UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

William Noonan, individually and on behalf of all others similarly situated, Plaintiff, v. Scope Health, Inc. Defendant.	Case No. 25-cv-04997 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff William Noonan ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, brings this Class Action Complaint against Defendant Scope Health Inc. ("Defendant" or "Scope") and alleges upon personal knowledge as to himself and upon information and belief as to all other matters as follows:

NATURE OF THE ACTION

1. This is a consumer protection and restitution action arising from Defendant's unlawful marketing and sale of over-the-counter ophthalmic products containing unapproved active pharmaceutical ingredients, in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq.

2. The United States Food and Drug Administration ("FDA") issued a Warning Letter to Defendant on July 9, 2025, identifying numerous violations of the FDCA, including the marketing of new drugs without an approved New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA"), misbranding, and failure to conform to Current Good Manufacturing Practices ("cGMP"). A copy of the Warning Letter is attached as Exhibit A.

3. The products subject to the FDA's enforcement action include, among others, OPTASE® Dry Eye Intense Drops and similar products marketed by Scope (collectively, the "Products").

4. Plaintiff and members of the Class purchased the Products unaware that they were misbranded and unapproved and, thus, were being sold in violation of federal law.

5. Plaintiff seeks to represent a class of similarly situated consumers and asserts claims for negligence per se and unjust enrichment, seeking appropriate monetary and equitable relief.

STATUTORY FRAMEWORK

6. 21 U.S.C. § 331(a) prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded."

7. A drug is considered misbranded if it does not comply with an applicable over the counter ("OTC") Monograph. 21 U.S.C. § 352(ee).

8. A drug is considered misbranded if it does not contain all adequate and required warnings. 21 U.S.C. § 352(f)(2).

9. 21 U.S.C. § 331(d) and 355(a) prohibit the introduction of "new drugs" into interstate commerce without approval.

10. "A drug product is a 'new drug' within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), if it is not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in its labeling.[1]"

[1] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/scope-health-inc-695085-07092025

FACTUAL BACKGROUND

11. Defendant Scope Health Inc. marketed and distributed four ophthalmic products that were expressly identified by the FDA in its July 9, 2025 Warning Letter as unlawful and misbranded under the FDCA (the "Products"):

a. OPTASE® Dry Eye Intense Drops

b. OPTASE® Hylo Night Ointment

c. OPTASE® Protect; and

d. OPTASE® Moist Heat Mask (when sold with drug claims)

12. Each of these Products was marketed with therapeutic claims that qualify them as drugs under 21 U.S.C. § 321(g)(1)(B).

13. "There are no FDA-approved applications in effect for any of the products identified above.[2]"

14. None of the Products in this case are considered GRASE.[3]

OPTASE® Dry Eye Intense Drops Product

15. The OPTASE® Dry Eye Intense Drops Product was marketed to treat moderate to severe dry eye symptoms.

16. The OPTASE® Dry Eye Intense Drops Product contains unapproved active ingredients: sodium hyaluronate and trehalose.

17. There are no FDA-approved applications in effect for the OPTASE® Dry Eye Intense Drops Product.[4]"

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[2] *Id*.
[3] See *Id*. at fn. 1 ("FDA is not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that your above-referenced topical ophthalmic drug products are GRASE for use under the conditions prescribed, recommended, or suggested in their labeling.").
[4] *Id*. ("There are no FDA-approved applications in effect for any of the products identified above.").

18. The OPTASE® Dry Eye Intense Drops Product is not GRASE.[5]

19. Thus, the OPTASE® Dry Eye Intense Drops Product is a "new drug" introduced into interstate commerce in violation of 21 U.S.C. § 331(d) and 355(a).

20. The OPTASE® Dry Eye Intense Drops Product also lacked the required monograph warning: "If solution changes color or becomes cloudy, do not use."

21. Thus, the OPTASE® Dry Eye Intense Drops Product is "misbranded" pursuant to 21 U.S.C. §§ 352(f)(2) and (ee).and its introduction into commerce violates 21 U.S.C. § 331(a).

OPTASE® Hylo Night Ointment Product

22. The OPTASE® Hylo Night Ointment Product is marketed as an ocular lubricant for nighttime dry eye relief.

23. The OPTASE® Hylo Night Ointment Product contained vitamin A palmitate, an ingredient not permitted under the monograph.

24. There are no FDA-approved applications in effect for the OPTASE® Hylo Night Ointment Product.[6]"

25. The OPTASE® Hylo Night Ointment Product is not GRASE.[7]

26. Thus, the OPTASE® Hylo Night Ointment Product is a "new drug" introduced into interstate commerce in violation of 21 U.S.C. § 331(d) and 355(a).

27. In addition, the labeling for the the OPTASE® Hylo Night Ointment Product lacks adequate directions for use required under 21 CFR §§ 349.50 and 349.75.

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[5] See *Id*. at fn. 1 ("FDA is not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that your above-referenced topical ophthalmic drug products are GRASE for use under the conditions prescribed, recommended, or suggested in their labeling.").
[6] *Id*. ("There are no FDA-approved applications in effect for any of the products identified above.").
[7] See *Id*. at fn. 1 ("FDA is not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that your above-referenced topical ophthalmic drug products are GRASE for use under the conditions prescribed, recommended, or suggested in their labeling.").

28. Thus, the OPTASE® Hylo Night Ointment Product is "misbranded" pursuant to 21 U.S.C. §§ 352(f)(2) and (ee) and its introduction into commerce violates 21 U.S.C. § 331(a).

OPTASE® Protect Product

29. The OPTASE® Protect Product is marketed as an antimicrobial spray for the eyelids and periocular area.

30. The OPTASE® Protect Product contains polyaminopropyl biguanide (PHMB), which is not approved for ophthalmic use.

31. There are no FDA-approved applications in effect for the OPTASE® Protect Product.[8]"

32. The OPTASE® Protect Product is not GRASE.[9]

33. Thus, the OPTASE® Protect Product is a "new drug" introduced into interstate commerce in violation of 21 U.S.C. § 331(d) and 355(a).

34. In addition, the OPTASE® Protect Product fails to include adequate directions for safe use and was not compliant with OTC drug regulations.

35. Thus, the OPTASE® Protect Product is "misbranded" pursuant to 21 U.S.C. §§ 352(f)(2) and (ee).and its introduction into commerce violates 21 U.S.C. § 331(a).

OPTASE® Moist Heat Mask

36. The OPTASE® Moist Heat Mask is marketed with therapeutic claims for treatment of blepharitis and meibomian gland dysfunction.

37. The OPTASE® Moist Heat Mask is also sold with drug-like instructions and sometimes in combination with drug products.

[8] *Id*. ("There are no FDA-approved applications in effect for any of the products identified above.").
[9] See *Id*. at fn. 1 ("FDA is not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that your above-referenced topical ophthalmic drug products are GRASE for use under the conditions prescribed, recommended, or suggested in their labeling.").

38. These practices caused the OPTASE® Moist Heat Mask to be regulated as a drug-device combination product without proper approval or labeling.

39. There are no FDA-approved applications in effect for the OPTASE® Moist Heat Mask.[10]"

40. The OPTASE® Moist Heat Mask is not GRASE.[11].

41. Thus, the OPTASE® Moist Heat Mask is a "new drug" introduced into interstate commerce in violation of 21 U.S.C. § 331(d) and 355(a).

42. Thus, the OPTASE® Moist Heat Mask is "misbranded" pursuant to 21 U.S.C. §§ 352(f)(2) and (ee).and its introduction into commerce violates 21 U.S.C. § 331(a).

JURISDICTION AND VENUE

43. This Court has subject matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. section §1332(d) in that (1) this is a class action involving more than 100 class members; (2) Defendant is a citizen of New York and at least one member of the Class is a citizen of a state different from Defendant; and (3) the amount in controversy is in excess of $5,000,000, exclusive of interests and costs.

44. This Court has personal jurisdiction over Defendant because Defendant conducts and transacts business in the state of New York, contracts to supply goods within the state of New York, and supplies goods within the state of New York.

[10] *Id*. ("There are no FDA-approved applications in effect for any of the products identified above.").
[11] See *Id*. at fn. 1 ("FDA is not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that your above-referenced topical ophthalmic drug products are GRASE for use under the conditions prescribed, recommended, or suggested in their labeling.").

45. Venue is proper because Plaintiff and many Class Members reside in the Eastern District of New York, and throughout the state of New York. A substantial part of the events or omissions giving rise to the Classes' claims occurred in this district.

PARTIES

Plaintiff

46. Plaintiff William Noonan is a citizen and resident of Staten Island, New York. In 2025, Plaintiff purchased OPTASE® Dry Eye Intense Drops from a retail pharmacy in Staten Island, New York.

47. Defendant Scope Health Inc. is a New York corporation with its principal place of business located in New York, New York.

48. Defendant markets, sells, and distributes ophthalmic products, including the Products, to consumers nationwide, including in New York.

CLASS ALLEGATIONS

49. Plaintiff brings this matter on behalf of himself and those similarly situated. As detailed at length in this Complaint, Defendant orchestrated deceptive marketing and labeling practices. Defendant's customers were uniformly impacted by and exposed to this misconduct. Accordingly, this Complaint is uniquely situated for class-wide resolution.

50. The Class is defined as all consumers who purchased the Products anywhere in the United States during the Class Period.

51. Plaintiff also seeks certification, to the extent necessary or appropriate, of a subclass of individuals who purchased the Products in the state of New York at any time during the Class Period (the "New York Subclass").

52. The Class and New York Subclass are referred to collectively throughout the Complaint as the Class.

53. The Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

54. Numerosity: Class Members are so numerous that joinder of all members is impracticable. Plaintiff believes that there are thousands of consumers in the Class and the New York Class who are Class Members as described above who have been damaged by Defendant's deceptive and misleading practices.

55. Commonality: The questions of law and fact common to the Class Members which predominate over any questions which may affect individual Class Members include, but are not limited to:

a. Whether Defendant was responsible for the conduct alleged herein which was uniformly directed at all consumers who purchased the Products;

b. Whether Defendant's misconduct set forth in this Complaint demonstrates that Defendant has engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sale of its Products;

c. Whether Defendant made false and/or misleading statements and omissions to the Class and the public concerning the contents of its Products;

d. Whether Defendant's false and misleading statements and omissions concerning its Products were likely to deceive the public; and

e. Whether Plaintiff and the Class are entitled to money damages under the same causes of action as the other Class Members.

56. Typicality: Plaintiff is a member of the Class. Plaintiff's claims are typical of the claims of each Class Member in that every member of the Class was susceptible to the same deceptive, misleading conduct and purchased Defendant's Products. Plaintiff is entitled to relief under the same causes of action as the other Class Members.

57. Adequacy: Plaintiff is an adequate Class representative because his interests do not conflict with the interests of the Class Members he seeks to represent, his consumer fraud claims are common to all members of the Class, he has a strong interest in vindicating his rights, he has retained counsel competent and experienced in complex class action litigation, and counsel intends to vigorously prosecute this action.

58. Predominance: Pursuant to Rule 23(b)(3), common issues of law and fact identified above predominate over any other questions affecting only individual members of the Class. The Class issues fully predominate over any individual issues because no inquiry into individual conduct is necessary; all that is required is a narrow focus on Defendant's deceptive and misleading marketing and labeling practices.

59. Superiority: A class action is superior to the other available methods for the fair and efficient adjudication of this controversy because:

a. The joinder of thousands of individual Class Members is impracticable, cumbersome, unduly burdensome, and a waste of judicial and/or litigation resources;

b. The individual claims of the Class Members may be relatively modest compared with the expense of litigating the claims, thereby making it

impracticable, unduly burdensome, and expensive—if not totally impossible—to justify individual actions;

c. When Defendant's liability has been adjudicated, all Class Members' claims can be determined by the Court and administered efficiently in a manner far less burdensome and expensive than if it were attempted through filing, discovery, and trial of all individual cases;

d. This class action will promote orderly, efficient, expeditious, and appropriate adjudication and administration of Class claims;

e. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude their maintenance as a class action;

f. This class action will assure uniformity of decisions among Class Members;

g. The Class is readily definable and prosecution of this action as a class action will eliminate the possibility of repetitious litigation;

h. Class Members' interests in individually controlling the prosecution of separate actions is outweighed by their interest in efficient resolution by a single class action; and

i. It would be desirable to concentrate in this single venue the litigation of all Class Members who were induced by Defendant's uniform false advertising to purchase its Products.

60. Accordingly, this Class is properly brought and should be maintained as a class action under Rule 23(b)(3) because questions of law or fact common to Class Members predominate over any questions affecting only individual members, and because a class action is superior to other available methods for fairly and efficiently adjudicating this controversy.

CLAIMS

FIRST CAUSE OF ACTION
NEGLIGENCE *PER SE*
(On Behalf of Plaintiff and New York Subclass Members)

61. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

62. Violation of a statute constitutes per se negligence where it can be shown that a plaintiff belongs to the class of legislatively intended beneficiaries and that a right of action would be clearly in furtherance of the legislative purpose.

63. Courts throughout the country have recognized that a negligence per se claim can be premised upon violations of the Food Drug & Cosmetics Act ("FDCA"). Defendant has violated the FDCA in numerous ways, detailed herein.

64. 21 U.S.C. § 331(a) prohibits the delivery into interstate commerce of any misbranded drug.

65. As detailed herein, Defendants violated 21 U.S.C. § 331(a) by selling drugs (the Products) which are considered "misbranded" under the FDCA for the following reasons:

a. Defendant omits from the Products required warnings and directions (deemed "misbranding" by 21 U.S.C. § 352(f)(2)); and

b. Defendant markets the Products outside monograph compliance (deemed "misbranding" by 21 U.S.C. § 352(ee)).

66. 21 U.S.C. § 331(d) and 355(a) prohibit the introduction of "new drugs" into interstate commerce without approval.

67. As detailed herein, Defendant violated 21 U.S.C. § 331(d) and 355(a) by selling the Products, which are deemed "new drugs" under 21 U.S.C. § 321(p) and have not obtained FDA approval and are not GRASE.

68. The FDCA is designed to protect consumers like Plaintiff from products, like the Products, which labeled in a deceptive manner.

69. Defendant had a statutory duty to Plaintiff and the Class to sell products which are not misbranded. Defendant also had a statutory duty to Plaintiff and the Class to only sell products which are approved or are GRASE.

70. Accordingly, Defendants violations of these statutes subject it to liability for negligence per se under New York law and state laws around the Country.

SECOND CAUSE OF ACTION
UNJUST ENRICHMENT
(On Behalf of Plaintiff and the Nationwide Class)

71. Plaintiff repeats and re-alleges the allegations above as if set forth herein.

72. When Plaintiff and the Class Members paid for the Products, they unknowingly paid money for Products which were misbranded and illegal to sell.

73. Defendant should not be legally permitted to retain monies earned from the sale of Products which are illegal to sell.

74. Equity and good conscience requires Defendant to refund Plaintiff and the Class Members for the price paid for the Products.

75. Defendant's retention of those funds would be unjust and inequitable as Defendant should not be rewarded for the sale of Products which are illegal to sell.

76. As such, Defendant is liable for unjust enrichment.

JURY DEMAND

Plaintiff demands a trial by jury on all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and the Class, prays for judgment as follows:

(a) Declaring this action to be a proper class action and certifying Plaintiff as the representative of the Class under Rule 23 of the FRCP;

(b) Awarding Plaintiff and the Class monetary damages and restitution damages equivalent to the full value of the Products they purchased;

(c) Awarding Plaintiff and Class Members their costs and expenses incurred in this action, including reasonable allowance of fees for Plaintiff's attorneys, experts, and reimbursement of Plaintiff's expenses; and

(d) Granting such other and further relief as the Court may deem just and proper.

Dated: September 4, 2025

FURIA LAW, LLC

By: Philip Furia

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New York, New York 10022
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Counsel for Plaintiff and the Class

Exhibit A

WARNING LETTER

Scope Health Inc

MARCS-CMS 695085 — JULY 09, 2025

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

Delivery Method:

Via Email

Product:

Drugs

Recipient:

Tom Freyne

CEO

Scope Health Inc

79 Madison Ave, Fl 8
New York, NY 10016
United States

hello@optase.com (mailto:hello@optase.com)

Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

WARNING LETTER

July 9, 2025

RE: 695085

Dear Mr. Freyne:

This letter is to advise you that on August 28, 2024 the U.S. Food and Drug Administration (FDA) reviewed your product labeling, including on your website at the internet address optase.com where your ophthalmic drug products are available for purchase in the United States without a prescription.

Based on our review, your MGD Advanced Dry Eye Drops, Dry Eye Intense Drops (multi-use bottle and single dose), Allegro Eye Drops, HYLO Night Eye Ointment, Tea Tree Oil Eyelid Wipes, Tea Tree Oil Eyelid Gel, and Protect Eyelid Cleansing Spray drug products are unapproved new drugs introduced or delivered for introduction into interstate commerce in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C.

355(a) and 331(d). In addition, your Dry Eye Intense Drops (multi-use bottle) product is misbranded under section 502(f)(2) of the FD&C Act, 21 U.S.C. 352(f)(2), and your Allegro Eye Drops, MGD Advanced Dry Eye Drops, Dry Eye Intense Drops (multi-use bottle and single dose), and HYLO Night Eye Ointment products are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee). Introduction or delivery for introduction of misbranded products into interstate commerce is prohibited under sections 301(d) and (a) of the FD&C Act, 21 U.S.C. 331(d) and (a). These violations are described in more detail below.

Unapproved New Drug and Misbranded Drug Violations

MGD Advanced Dry Eye Drops, Dry Eye Intense Drops (multi-use bottle and single dose), Allegro Eye Drops, HYLO Night Eye Ointment, Tea Tree Oil Eyelid Wipes, Tea Tree Oil Eyelid Gel, and Protect Eyelid Cleansing Spray are “drugs” as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C), because they are intended to affect the structure or any function of the body.

Examples of claims from the products’ labeling, including on your website listed above, that provide evidence of the intended use (as defined in 21 CFR 201.128) of these products as drugs include, but may not be limited to, the following:

MGD Advanced Dry Eye Drops
“OPTASE® MGD Advanced Drops provide a preservative free combination of ingredients designed to relieve dry eye symptoms . . . An Advanced Lipid-based drop for Evaporative Dry Eye & MGD Symptoms . . .” [from your product website at https://optase.com/product/mgd-advanced-dry-eye/]

Dry Eye Intense Drops (multi-use bottle and single dose)
“The special formulation of OPTASE® Intense provides comfort from moderate to severe dry eye including dry eye post operatively. . . .” [from your product websites at https://optase.com/product/dry-eye-intense-drops/ and https://optase.com/product/dryeye-intense-drops-sdu/]

Allegro Eye Drops
“Optase® Allegro Eye Drops is a preservative free lubricant that acts as a first line of defense to stop environmental irritants in their tracks . . . by creating a more protective tear film and strengthening the ocular mucosa. This unique formulation . . . creates a water rich shield to protect epithelial cells from environmental irritants” [from the product website at https://optase.com/product/allegro-eye-drops/]

HYLO Night Eye Ointment
“How It Works . . . OPTASE® HYLO Night™ relieves night-time symptoms of burning, sore, dry eyes by forming a comfortable long-lasting protective film on the eyes. . . .” [from your product website at https://optase.com/product/hylo-night/]

Tea Tree Oil Eyelid Wipes
“Cleaning your eyelids daily will help remove debris, bacteria and oils that can often lead to Blepharitis, MGD or Dry Eye symptoms. . . . FORMULATED WITH NATURAL INGREDIENTS FOR SENSITIVE SKIN . . . Anti-Inflammatory Tea Tree Leaf Oil . . .” [from your product website https://optase.com/product/tea-tree-oil-wipes/]

Tea Tree Oil Eyelid Gel
“OPTASE® Tea Tree Oil Gel . . . can be used as part of the recommended management regimen for Blepharitis . . . GENTLE FORMULA ENRICHED WITH NATURAL INGREDIENTS . . . Anti-Inflammatory Tea Tree Leaf Oil . . .” [from your product website https://optase.com/product/tea-tree-oil-gel/]

Multiple products

"About Meibomian Gland Dysfunction (MGD) . . . MGD is a chronic condition which occurs when the glands in the eyelids don't produce enough oil, or the oil that is produced is of poor quality. . . . How to manage MGD . . . Cleanse . . . maintain clean eyelids and lashes to ensure there is nothing that can block oils from reaching the surface of the eye. . . . Hydrate . . . If you suffer from severe MGD you may require an eye drop that can supplement the oily layer in your tear film to reduce tear evaporation. . . . Addressing the root cause of MGD . . . can also lead to a reduction of symptoms in related conditions such as Dry Eye Disease (DED) and Blepharitis. . . . Products To Relieve Symptoms . . . MGD Advanced Dry Eye Drops . . . Dry Eye Intense Drops . . . Single Dose Dry Eye Intense Drops . . . HYLO Night Eye Ointment" [from your website at https://optase.com/about-mgd/]

"About Blepharitis . . . What is Blepharitis . . . There are two main types of Blepharitis: . . . Anterior Blepharitis . . . This is where the inflammation affects the skin around the base of your eyelashes . . . Posterior Blepharitis . . . This is where the inflammation affects your eyelid glands. Meibomian Gland Dysfunction (MGD) can occur when the eyelid glands become clogged. . . . How to manage Blepharitis . . . Daily lid hygiene is key to the management of Blepharitis and other conditions of the eye such as Meibomian Gland Dysfunction (MGD) and Styes. . . . Products To Relieve Symptoms . . . Tea Tree Oil Eyelid Wipes . . . Tea Tree Oil Eyelid Gel . . . Protect Eyelid Cleansing Spray" [from your website at https://optase.com/about-blepharitis/]

Unapproved New Drug Violations

Based on the above labeling evidence, your MGD Advanced Dry Eye Drops, Dry Eye Intense Drops (multi-use bottle and single dose), Allegro Eye Drops, HYLO Night Eye Ointment, Tea Tree Oil Eyelid Wipes, Tea Tree Oil Eyelid Gel, and Protect Eyelid Cleansing Spray products are intended for use as topical ophthalmic drug products. As described below, these products are unapproved new drugs marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C. 355(a) and 331(d).

A drug product is a "new drug" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. 321(p), if it is not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in its labeling. Your above-referenced topical ophthalmic drug products are not generally recognized as safe and effective (GRASE) for their above referenced uses[1] and, therefore, are "new drugs" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, a new drug may not be legally introduced or delivered for introduction into interstate commerce without an approved application from the FDA in effect, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a). There are no FDA-approved applications in effect for any of the products identified above.

In addition, under section 505G of the FD&C Act, certain nonprescription drugs marketed without an approved application —commonly referred to as "over-the-counter (OTC) monograph drugs"—may be legally marketed if they meet applicable requirements. With respect to nonprescription ophthalmic drug products, in order to be GRASE and not new drugs, the products must, among other things, conform to the conditions in the applicable OTC monograph, Over-the-Counter Monograph M018, Ophthalmic Drug Products for Over-the-Counter Human Use (hereinafter M018).[2] However, your nonprescription ophthalmic drug products MGD Advanced Dry Eye Drops, Dry Eye Intense Drops (multi-use bottle and single dose), Allegro Eye Drops, and HYLO Night Eye Ointment do not conform to the conditions specified in M018 for the reasons described below, and thus cannot be legally marketed under section 505G.

Ophthalmic Demulcent Products

Your MGD Advanced Dry Eye Drops, Dry Eye Intense Drops (multi-use bottle and single dose), and Allegro Eye Drops are demulcent products formulated with several active ingredients that are not permitted for OTC monograph ophthalmic demulcent drug products. Specifically, according to your products' labeling, your MGD Advanced Dry Eye Drops product is

formulated with the active ingredients glycerin, sacha inchi seed oil, trehalose, and sodium hyaluronate. Your Dry Eye Intense Drops products are formulated with glycerin and sodium hyaluronate and your Allegro Eye Drops product is formulated with hydroxyethyl cellulose and Ectoin®.

However, sacha inchi seed oil, trehalose, sodium hyaluronate, and Ectoin® are not active ingredients permitted for ophthalmic demulcent drug products under M018.12. We note that, although you identify these ingredients as inactive ingredients on the product label, statements on your website show that they are active ingredients in their respective products because they are intended to furnish pharmacological activity for the treatment of a disease or condition.[3] Examples of these statements include, "Contains Sacha inchi seed oil, Trehalose and Hyaluronic Acid which combine to strengthen and replenish your tear film, and protect your eyes. . . ." (MGD Advanced Dry Eye Drops); "INACTIVE INGREDIENT: Sodium hyaluronate . . . Binds to eye surface with comfortable, soothing properties" (Dry Eye Intense Drops); and "This unique formulation includes . . . Ectoin® which creates a water rich shield to protect epithelial cells from environmental irritants . . ." (Allegro Eye Drops). Thus, these ingredients are active ingredients and, because they are not active ingredients permitted under M018.12, the MGD Advanced Dry Eye Drops, Dry Eye Intense Drops, and Allegro Eye Drops products do not conform with the conditions for lawful marketing of an OTC ophthalmic demulcent product as set forth in M018.

Ophthalmic Emollient Products

Your HYLO Night Eye Ointment product is an emollient product formulated with the active ingredient vitamin A. However, vitamin A is not an active ingredient that is permitted for ophthalmic emollient drug products under M018.14. We note that, although you identify this ingredient as an inactive ingredient on the product label, statements on your website show that it is an active ingredient in the product because it is intended to furnish pharmacological activity for the treatment of a disease or condition.[4] For example, your product website states, "OPTASE® HYLO Night™ is a soft and consistent ointment, containing Vitamin A . . . to help improve the tear film and protect the surface of the eye." Thus, this is an active ingredient that is not permitted under M018.14, therefore your HYLO Night Eye Ointment product does not conform with the conditions for lawful marketing of an OTC ophthalmic emollient product as set forth in M018.

For the above reasons, your above-referenced products MGD Advanced Dry Eye Drops, Dry Eye Intense Drops (multi-use bottle and single dose), Allegro Eye Drops, HYLO Night Eye Ointment, Tea Tree Oil Eyelid Wipes, Tea Tree Oil Eyelid Gel, and Protect Eyelid Cleansing Spray are unapproved new drugs. The introduction or delivery for introduction into interstate commerce of these unapproved new drug products violates sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C. 355(a) and 331(d).

Misbranded Drug Violations

Further, your Dry Eye Intense Drops (multi-use bottle) product is misbranded under section 502(f)(2) of the FD&C Act because its labeling does not "*[bear]…such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users*…". Here, the warning described in M018.60, "*If solution changes color or becomes cloudy, do not use*", is required for ophthalmic demulcent drug products, such as your Dry Eye Intense Drops (multi-use bottle) product, to be legally marketed under section 505G of the FD&C Act. This monograph warning also falls within the scope of the warnings described in section 502(f)(2) of the FD&C Act. Thus, omission of this monograph warning from the product labeling renders the product misbranded under section 502(f)(2).

Additionally, your Allegro Eye Drops, MGD Advanced Dry Eye Drops, Dry Eye Intense Drops, (multi-use bottle and single dose), and HYLO Night Eye Ointment products are misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. 352(ee), because these products are nonprescription drugs subject to section 505G of the FD&C Act, 21 U.S.C. 355h, but

do not comply with the requirements for marketing under that section (as described above) and are not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. 355.

The introduction or delivery for introduction of a misbranded drug into interstate commerce violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure, and injunction.

Please notify FDA in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct any violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction.

Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance by email to FDAAdvisory@fda.hhs.gov. Please include your firm name and the unique identifier “695085” in the subject line of your email.

Sincerely,
/S/

Tina Smith, M.S.
Captain, U.S. Public Health Service
Director
Office of Unapproved Drugs & Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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1 FDA is not aware of any adequate and well-controlled clinical trials in the published literature that support a determination that your above-referenced topical ophthalmic drug products are GRASE for use under the conditions prescribed, recommended, or suggested in their labeling.

2 M018 reflects the conditions as set forth in the relevant final orders established and in effect under section 505G; see Order OTC000023, available at FDA’s website OTC Monographs @ FDA, https://dps.fda.gov/omuf.

3 See 21 CFR 201.66(b)(2), which defines an active ingredient as “any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans.”

4 Id.

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