not have purchased them at all.

158. Defendants have yet to provide any adequate monetary remedy to consumers for their ICFA violations stated herein.

159. Based on Defendants' unfair and/or deceptive acts or practices, Plaintiff Vega and the Illinois Class Members are therefore entitled to relief, including restitution, actual damages, treble damages, punitive damages, costs and attorney's fees, under 815 ILCS 505/10a.

COUNT V

Illinois Deceptive Trade Practices Act
Violations of 815 ILCS 510/2, *et seq.*
(By Plaintiff Vega and on behalf of the Illinois Class)

160. Plaintiff Vega incorporates by reference the allegations contained in paragraphs 1 through 78 as if fully set forth herein.

161. The Illinois Deceptive Trade Practices Act, 815 ILCS 505/1, *et seq*. ("UDTPA") prohibits deceptive trade practices in the course of a business, vocation, or occupation. 815 ILCS 510/2(a).

162. In the course of business, Defendants, through themselves, their agents, employees, and/or subsidiaries, violated the Illinois UDTPA by knowingly and intentionally misrepresenting, omitting, concealing and failing to disclose material facts regarding the sterility, safety, legality and nature of the Products, as detailed herein.

163. Specifically, by misrepresenting the Products as sterile and suitable for their marketed and intended use, and by failing to disclose and actively concealing the dangers and risk posed by the adulterated nature of the Products, Defendants engaged in one or more of the following unfair or deceptive business practices prohibited by 815 ILCS 510/2(a):

a. Representing that the Products have characteristics, uses, benefits, and qualities which they do not have;

b. Representing that the Products are of a particular standard, quality, and grade when they are not;

c. Advertising the Products with the intent not to sell them as advertised; and

d. Engaging in other conduct which similarly creates a likelihood of confusion or misunderstanding.

815 ILCS 510/2(a)(5), (7), (9) and (12).

164. Defendants' unfair or deceptive acts or practices, including misrepresentations, concealments, omissions and suppressions of material facts, had a tendency or capacity to mislead and create a false impression in consumers, and were likely to and did in fact deceive reasonable consumers, including the Plaintiff Vega and Illinois Class Members, about the true safety and sterility of the Products, the quality of the Products and the true value of the Products.

165. Defendants' scheme and concealment of the true characteristics of the Products were material to the Plaintiff Vega and Illinois Class Members, as Defendants intended.

166. Had they known the truth, Plaintiff Vega and Illinois Class Members would not have purchased the Products or would have paid significantly less for them.

167. Plaintiff Vega and Illinois Class Members had no way of discerning that Defendants' representations were false and misleading, or otherwise learning the facts that Defendants concealed or failed to disclose.

168. Plaintiff Vega and Illinois Class Members did not, and could not, unravel Defendants' deception on their own.

169. Defendants had an ongoing duty to the Plaintiff Vega and Illinois Class Members to refrain from unfair or deceptive practices under the Illinois UDTPA in the course of their business.

170. Specifically, Defendants owed the Plaintiff Vega and Illinois Class Members a duty to disclose all the material facts concerning the Products because Defendants possessed exclusive

knowledge, intentionally concealed the true characteristics of the Products from Plaintiff Vega and Illinois Class Members, and/or made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

171. Plaintiff Vega and Illinois Class Members suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' concealment, misrepresentations, and/or failure to disclose material information.

172. Defendants' violations present a continuing risk to the Plaintiff Vega and Illinois Class Members, as well as to the general public.

173. Defendants' unlawful acts and practices complained of herein affect the public interest.

174. Pursuant to 815 ILCS 510/3, the Plaintiff Vega and Illinois Class Members seek an order enjoining Defendants' unfair or deceptive acts or practices and any other just and proper relief available under the Illinois UDTPA.

COUNT VI

Violation of State Consumer Protection Statutes
(By Plaintiffs and the Multi-State Consumer Protection Class)

175. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 78 as if fully set forth herein.

176. Plaintiffs and the Multi-State Consumer Protection Class Members were injured as a result of Defendants' violations of the state consumer protection statutes listed in paragraph 65, footnote 12, *supra*. These state consumer protection statutes provide a basis for redress to Plaintiffs and the Multi-State Consumer Protection Class based on Defendants' deceptive, unfair, and unconscionable acts, practices and conduct.

177. Defendants' conduct, as alleged herein, violates the consumer protection, unfair trade practices and deceptive laws of each of the jurisdictions encompassing the Multi-State Consumer Protection Class.

178. Defendants' marketing of the Products violates these prohibitions by deceiving consumers into believing that the Products are sterile and fit for their intended purpose despite their adulteration and illegality for sale.

179. Defendants engaged in fraudulent, unfair, and/or deceptive conduct which creates the likelihood of confusion or misunderstanding in violation of applicable law.

180. Specifically, Defendants advertised in a misleading and deceptive manner that the Products are sterile and fit for their intended purpose, yet the Products were not sterile and in fact were adulterated and illegal to sell. Defendants chose to package, label, and market the Products in this way to impact consumer choices, extract price premiums, and gain market dominance, as it is aware that all reasonable consumers who purchase the Products would be impacted by, and would reasonably believe, its false and misleading representations.

181. Defendants intended for Plaintiffs and Multi-State Consumer Protection Class Members to reasonably rely upon the material omissions, partial representations, and affirmative misrepresentations concerning the true nature of the Products.

182. Defendants' omissions, partial representations, and affirmative misrepresentations were likely to deceive and cause misunderstanding and/or, in fact, did cause Plaintiffs and Multi-State Consumer Protection Class Members to be deceived about the true nature of the Products.

183. Further, despite Defendants' knowledge of material facts concerning the existence of the serious safety risks posed by the Products, Defendants actively concealed the serious safety risks from consumers by failing to disclose the serious safety risks to consumers.

184. Defendants knew, or otherwise should have known, that the Products were not sterile, were illegal to sell and posed serious safety risks based upon: (1) Defendants' own internal testing, data and surveys; and (2) Defendants' Recall.

185. Defendants failed to disclose to consumers that the Products pose serious safety risks, including that the Products' materials, workmanship and/or design is inherently defective; unreasonably dangerous; not fit to be used for their intended purpose; are illegal to sell and/or are capable of causing serious injury. Rather than disclose this information, Defendants marketed the Products as sterile, safe, and suitable for their intended purpose.

186. The facts concealed by Defendants to consumers, including Plaintiffs and other Multi-State Consumer Protection Class Members, were material, in part, because they concerned an essential aspect of the Products, including the intended use and safety. Such facts affect the conduct of purchasers, and a reasonable person would have considered those facts to be important in deciding whether to purchase the Products. Rather than disclose this information, Defendants marketed the Products as sterile, complying with safety standards and regulations, with the utmost manufacturing and design and legal to sell.

187. Defendants intentionally concealed and/or failed to disclose such material facts for the purpose of inducing consumers, including Plaintiffs and other Multi-State Consumer Protection Class Members, to rely on their marketing and to purchase the Products.

188. As a direct and proximate result of Defendants' omissions, partial representations, and affirmative misrepresentations, Plaintiffs and Multi-State Consumer Protection Class Members suffered ascertainable losses.

189. Had they been aware of the true nature of the Products, Plaintiffs and Multi-State Consumer Protection Class Members either would have paid less for the Products or would not have made the purchases at all.

190. Pursuant to the aforementioned states' unfair and deceptive practices laws, Plaintiffs and Multi-State Consumer Protection Class Members are entitled to recover compensatory, restitution, punitive and special damages, including, but not limited to treble damages, reasonable attorneys' fees and costs and other relief as deemed appropriate or permitted by relevant law.

COUNT VII

Breach of Implied Warranty
(On Behalf of Plaintiff Heredia and the Nationwide Class or, in the Alternative, the California Class)

191. Plaintiff Heredia incorporates by reference the allegations contained in paragraphs 1 through 78 as if fully set forth herein.

192. Plaintiff Heredia brings this cause of action individually and on behalf of (1) all consumers who purchased Products directly from Defendants (for which there is privity), (2) all consumers who whose state law has abrogated the privity requirement for implied warranty of merchantability claims seeking economic loss, and (3) all California Class Members.

193. Defendants impliedly warranted that their Products were merchantable, fit and safe for ordinary use.

194. Under the UCC, which has been uniformly adopted in all states but Louisiana, "a warranty that the 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." UCC § 2-314(1).

195. Defendants are a "merchant" for the purposes of UCC § 2-314.

196. The Products were goods under UCC 2-105(1).

197. To be merchantable the goods, among other things, must be (1) "pass without objection in the trade under the contract description;" (2) "fit for the ordinary purposes for which such goods are used" and (3) "conform to the promise or affirmations of fact made on the container or label if any." UCC §§ 2-314(2)(a), (c), (f). Defendants violated these implied warranties.

198. First, the Products are not sterile, as required by state and federal law, and they are not fit for the ordinary purposes for which such Products are used nor would they pass without objection in the trade under the contract description. Nor are they of merchantable quality for the same reason. As alleged herein, under the law, any drug used in the eyes must be sterile to reduce the risk of infection. *See* 21 C.F.R. § 200.50

199. Additionally, as alleged, the Products do not conform to the promise or affirmations of fact made on the container or label because they stated that they were labeled "sterile" when they are not.

200. Plaintiff Heredia and members of the Class purchased the Products in reliance upon the fact that the Products were merchantable, fit, and safe for ordinary use for which they were sold. They were not. The defect in the Products render the Products unfit for human use or application as an eye treatment.

201. Moreover, the Products were not altered by Plaintiff Heredia or members of the Class; Plaintiff Heredia and members of the Class were foreseeable users of the Products; and Plaintiff Heredia and members of the Class used the Products in the manner intended.

202. Contrary to Defendants' implied warranties, the Products were defective, unmerchantable, and unfit for their ordinary use when sold and did not comply with label statements.

203. By reason thereof, Plaintiff Heredia and the other Class Members suffered damages in an amount to be proven at trial. The damages are equal to the difference between the price of the Product warranted and the adulterated Products delivered. Given that adulterated Products cannot be legally sold, they likely had no value, and the damages would, therefore, be the full purchase price of the Products.

COUNT VIII

Song-Beverly Consumer Warranty Act
Breach of California Civil Code §§ 1792 and 1791.1, *et seq*.
(On Behalf of Plaintiff Heredia and the California Class)

204. Plaintiff Heredia incorporates by reference the allegations contained in paragraphs 1 through 78 as if fully set forth herein.

205. Plaintiff Heredia brings this cause of action on behalf of herself, and all members of the California Class, all of whom are similarly situated consumers.

206. The Products are "consumer goods" and Plaintiff Heredia and California Class Members are "buyers" within the meaning of Cal. Civ. Code § 1791.

207. Defendants are "manufacturers" or "distributors" under Cal. Civ. Code § 1791.

208. The implied warranty of merchantability included with the sale of each Product means that Defendants warranted that each Product (a) would pass without objection in trade under the contract description; (b) was fit for the ordinary purposes for which it would be used; and (c) conformed to the promises or affirmations of fact made on the container or label.

209. The Products would not pass without objection in the trade because they contain the above-described defect, which also makes them unfit for the ordinary purpose for which they would be used.

210. The Products are not adequately labeled because they are labeled as sterile and fail to disclose the defect and does not advise class members of the existence of the associated risks.

211. The Products were not sold on an "as is" or "with all faults" basis.

212. Any purported disclaimer of implied warranties was ineffective because it was not conspicuous and not made available to the purchaser before the sale of the Products. Instead, if a disclaimer was made at all, it was tucked away in the Product packaging and not made available until after purchase.

213. Defendants' actions—misrepresenting the Products as sterile, safe, and suitable for their intended purposes while concealing the fact that the Products are adulterated and illegal to sell rendering Defendants' representation false and misleading—deprived Plaintiff Heredia and California Class Members of the benefit of their bargains and caused the Products to be worth less than what Plaintiff Heredia and California Class Members paid.

214. As a direct and proximate result of the breach of implied warranty, Plaintiff Heredia and California Class Members received goods whose condition substantially impairs their value. Plaintiff Heredia and California Class Members have been damaged by the diminished value of their Products.

215. Under Cal. Civ. Code §§ 1791.1(d) and 1794, Plaintiff Heredia and California Class Members are entitled to damages and other legal and equitable relief, including, at their election, the right to revoke acceptance of the Products or the overpayment or diminution in value of their Products. They are also entitled to all incidental and consequential damages resulting from the breach, as well as reasonable attorneys' fees and costs.

COUNT IX

Unjust Enrichment/Quasi-Contract
(in the alternative)
(On Behalf of Plaintiffs and the Nationwide Class or, in the Alternative, the California Class and Illinois Class)

216. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 78 as if fully set forth herein.

217. Plaintiffs bring this cause of action on behalf of themselves, and all members of the Nationwide Class or, in the alternative, the California Class and Illinois Class, all of whom are similarly situated consumers, in the alternative to their legal claims, as permitted by Federal Rule of Civil Procedure 8.

218. Plaintiffs and Class Members conferred a benefit on Defendants by purchasing the Products—payments that Defendants knowingly accepted while aware of the Products' defect and unfitness for their intended use.

219. Defendants either knew, or should have known, that the payments rendered by Plaintiffs and Class Members were given with the expectation that the Products had the qualities, characteristics and suitability for the use represented and warranted by Defendants. As such, it would be inequitable for Defendants to retain the benefit of the payments under these circumstances.

220. By their wrongful acts and omissions described herein, including selling the Products, which were adulterated, illegal to sell and were inoperative for the intended use, Defendants were unjustly enriched at the expense of Plaintiffs and Class Members.

221. Defendants' wrongful conduct directly caused Plaintiffs' detriment and resulted in Defendants' unjust enrichment, as the benefit they received flowed directly from the misconduct alleged in this Complaint.

222. Defendants unjustly profited from their unlawful, unfair and deceptive conduct at the expense of Plaintiffs and Class Members. It would be inequitable and contrary to principles of justice for Defendants to retain the profits, benefits, and other compensation obtained through the sale of the Products, as such enrichment was directly tied to the misconduct alleged herein.

223. Defendants were unjustly enriched by retaining revenue from Class Members' purchases of the Products. Such enrichment is unjust and inequitable because Defendants knowingly manufactured, marketed and sold the defective Products while omitting material facts, causing Plaintiffs and Class Members to purchase Products they otherwise would not have purchased had the truth been disclosed.

224. Defendants continued to manufacture the Products with the inherent defect even after knowing that the Products were adulterated and illegal to sell and instead, concealed the defect and tout the safety of their Products, considerably profiting for years.

225. Defendants' conduct allows them to knowingly realize and retain substantial revenue from selling the Products at the expense of, and to the detriment of, Plaintiffs and Class Members, and Defendants' benefit and enrichment. Defendants' retention of these benefits violates fundamental justice, equity and good conscience principles.

226. Under common law principles of unjust enrichment, it is inequitable for Defendants to retain the benefits conferred by Plaintiffs' and Class Members' overpayments.

227. Plaintiffs and the Class Members are, therefore, entitled to restitution in the form of the revenues derived from Defendants' sale of the Products.

228. As a direct and proximate result of Defendants' actions, Plaintiffs and Class Members suffered in an amount to be proven at trial.

229. Class Members suffered an injury in fact and lost money as a result of Defendants' unjust conduct.

230. Class Members lack an adequate remedy at law with respect to this claim and are entitled to non-restitutionary disgorgement of the financial profits Defendants obtained as a result of their unjust conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of other members of the proposed Class, respectfully requests that the Court enter judgment in Plaintiffs' favor and against Defendants as follows:

A. Declaring that this action is a proper class action, certifying the Class as requested herein, designating Plaintiffs as Class Representatives and appointing the undersigned counsel as Class Counsel;

B. Ordering payment of actual and punitive damages;

C. Ordering Defendants to pay attorneys' fees and litigation costs to Plaintiffs and the other members of the Class;

D. Ordering Defendants to pay both pre- and post-judgment interest on any amounts awarded; and

E. Ordering such other and further relief as may be just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury of all claims in this Complaint so triable.

Dated: September 17, 2026

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