

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

ANDREA FAHEY, on behalf of herself and
all others similarly situated,

Plaintiff,

v.

HELEN OF TROY LIMITED,

Defendant.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Andrea Fahey (“Plaintiff”) brings this action on behalf of herself and all others similarly situated against Defendant Helen of Troy Limited (“Helen Of Troy” or “Defendant”). Plaintiff makes the following allegations pursuant to the investigation of her counsel and based upon information and belief, except as to the allegations specifically pertaining to herself, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit regarding Defendant’s manufacturing, distribution, and sale of Sure antiperspirant aerosol and spray products (the “Products”) that contain dangerously high levels of benzene, a carcinogenic impurity that has been linked to leukemia and other cancers.

2. Sure is a brand of antiperspirants manufactured, distributed, and sold by Defendant. The Products discussed herein contain benzene, a carcinogenic chemical impurity that has been linked to leukemia and other cancers. The Products are not designed to contain benzene, and in fact no amount of benzene is acceptable in antiperspirant sprays such as the Products manufactured by Defendant. The presence of benzene in the Products renders them adulterated and misbranded, and therefore illegal to sell under both federal and state law. As a

result, the Products are unsafe and 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); *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2021 WL 222776, at *16 (D.N.J. Jan. 22, 2021).

3. 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

4. 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

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>)

lymphocytic leukemia (ALL), chronic lymphocytic leukemia (CLL), multiple myeloma, and non-Hodgkin lymphoma.⁴

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

6. 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.

7. On November 3, 2021, Valisure, an online pharmacy registered with the FDA, “detected high levels of benzene and other contaminants in specific batches of body spray products, some of which contain active pharmaceutical ingredients aluminum chlorohydrate or aluminum sesquichlorohydrate.”⁷

8. Valisure tested the Sure Products manufactured by Defendant, which were found to contain as much as 11.1 parts per million of benzene⁸:

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>.

⁷ VALISURE, VALISURE CITIZEN PETITION ON BENZENE IN BODY SPRAY PRODUCTS, Nov. 3, 2021, <https://www.valisure.com/wp-content/uploads/Valisure-FDA-Citizen-Petition-on-Body-Spray-v4.0-3.pdf> (the “Valisure Petition”), at 1.

⁸ *Id.* at 12-13.

Brand	UPC	Lot	Expiration	Description	Average ppm
Sure	88348002278	(L)21175	05/2023	Lasts All Day, Unscented, Aerosol	11.1
Sure	883484002278	21172	05/2023	Lasts All Day, Unscented, Aerosol	3.59
Sure	883484002278	(L)21099	03/2023	Lasts All Day, Unscented, Aerosol	2.36

9. The FDA does state that if the use of benzene is “**unavoidable** in order to produce a drug product with a significant therapeutic advance,” then the drug product may contain up to 2 ppm of benzene.⁹ However, many of Defendant’s Products that were tested contain levels of benzene above this amount. Regardless, according to Valisure, “[b]ecause many of the body spray products Valisure tested did not contain detectable levels of benzene, it does not appear that benzene use is unavoidable for her manufacture, and considering the long history and widespread use of these products, it also does not appear that she currently constitute a significant therapeutic advance.”¹⁰ Accordingly, **any** level of benzene in Defendant’s Products is unacceptable and therefore renders the Products adulterated, misbranded, unsafe, and worthless.

⁹ *Id.* at 1 (emphasis added).

¹⁰ *Id.* at 1-2.

10. Defendant did not disclose the actual or potential presence of benzene in its antiperspirant products on the Products' labeling, or in any advertising or website promoting the Products. Defendant did not disclose the presence of benzene in the Products to Plaintiff or Class members at the point of sale or at any time before the point of sale.

11. Antiperspirant body sprays are considered over-the-counter ("OTC") drugs that are regulated by the United States Food & Drug Administration ("FDA") pursuant to the federal Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as well as analogous state statutes and regulations.

12. 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.¹¹ 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).

¹¹ <https://www.fda.gov/media/72250/download>.

13. 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.

14. 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.

15. 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.

16. 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 she purport or are represented to possess.” 21 C.F.R. § 211.100.

17. 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.

18. “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.

19. Defendant disregarded the cGMPs outlined above. As a manufacturer, distributor, and seller of an OTC drug product, Defendant had and has a duty to ensure that its Products did not contain excessive (or any) levels of benzene, including through regular testing. But based on Valisure’s testing results set forth above, Defendant made no reasonable effort to test its Products for benzene or other impurities. Nor did it disclose to Plaintiff or any other consumers in any product advertising, labeling, packaging, or marketing that its antiperspirant products contained benzene, let alone at levels that are many multiples of the emergency, interim limit set by the FDA. To the contrary, Defendant represented and warranted, expressly and impliedly, that the Products were of merchantable quality, complied with federal and state law, and did not contain carcinogens, reproductive toxins, or other impurities such as benzene.

20. If Defendant had not routinely disregarded the FDA’s cGMPs, or had fulfilled her quality assurance obligations, Defendant would have identified the presence of the benzene contaminant almost immediately.

21. Further, had Defendant adequately tested its Products for benzene and other carcinogens, reproductive toxins, and impurities, it would have discovered that its Products

contained benzene at levels above the FDA's limit (to the extent even applicable), making those products ineligible for distribution, marketing, and sale.

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

23. 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, meaning that it is "carcinogenic to humans."

24. The presence of benzene—and Defendant's failure to comply with cGMPs—renders the Products both adulterated and misbranded under the FDCA. The Products are adulterated because she are "drug[s] and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(1).

25. The Products are misbranded because her labeling is "false" and "misleading" because it does not disclose the presence of benzene. 21 U.S.C. § 352(a)(1).

26. Under federal law, a product that is "adulterated" or "misbranded" cannot legally be manufactured, advertised, distributed, or sold. 21 U.S.C. § 331(a). Adulterated and misbranded products thus have no economic value and are legally worthless.

27. When Plaintiff purchased Defendant's Products, Plaintiff did not know, and had no reason to know, that Defendant's Products were adulterated and misbranded and thus

unlawful to sell or purchase as set forth herein. Not only would Plaintiff not have purchased Defendant's Products at all had she known the Products contained benzene, she would not have been capable of purchasing them if Defendant had done as the law required and tested those products for benzene and other carcinogens, reproductive toxins, and impurities.

28. Moreover, no reasonable consumer would have paid any amount for products containing benzene, a known carcinogen and reproductive toxin, much less above the limits set by the FDA (even assuming those allowances apply to Defendant's products).

29. Thus, if Plaintiff and Class members had been informed that Defendant's Products contained or may contain benzene, she would not have purchased or used the Products at all, or would have paid significantly less for the Products, making such omitted facts material to them.

30. Plaintiff and Class members were injured by the full purchase price of the Products because the Products are worthless, as she 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 her contamination, regardless whether the sold VCDs actually achieved the medical purpose of lowering blood pressure. Put differently, contaminated drugs, even if medically efficacious for her purpose, cannot create a benefit of the bargain because the contaminants, and her dangerous effects, were never bargained for.").

31. Plaintiff and Class members bargained for an antiperspirant product free of contaminants and dangerous substances, and were deprived the basis of her bargain when Defendant sold them products containing the dangerous substance benzene, which rendered the Products unmerchantable and unfit for use.

32. Plaintiff and Class members are further entitled to damages for the monies paid to purchase the Products, statutory and punitive damages, attorneys' fees and costs, and injunctive relief.

33. Plaintiff brings this action on behalf of herself 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 Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. §§ 501.201 *et seq.*; (iv) fraud; and (v) unjust enrichment.

PARTIES

34. Plaintiff Andrea Fahey is a resident of Sebastian, Florida and has an intent to remain there, and is therefore a domiciliary of Florida. In or about September 2021, Ms. Fahey purchased a canister of Defendant's Sure Lasts All Day, Unscented, Aerosol from a Walmart in Florida. When purchasing the Product, Ms. Fahey reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer that the Sure Product was properly manufactured, free from defects, safe for its intended use, not adulterated or misbranded, and legal to sell. Ms. Fahey relied on these representations and warranties in deciding to purchase the Sure Product manufactured by Defendant, and these representations and warranties were part of the basis of the bargain, in that they would not have purchased the Sure Product from Defendant if they had known that it was not, in fact, properly manufactured, free from defects, safe for its intended use, adulterated and misbranded, and legal

to sell. Ms. Fahey's Sure Product was contaminated with benzene, therefore rendering it improperly manufactured, defective, not safe for its intended use, adulterated and misbranded, and illegal to sell.

35. Defendant Helen of Troy Limited is a Texas corporation with its headquarters at 1 Helen of Troy Plaza, El Paso, Texas 79912. Helen of Troy Limited distributes the Products throughout the United States and the State of Florida. The Sure Products, including the adulterated Products purchased by Plaintiff and members of the putative Classes, are available at retail stores throughout Florida and the United States.

JURISDICTION AND VENUE

36. 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.

37. This Court has personal jurisdiction over Defendant because Plaintiff purchased the Product in this District.

38. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because in which a substantial part of the events or omissions giving rise to the claim occurred.

CLASS ACTION ALLEGATIONS

39. Plaintiff seeks to represent a class defined as all persons in the United States who purchased the Products (the "Class").

40. Plaintiff also seeks to represent a subclass of all Class members who purchased the Products in Florida (the "Subclass").

41. The Class and Subclass are collectively referred to as the “Classes.”

42. 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.

43. 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.

44. **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, Plaintiff reasonably estimates 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 Plaintiff, 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.

45. **Typicality.** The claims of the representative Plaintiff are typical of the claims of the Classes in that the representative Plaintiff, 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 Plaintiff, like all members of the Classes, has 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.

46. **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 her 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 Plaintiff and the Classes for unjust enrichment;
- (d) whether Defendant is liable to Plaintiff and the Classes for fraud;
- (e) whether Plaintiff and the Classes have sustained monetary loss and the proper measure of that loss;
- (f) whether Plaintiff and the Classes are entitled to declaratory and injunctive relief;
- (g) whether Plaintiff 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.

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

48. **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 her 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.

49. 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 her ability to protect her 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**

50. Plaintiff incorporates by reference and re-alleges each and every allegation set forth in paragraphs 1-49 above as though fully set forth herein.

51. Plaintiff brings this claim individually and behalf of the members of the proposed Classes against Defendant.

52. 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 antiperspirants 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.

53. As a direct and proximate cause of Defendant's breach of express warranty, Plaintiff and the Classes have been injured and harmed because she would not have purchased the Products on the same terms if she knew that the Products contained benzene, are not generally recognized as safe, and are not equivalent to her generic forms.

54. On November 15, 2021, prior to filing this action, Defendant was served with a pre-suit notice letter on behalf of Plaintiff that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breached an express

warranty and demanded that Defendant cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff's counsel's letter is attached hereto as **Exhibit 1**.

COUNT II
Breach of Implied Warranty

55. Plaintiff incorporates by reference and re-alleges each and every allegation set forth in paragraphs 1-49 above as though fully set forth herein.

56. Plaintiff brings this claim individually and on behalf of the members of the proposed Classes against Defendant.

57. 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.

58. Defendant breached the warranty implied in the contract for the sale of the defective Products because she 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 her intended and ordinary purpose because the Products manufactured, distributed, and sold by Defendant were defective in that she contained elevated levels of carcinogenic and toxic benzene, and as such are not generally recognized as safe for human use. As a result, Plaintiff and members of the Classes did not receive the goods as impliedly warranted by Defendant to be merchantable.

59. Plaintiff 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.

60. The Products were not altered by Plaintiff or members of the Classes.

61. The Products were defective when she left the exclusive control of Defendant.

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

63. The Products were defectively manufactured and unfit for her intended purpose, and Plaintiff and members of the Classes did not receive the goods as warranted.

64. As a direct and proximate cause of Defendant's breach of the implied warranty, Plaintiff and members of the Classes have been injured and harmed because: (a) she would not have purchased the Products on the same terms if she 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.

65. On November 15, 2021, prior to filing this action, Defendant was served with a pre-suit notice letter on behalf of Plaintiff that complied in all respects with U.C.C. §§ 2-313 and 2-607. Plaintiff's counsel sent Defendant a letter advising Defendant that it breached an implied warranty and demanded that Defendant cease and desist from such breaches and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff's counsel's letter is attached hereto as **Exhibit 1**.

COUNT III
Violation Of The Florida Deceptive And Unfair Trade Practices Act,
Fla. Sta. §§ 501.201, *et seq.*

66. Plaintiff incorporates by reference and re-alleges each and every allegation set forth in paragraphs 1-49 above as though fully set forth herein.

67. Plaintiff brings this claim individually and on behalf of the members of the proposed Subclass against Defendant.

68. FDUTPA renders unlawful unfair methods of competition, unconscionable acts or practice, and unfair or deceptive acts or practices in the conduct of any trade or commerce. Fla.

Stat. § 501.204.

69. Among other purposes, FDUTPA is intended “[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce.”

Fla. Stat. § 501.202.

70. FDUPTA can be violated in two ways, both of which are relevant to this case. First, Defendant has committed a “traditional” violation of FDUPTA by engaging in unfair and/or deceptive acts and practices which caused injury to Plaintiff and members of the Subclass.

71. Second, Defendant has committed a *per se* violation of FDUPTA predicated on a violation of the FDCA. Specifically, by selling adulterated and misbranded Products which is *per se* illegal in violation of 21 U.S.C. § 351 and 21 U.S.C. § 352 of the FDCA, and because the FDCA is designed to protect consumers from harmful and dangerous drugs, Defendant has committed *per se* violations of FDUPTA. Fla. Stat. Ann. § 501.203(3)(c) (explaining that a FDUPTA violation may be based on “[a]ny law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices.”).

72. While FDUPTA does not define “deceptive” or “unfair,” Florida courts have looked to the Federal Trade Commission’s interpretations for guidance. “[D]eception occurs if there is a representation, omission, or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer’s detriment.” *Lombardo v. Johnson & Johnson Consumer Companies, Inc.*, 124 F. Supp. 3d 1283, 1287 (S.D. Fla. 2015) (internal quotation marks and citation omitted). Courts define a “deceptive trade practice” as any act or practice that has the tendency or capacity to deceive consumers. *Fed. Trade Comm’n v. Partners In Health*

Care Ass'n, Inc., 189 F. Supp. 3d 1356, 1367 (S.D. Fla. 2016). Courts define an “unfair trade practice” as any act or practice that “offends established public policy and one that is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.” *Kenneth F. Hackett & Assocs., Inc. v. GE Capital Info. Tech. Sols., Inc.*, 744 F. Supp. 2d 1305, 1312 (S.D. Fla. 2010).

73. Defendant engaged in conduct that is likely to deceive members of the public. This conduct includes representing that the Products contained only the ingredients listed in the label, which is untrue, and failing to make any mention that the Products contained harmful levels of benzene and were adulterated and misbranded.

74. As alleged herein, Plaintiff has suffered injury in fact and lost money as a result of Defendant’s conduct because she purchased the Products from Defendant in reliance on Defendant’s representation that the Products were safe and effective and not contaminated with benzene, as well as Defendant’s material omissions regarding the true nature of the Products.

75. As alleged herein, Defendant’s actions are deceptive and in clear violation of FDUTPA, entitling Plaintiff and the Subclass to damages and relief under Fla. Stat. §§ 501.201-213.

76. By committing the acts alleged above, Defendant engaged in unconscionable, deceptive, or unfair acts or practices, which constitute unfair competition within the meaning of FDUTPA.

77. Defendant’s conduct is substantially injurious to consumers. Consumers are purchasing and using Defendant’s Products without knowledge that the Products are adulterated with a human carcinogen. This conduct has caused, and continues to cause, substantial injury to consumers because consumers would not have paid for the Products, which are contaminated

with benzene, but for Defendant's false labeling, advertising, promotion, and material omissions. Thus, Plaintiff and the Subclass have been "aggrieved" (*i.e.*, lost money) as required for FDUTPA standing, and such an injury is not outweighed by any countervailing benefits to consumers or competition.

78. Indeed, no benefit to consumers or competition results from Defendant's conduct. Because consumers reasonably rely on Defendant's representation of the ingredients contained on Products' label and injury resulted from ordinary use of the Products, consumers could not have reasonably avoided such injury.

79. Further, Defendant's conduct is ongoing and continuing, such that prospective injunctive relief is necessary. Plaintiff desires to purchase Defendant's Products in the future if she can be assured that the Products are not adulterated or misbranded and meet the advertising claims on the Products' label.

COUNT IV
Fraud

80. Plaintiff incorporates by reference and re-alleges each and every allegation set forth in paragraphs 1-49 above as though fully set forth herein.

81. Plaintiff brings this claim individually and on behalf of the members of the Classes against Defendant.

82. Defendant made fraudulent misrepresentations to Plaintiff and Class members regarding the Products, specifically that the Products contained only the active and inactive ingredients stated on the label, and not harmful impurities such as benzene. Defendant also materially omitted facts from Plaintiff and Class members, including that the Products in fact contained harmful levels of benzene.

83. Defendant had a duty to disclose material facts to Plaintiff and the Classes given its relationship as contracting parties and intended users of the Products. Defendant also had a duty to disclose material facts to Plaintiff 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.

84. 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, Plaintiff and members of the Classes were using the Products without knowing it contained dangerous levels of benzene.

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

86. In so failing to disclose these material facts to Plaintiff and the Classes, Defendant intended to hide from Plaintiff and the Classes that she 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.

87. Plaintiff and the Classes reasonably relied on Defendant's failure to disclose insofar as she would not have purchased the defective Products manufactured and sold by Defendant had she known she contained unsafe levels of benzene.

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

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

COUNT V
Unjust Enrichment

90. Plaintiff incorporates by reference and re-alleges each and every allegation set forth in paragraphs 1-49 above as though fully set forth herein.

91. Plaintiff brings this claim individually and on behalf of the members of the Classes against Defendant.

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

93. Defendant voluntarily accepted and retained this benefit.

94. 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, Plaintiff respectfully requests, individually and on behalf of the alleged Classes, that the Court enter judgment in her 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 Plaintiff as the representatives for the Classes and Plaintiff's 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 Plaintiff 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 Plaintiff and the Classes her reasonable attorneys' fees and expenses and costs of suit.

DEMAND FOR JURY TRIAL

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

Dated: November 15, 2021

Respectfully Submitted,

BURSOR & FISHER, P.A.

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**Pro Hac Vice Application Forthcoming*

Attorneys for Plaintiff