UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

KATHY EVEN, individually and on behalf of all others similarly situated, Plaintiff(s), v. **ALCON LABORATORIES INC.**, and DOES 1 to 10, inclusive, Defendant(s).	Case No.: JUDGE: **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

CLASS ACTION COMPLAINT

Plaintiff Kathy Even ("Plaintiff"), individually and on behalf of all others similarly situated, brings this class action based upon her personal knowledge as to herself and her own acts, and for all other matters based upon, among other things, the investigation of her attorneys.

NATURE OF THE ACTION

1. This class action is brought by Plaintiff on behalf of herself and others similarly situated who purchased Alcon Laboratories Inc.'s ("Defendant" or "Alcon") Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count (the "Product"). Defendant manufactures, designs, imports, advertises, labels, distributes, markets, and sells over-the-counter eye care products, including the Product, which contains Polyethylene Glycol and Propylene Glycol. Defendant acknowledged its Product is adulterated and contaminated with fungus, though refused to specify further. The presence of this pathogen poses a significant and severe health risk to consumers, including Plaintiff and the putative class, who purchased and used the Product.

Plaintiff and the Class suffered economic damages due to Defendant's misconduct and seek injunctive relief and restitution for the full purchase price of the Product.

JURISDICTION AND VENUE

2. This Court has diversity jurisdiction under 28 U.S.C. §§1332(a)(1) and (d)(2)(A) because the amount in controversy exceeds $5,000,000 and Plaintiff and Class members are citizens of a different state than Defendant.

3. This Court has personal jurisdiction over Defendant Alcon Laboratories, Inc. because Alcon purposefully availed itself of the privilege of conducting business in the District of Colorado by advertising and selling its Product within Colorado. Alcon has maintained systematic and continuous business contacts with Colorado.

4. Venue is proper in this District under 28 U.S.C. § 1391 because Defendant is deemed to reside in any judicial district in which it is subject to personal jurisdiction. Defendant marketed, advertised and sold its Product within this District.

PARTIES

5. Plaintiff Kathy Even is a citizen and resident of Colorado, and at all relevant times has been a resident of Aurora, Colorado. Even purchased the Product while living in Colorado. Based on Defendant's false and misleading claims that the Product was "STERILE," Plaintiff was unaware that Defendant's Product was adulterated and contaminated with fungus. Plaintiff purchased Defendant's Product on the assumption that the Product's labeling was accurate and that it was unadulterated, safe, and effective and, most importantly, was not contaminated with fungus. Plaintiff would not have purchased Defendant's Product had she known there was a risk the product may contain the fungus and cause severe infection. As a result, Plaintiff suffered injury

in fact because she spent money to purchase the Product, which she otherwise would not have purchased absent Defendant's failure to adhere to current good manufacturing practices and sufficient quality control. Plaintiff paid a price premium for the name brand "Alcon Systane" Product. Plaintiff also suffered personal injury as a result of using the Product, including red eyes, ocular swelling and itching, and discharge. Plaintiff was required to seek medical attention from an eye doctor because she used the adulterated Product for months and fears future injury caused by prior use of the Product. Plaintiff would purchase similar Product in the future provided it is not adulterated or contaminated.

6. Defendant Alcon Laboratories Inc. is a Texas corporation with its principal place of business located at 6201 South Freeway, Fort Worth, Texas 76134. Alcon Laboratories Inc. markets, advertises, labels, distributes, and sells the Product.

FACTUAL ALLEGATIONS

A. The Product

7. As per the Product's packaging, Alcon Laboratories Inc.'s Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count are intended to be used in the following manner: (1) for temporary relief of burning and irritation due to dryness of the eye; and (2) for temporary relief or discomfort due to minor irritations of the eye or to exposure to wind or sun. Consumers are directed to put 1 or 2 drops in the affected eye(s) as needed.

8. Plaintiff used the Product as Alcon directed.

9. The Product's packaging claims it is "STERILE."

B. Product Recall Notice

10. On December 21, 2024, Defendant recalled the Product:

> FOR IMMEDIATE RELEASE – 12/21/2024 – Fort Worth, Texas. Alcon Laboratories is voluntarily recalling one (1) lot of Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count (Lot 10101) to the consumer level. Alcon evaluated a consumer complaint of foreign material observed inside a sealed single use vial and determined the material to be fungal in nature.

> Risk Statement: Fungal contamination of an ophthalmic product is known to potentially cause eye infections. If an infection occurs, it may be vision-threatening, and in very rare cases potentially life-threatening in immunocompromised patients. To date, Alcon Laboratories has not received any reports of adverse events related to this recall.
> Systane Lubricant Eye Drops Ultra PF is used for the temporary relief of burning and irritation in persons experiencing dry eye symptoms and is packaged in a cardboard carton containing 25 sterile, single-use LDPE plastic vials of preservative free solution for ophthalmic use (NDC 0065-1432-06, UPC 300651432060). The affected Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count is limited to lot number 10101, expiration date 2025/09. The product can be identified by the green and pink carton design, presence of "Systane" and "ULTRA PF" brand names on the front of the carton, and the "25 vials" package size. Please see product images included in this release. Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count (Lot 10101) was distributed nationwide to retail and internet outlets.
> Consumers that have the recalled Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count (Lot 10101) which is being recalled should stop using them immediately and return to the place of purchase for a replacement or refund. Consumers with questions regarding this recall can contact Alcon Laboratories at 1-800-241-5999 between 7:30am and 6:00pm (Central), Monday to Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.

11. On December 23, 2024, the U.S. Food and Drug Administration ("FDA") published the company recall announcement.

C. Plaintiff's Recall Notice

12. Plaintiff received a product recall notice on December 24, 2024. The recall notice informed consumers "the U.S. Food and Drug Administration (FDA) has informed us that the product listed may not meet current mandatory or voluntary safety standards." The recall notice "urges" consumers to "stop using [the Product] immediately."

13. The recall notice did not directly offer Plaintiff a refund. To date, Plaintiff has not received a refund for the Product.

D. Fungal Contamination

14. Fungal contamination in eye drops can occur due to failures in manufacturing processes, quality control, or packaging. For example, the failures described below can result in contaminated eye drops.

15. A compromised sterile manufacturing environment can cause contamination. This can be caused by aseptic process failures. Sterile products like eye drops are made in controlled cleanrooms. If air filtration systems fail, or if personnel violate gowning or gloving protocols, fungal spores can cause contamination during production. Poor environmental monitoring in manufacturing facilities, like inadequate testing of air, surfaces, and equipment for microbial contamination also increased risk of contamination.

16. Contamination can also occur from inadequate ingredient sterilization. Raw material ingredients like water or active agents) may harbor fungi if not properly sterilized or tested before use.

17. Packaging defects can also cause contamination. For example, faulty seals, cracked bottles, or defective caps can allow fungal spores to enter the product after sterilization. Contamination can occur when a product is packaged in non-sterile packaging materials. In other words, contamination occurs when the product is packaged in bottles, vials, or droppers that were not pre-sterilized adequately.

18. Fungal contamination may also occur during vial filling. For example, malfunctioning filling equipment or unclean production lines can introduce contaminants during bottling. Improper handling like touching sterile surfaces with ungloved hands can also cause contamination.

19. Contamination can also result from improper storage. Warehousing with high humidity or temperature fluctuations can cause fungal growth.

20. The active ingredient in the Product, Polyethylene Glycol, can serve as a carbon source for fungi.

21. While Defendant's recall announcement does not indicate the precise reason for the Product's fungal contamination, the fungal contamination was present in a *sealed* vial of the Product. The aforementioned issues in manufacturing processes, quality control, or packaging are within Defendant's control, and Plaintiff intends to investigate through discovery exactly how the Product was contaminated.

CLASS ALLEGATIONS

22. Plaintiff brings this action on behalf of herself and all other similarly situated class members (the "Class") pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class against Defendant for violations of Colorado state laws:

> **Class**: All consumers who purchased Alcon Laboratories Inc.'s Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count in Colorado for personal use.
>
> Excluded from the Class are any Defendant, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

23. The Class members are so numerous that joinder of all Class members is impracticable. Plaintiff is informed and believes that the proposed Class contains thousands of purchasers of Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count who have been damaged by Defendant's conduct as alleged herein. The precise number of Class members is

unknown to Plaintiff.

24. Plaintiff's claims are typical to those of all Class members because Class members are similarly injured through Defendant's uniform misconduct described above and were subject to Defendant's deceptive claim that its Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count product was "STERILE." Plaintiff presents the same claims and legal theories on behalf of herself and all Class members.

25. Plaintiff's claims raise questions of law and fact common to all Class members, and they predominate over any questions affecting only individual Class members. Plaintiff's claims and all prospective Class members involve the same alleged defect/contamination. These common legal and factual questions include the following:

(a) whether Defendant's Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count Product contained fungus;

(b) whether Defendant's omissions are true, or are misleading, or objectively reasonably likely to deceive;

(c) whether the alleged conduct constitutes violations of the laws asserted;

(d) whether Defendant's alleged conduct violates public policy;

(e) whether Defendant engaged in false or misleading advertising;

(f) whether Defendant was unjustly enriched as a result of its labeling, marketing, advertising, and/or selling contaminated Product, Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count;

(g) whether Plaintiff and the Class members are entitled to damages and/or restitution and the proper measure of that loss; and

(h) whether an injunction is necessary to prevent Defendant from continuing to market and sell defective and adulterated/contaminated Product.

26. Plaintiff and her counsel will fairly and adequately protect and represent the interests of each member of the Class. Plaintiff has retained counsel experienced in complex litigation and class actions. Plaintiff's counsel has successfully litigated other class action cases and has the resources and abilities to fully litigate and protect the interests of the Class. Plaintiff intends to prosecute this claim vigorously. Plaintiff has no adverse or antagonistic interests to those of the Class, nor is Plaintiff subject to any unique defenses.

27. A class action is superior to the other available methods for a fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by Plaintiff and the individual Class members is small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendant. It would thus be nearly impossible for Plaintiff and Class members, on an individual basis, to obtain meaningful and effective redress for the wrongs done to them. It is also desirable to concentrate the litigation of the Class members' claims in one forum, as it will conserve party and judicial resources and facilitate the consistency of adjudications. Plaintiff knows of no difficulty that would be encountered in the management of this case that would preclude its maintenance as a class action.

28. The Class also may be certified because Defendant has acted or refused to act on grounds applicable to the Class, thereby making appropriate final declaratory and/or injunctive relief for the Class members as a whole.

29. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent

Defendant from engaging in the acts described above, such as continuing to market and sell Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count that may be adulterated or contaminated with fungus, and requiring Defendant to provide a full refund of the purchase price of Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25 count to Plaintiff and the Class members.

30. Unless a Class is certified, Defendant will retain monies received as a result of its conduct; monies that were taken from Plaintiff and the Class members. Notwithstanding Defendant's voluntary recall, unless a Class-wide injunction is issued, Defendant may continue to commit the violations alleged and the Class members and the public will continue to be misled and placed in harm's way.

FIRST CAUSE OF ACTION
Negligent Misrepresentation/Omission

31. Plaintiff realleges each of the prior paragraphs.

32. Through labeling and advertising, and in the course of their regular business, Defendant made representations to Plaintiff and the Class members concerning the active and inactive ingredients in the Product, including that the Product was uncontaminated and "STERILE."

33. Defendant intended that the Plaintiff and the Class members rely on its representations in purchasing and using the Product.

34. Defendant's representations were material to Plaintiff and the Class members' decision to purchase the Product. Defendant had a duty to provide accurate information to consumers regarding the ingredients and contaminants in the Product, due to, for example, its

exclusive knowledge of such ingredients and contaminants.

35. Defendant breached its duty to accurately disclose in its labeling and advertising that the Product was contaminated with a dangerous and potentially deadly fungus.

36. Additionally, Defendant had a duty to not make false representations regarding the Product.

37. Defendant breached its duty to use ordinary care when it made false representations regarding the quality and safety of the Product.

38. Defendant's failures to timely disclose the Product's fungal contamination amount to negligent omission, and its representations that the Product was safe, STERILE, and of acceptable quality amount to negligent misrepresentation.

39. Plaintiff and the other Class members reasonably relied upon such representations and omissions to their detriment.

40. By reason thereof, Plaintiff and other Class members have suffered damages in an amount to be proven at trial.

SECOND CAUSE OF ACTION
Breach of Express Warranty

41. Plaintiff realleges each of the prior paragraphs.

42. As detailed above, Defendant, through its advertising, marketing, packaging, and labeling, expressly warranted that the Product was safe and fit for the purposes intended, that it was of merchantable quality, and that it did not pose dangerous health risks.

43. Moreover, the Product's label represents that the use of the lubricant drops serve to protect the eye from burning and/or irritation, and that the drops are "STERILE" and safe for use in the eye. Such statements constitute an affirmation of fact or promise or a description of the

product as being safe and not posing a dangerous health risk.

44. Defendant breached this express warranty because the Product is not safe. To the contrary, the Product poses a serious and dangerous health risk because it is contaminated with fungus.

45. Plaintiff and other Class members read and relied on these express warranties provided by Defendant in Product labeling, packaging, and advertisements.

46. Defendant breached its express warranties because the Product at issue was adulterated and/or contaminated and not reasonably safe for its intended use.

47. Defendant knew or should have known that the Product did not conform to the express warranties and representations and that, in fact, it is not safe and poses serious health risks because it is contaminated with a dangerous and deadly fungus.

48. Plaintiff and other Class members read and relied on these express warranties provided by Defendant in Product labeling, packaging, and advertisements.

49. Defendant's representations were made to induce Plaintiff and other Class members to purchase the Product and were material factors in Plaintiff's and other Class members' decisions to purchase the Product.

50. Plaintiff and other Class members have suffered harm by Defendant's breach of its express warranty regarding the fitness for use and safety of the Product and are entitled to damages to be determined at trial.

THIRD CAUSE OF ACTION
Breach of Implied Warranty

51. Plaintiff realleges each of the prior paragraphs.

52. Because the Product is contaminated with fungus, it was not of the same quality as

those generally acceptable in the eye care trade and were not fit for the ordinary purposes for which such lubricant eye drops are used.

53. Plaintiff and Class members purchased the Product in reliance upon Defendant's skill and judgment and its implied warranties of fitness for the purpose intended.

54. The Product was not altered by Plaintiff or Class members.

55. Plaintiff and Class members were foreseeable users of the Product.

56. Plaintiff and Class members used the Product in the manner intended.

57. Defendant's Product was not adequately labeled and did not disclose that it was contaminated with fungus.

58. The Product did not measure up to the promises or facts stated in Defendant's Product marketing, packaging, labeling, advertisement, and communications.

59. Defendant impliedly warranted that the Product was merchantable, fit, and safe for ordinary use.

60. Defendant further impliedly warranted that the Product was fit for the particular purpose for which it was intended and sold.

61. Contrary to these implied warranties, Defendant's Product was defective, unmerchantable, and unfit for its ordinary use when sold, and unfit for the particular purpose for which it was sold.

62. Therefore, Plaintiff and other Class members have suffered damages in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
Unjust Enrichment

63. Plaintiff realleges each of the prior paragraphs.

64. As a result of Defendant's wrongful and deceptive conduct, Defendant knowingly and voluntarily accepted and retained wrongful benefits in the form of money paid by the Plaintiff and Class members when they purchased the Product.

65. In so doing, Defendant acted with conscious disregard for the rights of Plaintiff and Class members.

66. As a result of Defendant's wrongful conduct, Defendant has been unjustly enriched at the expense and detriment of Plaintiff and Class members.

67. Defendant's unjust enrichment is traceable to, and resulted directly and proximately from, the conduct alleged herein.

68. Under the common-law doctrine of unjust enrichment, it is inequitable for Defendant to retain the benefits it received, and is still receiving, without justification, from the false and deceptive manufacturing, labeling, and marketing of the Product to Plaintiff and Class members.

69. Defendant's retention of such funds under circumstances making it inequitable to do so constitutes unjust enrichment.

70. The financial benefits derived by Defendant rightfully belong to Plaintiff and Class members.

71. Defendant should be compelled to disgorge in a common fund for the benefit of Plaintiff and Class members all wrongful or inequitable proceeds received.

72. Finally, Plaintiff and Class members may assert an unjust enrichment claim even though a remedy at law may otherwise exist.

FIFTH CAUSE OF ACTION
Violations of the Colorado
Consumer Protection Act
Colo. Rev. Stat §§ 6-1-101, *et seq.*

73. Plaintiff realleges each of the prior paragraphs.

74. The Colorado Consumer Protection Act ("CCPA") provides a remedy with respect to any person that engaged in deceptive trade practices within the meaning of the CCPA.

75. By the conduct described above, Defendant engaged in unfair or deceptive acts in violation of the CCPA.

76. Defendant's omissions regarding the fungal contamination, and representation that the Product was "STERILE," is a material fact that a reasonable person would have considered in deciding whether to purchase the Product and at what price.

77. Defendant intended for Plaintiff and other Class members to rely on its representations regarding the Product.

78. Plaintiff and other Class members justifiably acted or relied to their detriment upon Defendant's omissions of fact and representations concerning the Product, as evidenced by their purchase of the Product.

79. Had Defendant disclosed all material information regarding the Product to Plaintiff and other Class members, then Plaintiff and other Class members would not have purchased the Product.

80. Defendant's representations and omissions deceived Plaintiff and other Class members.

81. Defendant acted willfully in concealing from Plaintiff and other Class members, and not disclosing, the Product's fungal contamination.

82. In addition to being deceptive, the Defendant's business practices were unfair because Defendant knowingly sold to Plaintiff and other Class members a Product that is unusable for the purposes for which it was sold. The injuries to Plaintiff and other Class members are substantial and greatly outweigh any alleged countervailing benefit to Plaintiff and other Class members or to any competition under all circumstances. Moreover, in light of Defendant's exclusive knowledge of the Product's fungal contamination, the injury is not one that Plaintiff and other Class members could have reasonably avoided.

83. Further, to the extent required by law, Defendant had a duty to disclose the contamination because disclosure was necessary to dispel misleading impressions about the Product's safety and usability that were or might have been created by Defendant's partial representations. Specifically, Defendant promoted, through its advertisements available to all Class members, that the Product was "STERILE." Defendant owed Plaintiff and other Class members a duty to disclose all the material facts concerning the Product's fungal contamination because it possessed exclusive knowledge of the contamination, it intentionally concealed such contamination from Plaintiff and other Class members, and/or it made misrepresentations that were rendered misleading because they were contradicted by withheld facts.

84. Defendant's unfair or deceptive acts or practices were likely to, and did, in fact, deceive consumers, including Plaintiff and other Class members, about the safety and quality of the Product.

85. Plaintiff and other Class members suffered ascertainable loss and actual damages as a direct result of Defendant's concealment of and failure to disclose material information.

86. Defendant engaged in bad faith conduct, entitling Plaintiff and other Class members

to treble damages.

87. Plaintiff and other Class members seek an award of compensatory damages, punitive damages, reasonable attorneys' fees, and any other just and proper relief available under the CCPA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the Class, prays for relief as follows:

1. An order declaring this action to be a proper class action, appointing Plaintiff and her counsel to represent the Class, and requiring Defendant to bear the costs of class notice;

2. An order enjoining Defendant from selling the Product;

3. An order enjoining Defendant from suggesting or implying that the Product is safe and effective for human application;

4. An order requiring Defendant to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief, such as continuing to recall existing Product, as well as preventing it from importing the Product;

5. An order awarding declaratory relief and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendant from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendant's past conduct;

6. An order requiring Defendant to pay restitution or damages to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, plus pre-and post-judgment interest thereon;

7. An order requiring Defendant to disgorge any ill-gotten benefits received from

Plaintiff and Class members as a result of any wrongful or unlawful act or practice, such as violating health and safety standards when manufacturing and selling the Product;

8. An order requiring Defendant to pay all actual and statutory damages permitted under the counts alleged herein;

9. An order awarding attorneys' fees and costs to Plaintiff and the Class; and

10. An order providing for all other such equitable relief as may be just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of herself and all others similarly situated, hereby demands a trial by jury.

February 20, 2025

Respectfully submitted,

s/ Thiago M. Coelho

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**Applications for Admission forthcoming*

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