UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JUAN HUERTAS and EVA MISTRETTA, on behalf of themselves and all others similarly situated, Plaintiffs, v. BAYER U.S. LLC, Defendant.	Case No. **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs Juan Huertas and Eva Mistretta ("Plaintiffs") bring this action on behalf of themselves and all others similarly situated against Defendant Bayer U.S. LLC ("Bayer" or "Defendant"). Plaintiffs make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to the allegations specifically pertaining to themselves, which are based on personal knowledge.

NATURE OF THE ACTION

1. This is a class action lawsuit regarding Defendant's manufacturing, distribution, and sale of Lotrimin and Tinactin spray products (the "Products") that contain dangerously high levels of benzene, a carcinogenic impurity that has been linked to leukemia and other cancers.

2. Both Lotrimin and Tinactin are anti-fungal drug products regulated by the United States Food & Drug Administration ("FDA") pursuant to the federal Food, Drug and Cosmetics Act ("FDCA"). The presence of benzene in the Products renders them adulterated and misbranded. As a result, the Products are illegal to sell under federal law and therefore worthless. *See* 21 U.S.C. §§ 331(a), 352; *see also Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *see also In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.,* 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021).

3. Bayer is one of the largest pharmaceutical companies in the world. Bayer sells Lotrimin and Tinactin products throughout the United States and the State of New York.

4. Lotrimin is the brand name for Clotrimazole, which is an antifungal medication. Lotrimin is an over-the-counter ("OTC") medical product that is used to treat vaginal yeast infections, oral thrush, diaper rash, pityriasis versicolor, and types of ringworm including athlete's foot and jock itch. Lotrimin comes in both aerosol (spray) and cream form.

5. Tinactin is the brand name for Tolnaftate, another antifungal medication that is OTC and treats a range of conditions. Tolnaftate has been found to be less useful at treating athlete's foot than Clotrimazole, but has been found

effective at treating ringworm that is passed from pets to humans. Tinactin comes in both aerosol (spray) and cream form.

6. Benzene is a component of crude oil, gasoline, and cigarette smoke, and is one of the elementary petrochemicals. The Department of Health and Human Services has determined that benzene causes cancer in humans. Likewise, the Food and Drug Administration ("FDA") lists benzene as a "Class 1 solvent" that "should not be employed in the manufacture of drug substances, excipients, and drug products because of [its] unacceptable toxicity." Benzene is associated with blood cancers such as leukemia.[1] A study from 1939 on benzene stated that "exposure over a long period of time to any concentration of benzene greater than zero is not safe,"[2] which is a comment reiterated in a 2010 review of benzene research specifically stating: "There is probably no safe level of exposure to benzene, and all exposures constitute some risk in a linear, if not supralinear, and additive fashion."[3]

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[1] National Cancer Institute, Cancer-Causing Substances, Benzene. https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene.

[2] Hunter, F.T. (1939). Chronic Exposure to Benzene (Benzol). II. The Clinical Effects. *Journal of Industrial Hygiene and Toxicology*. 1939 Vol.21 pp.331-54, https://www.cabdirect.org/cabdirect/abstract/19402700388.

[3] Smith, Martyn T. (2010). Advances in Understanding Benzene Health Effects and Susceptibility. *Annual Review of Public Health*. 2010 Vol. 31:133-148, https://www.annualreviews.org/doi/full/10.1146/annurev.publhealth.012809.103646.

7. According to the American Cancer Society:

> IARC classifies benzene as "carcinogenic to humans," based on sufficient evidence that benzene causes acute myeloid leukemia (AML). IARC also notes that benzene exposure has been linked with acute lymphocytic leukemia (ALL), chronic lymphocytic leukemia (CLL), multiple myeloma, and non-Hodgkin lymphoma.[4]

8. Moreover, "[d]irect exposure of the eyes, skin, or lungs to benzene can cause tissue injury and irritation."[5]

9. According to the National Institute for Occupational Safety and Health, humans can become exposed to benzene through "inhalation, **skin absorption**, ingestion, **skin** and/or eye contact."[6] Skin absorption is particularly concerning as there have been multiple FDA studies showing that structurally similar chemicals in sunscreen products are found in the blood at high levels after application to exposed skin.

10. Defendant manufactures, markets, and sells a variety of Lotrimin and Tinactin aerosol products, including:

- Lotrimin® Anti-Fungal (AF) Athlete's Foot Powder Spray

[4] American Cancer Society. Benzene and Cancer Risk (January 5, 2016), https://www.cancer.org/cancer/cancer-causes/benzene.html.

[5] Centers for Disease Control and Prevention, Facts About Benzene, https://emergency.cdc.gov/agent/benzene/basics/facts.asp.

[6] National Institute for Occupational Safety and Health (NIOSH), Benzene, https://www.cdc.gov/niosh/npg/npgd0049.html.

- Lotrimin® Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray
- Lotrimin® Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray
- Lotrimin® AF Athlete's Foot Liquid Spray
- Lotrimin® AF Athlete's Foot Daily Prevention Deodorant Powder Spray
- Tinactin® Jock Itch (JI) Powder Spray
- Tinactin® Athlete's Foot Deodorant Powder Spray
- Tinactin® Athlete's Foot Powder Spray
- Tinactin® Athlete's Foot Liquid Spray

11. In October 2021, Bayer announced a recall of "all unexpired Lotrimin AF and Tinactin spray products with lot numbers beginning with TN, CV or NAA, distributed between September 2018 to September 2021, to the consumer level due to the presence of benzene in some samples of the products." Bayer has instructed users to "stop using" the Products.[7]

12. While the specific level of benzene contamination is unknown, Bayer admitted in the recall notice that "[b]enzene is ***not*** an ingredient in any of Bayer Consumer Health products."[8] Thus, the presence of benzene in Defendant's Products appears to be ***the result of contamination***.

[7] FDA, Bayer Issues Voluntary Recall of Specific Lotrimin® and Tinactin® Spray Products Due to the Presence of Benzene, Oct. 1, 2021, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-specific-lotriminr-and-tinactinr-spray-products-due-presence-benzene.

[8] *Id.* (emphasis added)

13. Accordingly, because the presence of benzene is the result of contamination, benzene is not unavoidable in the manufacture of the Products, any significant detection of benzene in such products is unacceptable.

14. As OTC drug products regulated by the FDA, the Products must be both safe and effective and are subject to federal current Good Manufacturing Practices ("cGMP") regulations and the FDCA's state-law analogues. These cGMP regulations require OTC medications like the Products to meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 51(a)(2)(B). Federal and state regulatory regimes require that labeling for OTC products identify each active and inactive ingredient.[9] 21 C.F.R. 201.66 establishes labeling requirements for OTC products and defines an inactive ingredient as "any component other than an active ingredient." An "active ingredient" is "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. **The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form** intended to furnish the specified activity or effect." (Emphasis added).

[9] https://www.fda.gov/media/72250/download.

15. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." In other words, entities at all phases of the design, manufacture, and distribution chain are bound by these requirements.

16. The FDA's cGMP regulations are found in 21 C.F.R. Parts 210 and 211. These detailed regulations set forth minimum standards regarding: organization and personnel (Subpart B); buildings and facilities (Subpart C); equipment (Subpart D); control of components and drug product containers and closures (Subpart E); production and process controls (Subpart F); packaging and label controls (Subpart G); holding and distribution (Subpart H); laboratory controls (Subpart I); records and reports (Subpart J); and returned and salvaged drug products (Subpart K). The FDA has worldwide jurisdiction to enforce these regulations if the facility is making drugs intended to be distributed in the United States.

17. Any drug product not manufactured in accordance with cGMPs is deemed "adulterated" or "misbranded" and may not be distributed or sold in the

United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

18. FDA regulations require a drug product manufacturer to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

19. A drug product manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160.

20. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" and a "statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194.

21. Defendant disregarded the cGMPs outlined above. If Defendant had not routinely disregarded the FDA's cGMPs, or had fulfilled their quality

assurance obligations, Defendant would have identified the presence of the benzene contaminant almost immediately.

22. Further, had Defendant adequately tested the Products for benzene and other carcinogens, reproductive toxins, and impurities, it would have discovered that the Products contained benzene at levels far above the legal limit, making those products ineligible for distribution, marketing, and sale.

23. Accordingly, Defendant knowingly, or at least negligently, introduced contaminated, adulterated, and/or misbranded antifungal medications containing dangerous amounts of benzene into the U.S. market.

24. Defendant also knew or should have known about the carcinogenic potential of benzene because it is classified as a Group 1 compound by the World Health Organization and the International Agency for Research on Cancer, thereby defining it as "carcinogenic to humans.

25. Pursuant to 21 U.S.C. § 331(a) of the Food, Drug, and Cosmetics Act, the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded" is categorically prohibited.

26. Defendant's failure to control for benzene contamination and sale of its adulterated products constitutes actionable fraud.

27. Plaintiffs and the Class were injured by the full purchase price of the Products because the Products are worthless, as they are adulterated and contain harmful levels of benzene, and Defendant has failed to warn consumers of this fact. Such illegally sold products are worthless and have no value. *See Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076, 1085 (11th Cir. 2019); *see also In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021) ("This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for."). Plaintiffs and class members bargained for an antifungal product free of contaminants and dangerous substances, and were deprived the basis of their bargain when Defendant sold them products containing the dangerous substance benzene, which rendered the Products unmerchantable and unfit for use.

28. As the Products expose consumers to benzene well above the legal limit, the Products are not fit for use by humans. Plaintiffs are further entitled to damages for the injury sustained in being exposed to high levels of acutely-toxic benzene, damages related to Defendant's conduct, and injunctive relief.

29. In sum, Plaintiffs seek to recover damages because the Products are adulterated, defective, worthless, and unfit for human use due to the presence of benzene, a carcinogenic and toxic chemical impurity.

30. As part of the recall, Bayer claims it will provide consumers a refund for the Products, provided the consumer submits proof of purchase. The recall is inadequate for at least the following reasons:

A. Bayer did not adequately publicize the refund remedy, such that consumers would not be aware that they could request a refund from Bayer. Indeed, Plaintiffs was not aware at all of their ability to request a refund.

B. Bayer requires consumers to submit a picture of the product, even though the Products are disposable OTC medications that many consumers may no longer have. Thus, the refund remedy excludes innumerable consumers who purchased and used the Products but have no record of the same. This is particularly important given that the contamination extended at least as far back as September 2018, and consumers are unlikely to have empty bottles of the Products that are three years old.

C. The recall does not promise any changes to Bayer's manufacturing and distribution process so as to prevent future contamination.

D. The recall does not fully compensate consumers in states like New York, where consumers are entitled to statutory damages above the purchase price of the Products under New York's consumer protection laws.

E. It is unknown what criteria Bayer uses to determine whether to issue a refund to consumers who purchased the Products.

31. Plaintiffs bring this action on behalf of themselves and the Class for equitable relief and to recover damages and restitution for: (i) breach of express warranty; (ii) breach of implied warranty; (iii) violation of New York General Business Law ("GBL") § 349; (iv) violation of GBL § 350; (v) fraud; and (vi) unjust enrichment.

PARTIES

32. Plaintiff Juan Huertas is a resident of Levittown, New York and has an intent to remain there, and is therefore a domiciliary of New York. In or about August 2021, Mr. Huertas purchased a canister of Defendant's Lotrimin Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray with the lot number TN009K7 from a CVS in Freeport, New York. According to Defendant's recall notice, Mr. Huertas's cannister of Lotrimin contained benzene. However, Mr. Huertas never received notice of the recall from Defendant for his contaminated Lotrimin product. When purchasing the Product, Mr. Huertas reviewed the

accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the Lotrimin was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Clotrimazole. Mr. Huertas relied on these representations and warranties in deciding to purchase the Lotrimin manufactured by Defendant, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased the Lotrimin from Defendant if he had known that it was not, in fact, properly manufactured, free from defects, and not equivalent to Clotrimazole. Further, Mr. Huertas used the Lotrimin to treat fungal infections on his skin, not knowing the Lotrimin was contaminated with harmful levels of benzene. Mr. Huertas thus suffered cellular and genetic injury that creates and/or increases the risk that Mr. Huertas will develop cancer.

33. Plaintiff Eva Mistretta is a resident of East Elmhurst, New York and has an intent to remain there, and is therefore a domiciliary of New York. In or about July 2021, Mr. Huertas purchased a canister of Defendant's Tinactin Athlete's Foot Liquid Spray with the lot number CV01E2X from a Walgreens in Queens, New York. According to Defendant's recall notice, Ms. Mistretta's cannister of Tinactin contained benzene. However, Ms. Mistretta never received notice of the recall from Defendant for her contaminated Tinactin product. When purchasing the Product, Ms. Mistretta reviewed the accompanying labels and

disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the Tinactin was properly manufactured, free from defects, safe for its intended use, and the brand-name equivalent of uncontaminated Tolnaftate. Ms. Mistretta relied on these representations and warranties in deciding to purchase the Lotrimin manufactured by Defendant, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased the Tinactin from Defendant if she had known that it was not, in fact, properly manufactured, free from defects, and not equivalent to Tolnaftate. Further, Ms. Mistretta used the Tinactin to treat fungal infections on her skin, not knowing the Tinactin was contaminated with harmful levels of benzene. Ms. Mistretta thus suffered cellular and genetic injury that creates and/or increases the risk that Ms. Mistretta will develop cancer.

34. Defendant Bayer U.S. LLC is a Delaware corporation with its headquarters at 100 Bayer Boulevard, Whippany, New Jersey 07981. Bayer distributes the Products throughout the United States and the State of New York. The Lotrimin and Tinactin products, including the adulterated products purchased by Plaintiffs and members of the putative Classes, are available at retail stores throughout New York and the United States.

JURISIDICTION AND VENUE

35. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendant, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

36. Defendant is an "unincorporated association" under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d), and Defendant is therefore "a citizen of the State where it has its principal place of business [New Jersey] and the State under whose laws it is organized [Delaware]." *See* 28 U.S.C. § 1332(d)(10).

37. This Court has personal jurisdiction over Defendant because Defendant is headquartered in New Jersey.

38. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because Defendant resides in this District.

CLASS ACTION ALLEGATIONS

39. Plaintiff Huertas seeks to represent a class defined as all persons in the United States who purchased the following Lotrimin spray products (the "Lotrimin Class"):

- Lotrimin® Anti-Fungal (AF) Athlete's Foot Powder Spray

- Lotrimin® Anti-Fungal Jock Itch (AFJI) Athlete's Foot Powder Spray
- Lotrimin® Anti-Fungal (AF) Athlete's Foot Deodorant Powder Spray
- Lotrimin® AF Athlete's Foot Liquid Spray
- Lotrimin® AF Athlete's Foot Daily Prevention Deodorant Powder Spray

40. Plaintiff Mistretta seeks to represent a class defined as all persons in the United States who purchased the following Tinactin spray products (the "Tinactin Class") (collectively with the Lotrimin Class, the "Nationwide Classes"):

- Tinactin® Jock Itch (JI) Powder Spray
- Tinactin® Athlete's Foot Deodorant Powder Spray
- Tinactin® Athlete's Foot Powder Spray
- Tinactin® Athlete's Foot Liquid Spray

41. Plaintiff Huertas also seeks to represent a subclass of all Lotrimin Class members who purchased the Lotrimin products in New York (the "Lotrimin Subclass").

42. Plaintiff Mistretta also seeks to represent a subclass of all Tinactin Class members who purchased the Tinactin products in New York (the "Tinactin Subclass") (collectively with the Lotrimin Subclass, the "Subclasses").

43. The Nationwide Classes and New York Subclasses shall collectively be referred to as the "Classes."

44. Subject to additional information obtained through further investigation and discovery, the foregoing definitions of the Classes may be

expanded or narrowed by amendment to the complaint or narrowed at class certification.

45. Specifically excluded from the Classes are Defendant, Defendant's officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendant, and its heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

46. **Numerosity.** The members of the proposed Classes are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiffs reasonably estimate that there are hundreds of thousands of individuals that are members of the proposed Classes. Although the precise number of proposed members are unknown to Plaintiffs, the true number of members of the Classes are known by Defendant. Members of the Classes may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

47. **Typicality.** The claims of the representative Plaintiffs are typical of the claims of the Classes in that the representative Plaintiffs, like all members of

the Classes, purchased the Products, which were worthless due to the presence of benzene, a harmful and carcinogenic chemical impurity. The representative Plaintiffs, like all members of the Classes, have been damaged by Defendant's misconduct in the very same way as the members of the Classes. Further, the factual bases of Defendant's misconduct are common to all members of the Classes and represent a common thread of misconduct resulting in injury to all members of the Classes.

48. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all members of the Classes and predominate over any questions affecting only individual members of the Classes. These common legal and factual questions include, but are not limited to, the following:

(a) whether the Products manufactured by Defendant contain dangerously high levels of benzene, thereby breaching the express and implied warranties made by Defendant and making the Products unfit for human use and therefore unfit for their intended purpose;

(b) whether Defendant knew or should have known the Products contained elevated levels of benzene prior to selling them, thereby constituting fraud and/or fraudulent concealment;

(c) whether Defendant is liable to Plaintiffs and the Classes for unjust enrichment;

(d) whether Defendant is liable to Plaintiffs and the Classes for fraud;

(e) whether Plaintiffs and the Classes have sustained monetary loss and the proper measure of that loss;

(f) whether Plaintiffs and the Classes are entitled to declaratory and injunctive relief;

(g) whether Plaintiffs and the Classes are entitled to restitution and disgorgement from Defendant; and

(h) whether the marketing, advertising, packaging, labeling, and other promotional materials for the Products are deceptive.

49. **Adequacy of Representation.** Plaintiffs will fairly and adequately protect the interests of the Classes. Plaintiffs have retained counsel who are highly experienced in complex consumer class action litigation, and Plaintiffs intend to vigorously prosecute this action on behalf of the Classes. Plaintiffs have no interests that are antagonistic to those of the Classes.

50. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by members of the Classes are relatively small

compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for members of the Classes, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if members of the Classes could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

51. In the alternative, the Classes may be certified because:

(a) the prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudication with respect to individual members of the Classes that would establish incompatible standards of conduct for the Defendant;

(b) the prosecution of separate actions by individual members of the Classes would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other members of the Classes not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendant has acted or refused to act on grounds generally applicable to the Classes as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

CAUSES OF ACTION

COUNT I
Breach Of Express Warranty

52. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs 1-51 above as though fully set forth herein.

53. Plaintiffs bring this claim individually and behalf of the members of the proposed Classes against Defendant.

54. In connection with the sale of the Products, Defendant, as the designer, manufacturer, marketer, distributor, and/or seller issued written warranties by representing that the Products were antifungal medications that contained only those active and inactive ingredients listed on the Products' labels. Those active and inactive ingredients do not include benzene, a known human carcinogen dangerous to humans. Defendant further expressly warrants that the Products are antifungal medications used for the treatment of certain infections and are equivalent to the formulation of the Products as approved by the FDA, rather than adulterated antifungal products containing dangerous chemicals that are not equivalent to their generic forms.

55. As a direct and proximate cause of Defendant's breach of express

warranty, Plaintiffs and the Classes have been injured and harmed because they would not have purchased the Products on the same terms if they knew that the Products contained benzene, are not generally recognized as safe, and are not equivalent to their generic forms.

56. On November 12, 2021, prior to filing this action, Defendant was served with a pre-suit notice letter on behalf of Plaintiffs that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiffs' counsel sent Defendant a letter advising them that they breached an express warranty and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copies of Plaintiffs' counsel's letter is attached hereto as **Exhibit 1**.

COUNT II
Breach of Implied Warranty

57. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs 1-51 above as though fully set forth herein.

58. Plaintiffs bring this claim individually and on behalf of the members of the proposed Classes against Defendant.

59. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that the Products (i) would not contain elevated levels of benzene and (ii) are generally recognized as safe for human use.

60. Defendant breached the warranty implied in the contract for the sale

of the defective Products because they could not pass without objection in the trade under the contract description, the Products were not of fair or average quality within the description, and the Products were unfit for their intended and ordinary purpose because the Products manufactured, distributed, and sold by Defendant were defective in that they contained elevated levels of carcinogenic and toxic benzene, and as such are not generally recognized as safe for human use. As a result, Plaintiffs and members of the Classes did not receive the goods as impliedly warranted by Defendant to be merchantable.

61. Plaintiffs and members of the Classes purchased the Products in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

62. The Products were not altered by Plaintiffs or members of the Classes.

63. The Products were defective when they left the exclusive control of Defendant.

64. Defendant knew that the Products would be purchased and used without additional testing by Plaintiffs and members of the Classes.

65. The Products were defectively manufactured and unfit for their intended purpose, and Plaintiffs and members of the Classes did not receive the goods as warranted.

66. As a direct and proximate cause of Defendant's breach of the implied

warranty, Plaintiffs and members of the Classes have been injured and harmed because: (a) they would not have purchased the Products on the same terms if they knew that the Products contained harmful levels of benzene, and are not generally recognized as safe for human use; and (b) the Products do not have the characteristics, ingredients, uses, or benefits as promised by Defendant.

67. On November 12, 2021, prior to filing this action, Defendant was served with a pre-suit notice letter on behalf of Plaintiffs that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiffs' counsel sent Defendant a letter advising them that they breached an implied warranty and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copies of Plaintiffs' counsel's letter is attached hereto as **Exhibit 1**.

COUNT III
Violation of New York General Business Law § 349

68. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs 1-51 above as though fully set forth herein.

69. Plaintiffs bring this claim individually and on behalf of the members of the Subclasses against Defendant.

70. GBL § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

71. In its sale of goods throughout the State of New York, Defendant

conducts business and trade within the meaning and intendment of GBL § 349.

72. Plaintiffs and members of the Subclasses are consumers who purchased products from Defendant for their personal use.

73. By the acts and conduct alleged herein, Defendant has engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that the Products (i) would not contain dangerously high levels of benzene, (ii) are generally recognized as safe for human use, and (iii) are equivalent to the formulation of the Products as approved by the FDA. Defendant also materially omitted key facts regarding the true nature of the Products, specifically that the Products contained dangerous levels of benzene, was adulterated, and was unsafe for use as an antifungal treatment. Had Plaintiffs and members of the Subclasses been apprised of these facts, they would have been aware of them and would not have purchased the Products.

74. The foregoing deceptive acts and practices were directed at consumers.

75. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of the Products to induce consumers to purchase the same. No reasonable consumer would knowingly purchase an antifungal product that may contain high levels of a known carcinogen and reproductive toxin and that was illegal to

purchase or sell.

76. By reason of this conduct, Defendant engaged in deceptive conduct in violation of GBL § 349.

77. Defendant's actions are the direct, foreseeable, and proximate cause of the damages that Plaintiffs and members of Subclasses have sustained from having paid for and used Defendant's products.

78. As a result of Defendant's violations, Plaintiffs and members of the Subclasses have suffered damages because: (a) they paid a premium price in the amount of the full purchase price of the Products based on Defendant's deceptive conduct; and (b) the Products do not have the characteristics, uses, benefits, or qualities as promised.

79. On behalf of themselves and other members of the Subclasses, Plaintiffs seek to recover their actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IV
Violation of New York General Business Law § 350

80. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs 1-51 above as though fully set forth herein.

81. Plaintiffs bring this claim individually and on behalf of the members of the Subclasses against Defendant.

82. GBL § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

83. Pursuant to said statute, false advertising is defined as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

84. Based on the foregoing, Defendant has engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of GBL § 350.

85. Defendant's false, misleading, and deceptive statements and representations of fact were and are directed towards consumers.

86. Defendant's false, misleading, and deceptive statements and representations of fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

87. Defendant's false, misleading, and deceptive statements and representations of fact have resulted in consumer injury or harm to the public interest.

88. Defendant also materially omitted key facts regarding the true nature of the Products, specifically that the Products contained dangerous levels of benzene, were adulterated, and were unsafe for use as antifungal medications. Had

Plaintiffs and members of the Subclasses been apprised of these facts, they would have been aware of them and would not have purchased the Products.

89. As a result of Defendant's false, misleading, and deceptive statements and representations of fact, Plaintiffs and the Subclasses have suffered and continue to suffer economic injury.

90. As a result of Defendant's violations, Plaintiffs and members of the Subclasses have suffered damages due to said violations because: (a) they paid a premium price in the amount of the full purchase price of the Products based on Defendant's deceptive conduct; and (b) the Products do not have the characteristics, uses, benefits, or qualities as promised.

91. On behalf of themselves and other members of the Subclasses, Plaintiffs seek to recover their actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT V
Fraud

92. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs 1-51 above as though fully set forth herein.

93. Plaintiffs bring this claim individually and on behalf of the members of the Classes against Defendant.

94. Defendant had a duty to disclose material facts to Plaintiffs and the Classes given their relationship as contracting parties and intended users of the

Products. Defendant also had a duty to disclose material facts to Plaintiffs and the Classes, namely that it was in fact manufacturing, distributing, and selling harmful products unfit for human use, because Defendant had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

95. Defendant knew or should have known that the Products were contaminated with benzene, but continued to manufacture them nonetheless. Defendant was required to engage in impurity testing to ensure that harmful impurities such as benzene were not present in the Products. Had Defendant undertaken proper testing measures, it would have been aware that the Products contained dangerously high levels of benzene. During this time, Plaintiffs and members of the Classes were using the Products without knowing it contained dangerous levels of benzene.

96. Defendant failed to discharge its duty to disclose these material facts.

97. In so failing to disclose these material facts to Plaintiffs and the Classes, Defendant intended to hide from Plaintiffs and the Classes that they were purchasing and using the Products with harmful defects that were unfit for human use, and thus acted with scienter and/or an intent to defraud.

98. Plaintiffs and the Classes reasonably relied on Defendant's failure to disclose insofar as they would not have purchased the defective Products

manufactured and sold by Defendant had they known they contained unsafe levels of benzene.

99. As a direct and proximate cause of Defendant's fraudulent concealment, Plaintiffs and the Classes suffered damages in the amount of monies paid for the defective Products.

100. As a result of Defendant's willful and malicious conduct, punitive damages are warranted.

COUNT VI
Unjust Enrichment

101. Plaintiffs incorporate by reference and re-allege each and every allegation set forth in paragraphs 1-51 above as though fully set forth herein.

102. Plaintiffs bring this claim individually and on behalf of the members of the Classes against Defendant.

103. Plaintiffs and the Classes conferred a benefit on Defendant in the form of monies paid to purchase Defendant's defective and worthless Products.

104. Defendant voluntarily accepted and retained this benefit.

105. Because this benefit was obtained unlawfully, namely by selling and accepting compensation for products unfit for human use, it would be unjust and inequitable for Defendant to retain the benefit without paying the value thereof.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request, individually and on behalf of the alleged Classes, that the Court enter judgment in their favor and against Defendant as follows:

(a) For an order certifying the Classes under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as the representatives of the Classes and Plaintiffs' attorneys as Class Counsel;

(b) For an order declaring that Defendant's conduct violates the causes of action referenced herein;

(c) For an order finding in favor of Plaintiffs and the Classes on all counts asserted herein;

(d) For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

(e) For prejudgment interest on all amounts awarded;

(f) For an order of restitution and all other forms of equitable monetary relief;

(g) For injunctive relief as pleaded or as the Court may deem proper; and

(h) For an order awarding Plaintiffs and the Classes their reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of any and all issues in this action so triable as of right.

Dated: November 16, 2021

Respectfully Submitted,

BURSOR & FISHER, P.A.

By: */s/ Andrew J. Obergfell*
Andrew J. Obergfell

Andrew J. Obergfell
Max S. Roberts*
888 Seventh Avenue
New York, NY 10019
Telephone: (646) 837-7150
Facsimile: (212) 989-9163
E-Mail: aobergfell@bursor.com
mroberts@bursor.com

BURSOR & FISHER, P.A
Yeremey O. Krivoshey*
1990 North California Blvd., Suite 940
Walnut Creek, CA 94596
Telephone: (925) 300-4455
Facsimile: (925) 407-2700
E-Mail: ykrivoshey@bursor.com

**Pro Hac Vice* Application Forthcoming

Attorney for Plaintiff