**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| MOUSSA KOUYATE, individually, and on behalf of all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>THE HARVARD DRUG GROUP LLC d/b/a RUGBY LABORATORIES,<br><br>Defendant. | CASE NO. 24-6223<br><br>CLASS ACTION COMPLAINT FOR:<br><br>1. VIOLATION OF NEW YORK FALSE ADVERTISING ACT<br>2. FRAUD/MISREPRESENTATION<br>3. NEGLIGENCE PER SE<br><br>DEMAND FOR JURY TRIAL |

## CLASS ACTION COMPLAINT

Plaintiff Moussa Kouyate ("Plaintiff"), individually, and on behalf of all others similarly situated, by and through his attorneys, bring this class action complaint against Defendant, The Harvard Drug Group LLC d/b/a Rugby Laboratories ("Defendant"). Plaintiff alleges the following based upon personal knowledge as well as investigation by counsel, and as to all other matters, upon information and belief. Plaintiff further believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is a class action lawsuit concerning Defendant's manufacturing, distribution, advertising, marketing, and sale of Rugby Laboratories' Benzoyl Peroxide Wash USP 10% (hereafter "BPO Product"), which is alleged to contain benzene and/or degrade to form benzene—a carcinogen that has been linked to leukemia and other blood cancers.

2. Throughout this Complaint, references to federal law and Food and Drug Administration ("FDA") regulations are merely to provide context and are not intended to raise a federal question of law. All claims alleged herein arise out of violations of Missouri and Florida law, which in no way conflict, interfere with, or impose obligations that are materially different

than those imposed by federal law.

3. Prior to placing the BPO Product into the stream of commerce and into the hands of consumers to use on their skin, Defendant knew or should have known that the BPO Product contained benzene, but misrepresented, omitted, and concealed this fact to consumers, including Plaintiff and Class members, by not including benzene on the BPO Product label or otherwise warning consumers about its presence.

4. Plaintiff and Class members reasonably relied on Defendant's representations that the BPO Product was safe, unadulterated, and free of any carcinogens that are not listed on the label.

5. Plaintiff and Class members purchased BPO Products that contain benzene.

6. Because the BPO Products contain benzene, the Products are adulterated and misbranded under New York state law.

7. Defendant is therefore liable to Plaintiff and Class members for misrepresenting and/or failing to disclose or warn that the BPO Product contains benzene and/or degrades to form benzene.

**PARTIES**

8. Plaintiff Kouyate is a resident and citizen of Bronx, New York. In approximately 2024, Plaintiff was prescribed Rugby Laboratories' Benzoyl Peroxide Wash USP 10% by his physician, and he filed that prescription at a pharmacy in Bronx, NY. He paid approximately $15 for the BPO Product. After purchasing the BPO Product, Plaintiff subjected the BPO Product to testing by an independent laboratory. The BPO Product was found to contain excessive levels of benzene—in amounts well above the maximum set by the FDA for drug products sold in the United States—thus rendering the BPO Product dangerous to human health and illegal to sell. When purchasing the BPO Product, Plaintiff reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer that the BPO Product was

properly manufactured, free from defects, safe for its intended use, and not adulterated or misbranded. Plaintiff relied on these representations and warranties in deciding to purchase the BPO Product manufactured by Defendant, and these representations and warranties were part of the basis of the bargain. Had Plaintiff known that the BPO Product contained benzene and/or degrades to form benzene at the time of purchase, Plaintiff would not have purchased and used the Product at all or would have paid significantly less for it. Plaintiff would have never paid a premium for a BPO Product that contained benzene, a known carcinogen.

9. Standing is satisfied by Plaintiff alleging economic injury. Here, Plaintiff suffered economic injury when he spent money to purchase a BPO Product he would not otherwise have purchased, or paid less for, absent Defendant's misconduct, as alleged herein. Members of the putative class have likewise suffered economic injuries in that they have spent money to purchase BPO Products they would not otherwise have purchased, or paid less for, absent Defendant's misconduct, as alleged herein.

10. Defendant, The Harvard Drug Group LLC d/b/a Rugby Laboratories, is a Michigan limited liability company with its principal place of business at 17177 N. Laurel Dr., Livonia, Michigan 48152.

11. Upon information and belief, Defendant engages in the manufacture, marketing, distribution and sale of over-the-counter drug products (including the BPO Product at issue) throughout the United States, including in New York. Defendant authorized the false, misleading, and deceptive marketing, advertising, distribution, and sale of its BPO Product.

## JURISDICTION AND VENUE

12. This Court has jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), because the matter in controversy exceeds the sum or value of $5,000,000 exclusive

of interest and costs, Plaintiff and Defendant are citizens of different states, and this is a class action in which there are more than 100 class members, many members of which are citizens of a state different than Defendant.

13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because Plaintiff suffered injury as a result of Defendant's acts in this district, many of the acts and transactions giving rise to this action occurred in this district, Defendant conducts substantial business in this district, Defendant has intentionally availed itself of the laws and markets of this district, and Defendant is subject to personal jurisdiction in this district.

## FACTUAL ALLEGATIONS

### I. Defendant's History in the Industry

14. Defendant manufacturers, markets, distributes, and/or sells various acne medication products, including the BPO Product at issue.

15. Benzoyl peroxide is an active ingredient in all the Defendant's BPO Products.

16. All of Defendant's BPO Products are manufactured in the same manner.

17. Collectively, all lots of Defendant's BPO Products contain and/or or systematically degrade to form benzene. As noted below, this is supported by testing conducted by Valisure LLC ("Valisure") of 66 acne treatment products containing benzoyl peroxide (including Rugby Laboratories' BPO Products), all of which tested positive for benzene at various levels ranging from 2,000 ppm to 1.8 ppm. These results have been published in peer-reviewed literature.[1]

18. According to Valisure's testing, which tested three of Defendant's BPO Products with different Universal Product Codes, the Defendant's BPO Products contain benzene at levels

[1] Kucera K, Zenzola N, Hudspeth A, Dubnicka M, Hinz W, Bunick CG, Dabestani A, Light DY. Benzoyl Peroxide Drug Products Form Benzene. Environ Health Perspect. 2024 Mar;132(3):37702. doi: 10.1289/EHP13984. Epub 2024 Mar 14. PMID: 38483533; PMCID: PMC10939128.

that vastly exceed 2 ppm—the level at which the FDA has said a recall is necessary.[2]

19. Further, the specific BPO Product purchased by Plaintiff—Rugby's Benzoyl Peroxide Wash USP 10%—has also undergone independent testing (at room temperature)[3] by Plaintiff and shown to contain benzene at levels that vastly exceed 2 ppm, which render the Product dangerous to human health and illegal to sell in the United States, including in the State of New York.

20. The rates of degradation and benzene impurities in the BPO Products occur at a systematic rate.

## II. Evidence of Benzene's Danger

21. Benzene is used primarily as a solvent in the chemical and pharmaceutical industries, as a starting material and intermediate in the synthesis of numerous chemicals, and in gasoline. The major United States source of benzene is petroleum. The health hazards of benzene have been recognized for over one hundred years.

22. "Human exposure to benzene has been associated with a range of acute and long-term adverse health effects and diseases, including cancer and haematological effects."[4]

23. A toxicity assessment by the Centers for Disease Control and Prevention has shown benzene can harm the central nervous system and may affect reproductive organs.[5]

24. According to the World Health Organization, "Benzene is a genotoxic carcinogen

[2] 2018 ICH Q3C guidance, at p. 5. US FDA, June 2017 (available at https://www.fda.gov/media/71737/download).
[3] Plaintiff's testing was not conducted by Valisure and is separate from the testing and results disclosed by Valisure in its March 5, 2024 citizen petition regarding BPO products and in Valisure's peer-reviewed article. Unlike Valisure's testing—which heated the BPO products to 34°C, 50°C and 80°C respectively—the BPO product purchased and tested by Plaintiff was not subjected to elevated temperatures during testing.
[4] https://www.who.int/publications/i/item/WHO-CED-PHE-EPE-19.4.2.
[5] https://www.atsdr.cdc.gov/toxprofiles/tp3.pdf.

in humans and no safe level of exposure can be recommended."[6]

25. According to the National Cancer Institute, "[e]xposure to benzene increases the risk of developing leukemia and other blood disorders."[7]

26. According to the National Toxicology Program, benzene is "known to be a human carcinogen based on sufficient evidence of carcinogenicity from studies in humans."[8]

27. Benzene has also been "found to be carcinogenic to humans" by the International Agency for Research on Cancer ("IARC"). Benzene was "[f]irst evaluated by IARC in 1974 . . . and was found to be carcinogenic to humans (Group 1), a finding that has stood since that time."[9] As noted by the IARC:

> In the current evaluation, the Working Group again confirmed the carcinogenicity of benzene based on *sufficient evidence* of carcinogenicity in humans, *sufficient evidence* of carcinogenicity in experimental animals, and *strong* mechanistic evidence. … The Working Group affirmed the strong evidence that benzene is genotoxic, and found that it also exhibits many other key characteristics of carcinogens, including in exposed humans. In particular, benzene is metabolically activated to electrophilic metabolites; induces oxidative stress and associated oxidative damage to DNA; is genotoxic; alters DNA repair or causes genomic instability; is immunosuppressive; alters cell proliferation, cell death, or nutrient supply; and modulates receptor-mediated effects.[10]

28. The FDA also recognizes that "[b]enzene is a carcinogen that can cause cancer in humans"[11] and classifies benzene as a "Class 1" solvent that should be "avoided" in drug manufacturing.[12] FDA guidance provides: "Solvents in Class 1 [e.g. benzene] should not be employed in the manufacture of drug substances, excipients, and drug products because of [its]

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[6] WHO Guidelines for Indoor Air Quality: Selected Pollutants (2010).
[7] https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/benzene.
[8] http://ntp.niehs.nih.gov/go/roc/content/profiles/benzene.pdf (emphasis in original).
[9] Benzene / IARC Working Group on the Evaluation of Carcinogenic Risks to Humans (2017: Lyon, France), at p. 33.
[10] *Id*. at 34.
[11] https://www.fda.gov/food/chemicals/questions-and-answers-occurrence-benzene-soft-drinks-and-other-beverages#q1.
[12] https://www.fda.gov/media/71737/download.

unacceptable toxicity."[13]

29. In July 2021, the FDA conducted a "Health Hazard Evaluation" on "Multiple Aerosol Sunscreen Products" manufactured by Johnson & Johnson.[14] The evaluation was requested following testing which showed benzene levels ranging "from 11.2 to 23.6 ppm" in Johnson & Johnson's aerosol sunscreen products. Specifically, the agency requested "an evaluation of the likelihood and risks associated with using aerosol sunscreens that contain benzene 11.2 to 23.6 ppm," which "levels exceed the guideline value provided by ICH [Q3C][15] and USP[16]" limits, states the report. The evaluation concluded that serious adverse effects, including potential for "life-threatening" issues or "permanent impairment of a body function" were "likely to occur" at exposure levels within that range. In addition, the evaluation stated that "individuals with altered skin absorption (i.e., infants, elderly, broken skin) and individuals who are exposed to benzene from other sources . . . may be at greater risk."

30. Notably, the levels of benzene detected in Defendant's BPO Products—as tested by Valisure and by Plaintiff—either meet or exceed the exposure levels determined by the FDA's Health Hazard Evaluation (referenced above) to present the likely potential for "life-threatening" issues or "permanent impairment of a body function."

31. On December 27, 2023, in response to reports of benzene contamination in various drug products, the FDA issued an "Alert," stating: "Drug manufacturers with a risk for benzene contamination should test their drugs accordingly and should not release any drug product batch that contains benzene above 2 ppm[.] … If any drug product batches with benzene above 2 ppm are already in distribution, the manufacturer should contact FDA to discuss the voluntary initiation

[13] *Id.*
[14] https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment.
[15] The term "ICH" refers to The International Conference on Harmonization (ICH) Q3C Impurities: Residual Solvents guidance (December 1997), at https://www.fda.gov/media/71736/download?attachment.
[16] The term "USP" refers to United States Pharmacopeia (USP) Residual Solvents, at https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf.

of a recall[.]"[17]

32. "Even in trace amounts, benzene is known to pose a health risk from exposure routes that include inhalation, ingestion, dermal absorption, and skin or eye contact."[18]

33. As with other topically applied products, such as sunscreen, the application of BPO Products specifically increases the absorption rate of benzene through the skin, thereby increasing the risk of harm.[19] Indeed, "[d]irect exposure of the eyes, skin, or lungs to benzene can cause tissue injury and irritation."[20] Accordingly, The National Institute for Occupational Safety and Health ("NIOSH") recommends protective equipment be worn by workers exposed or expecting to be exposed to benzene at concentrations of 0.1 ppm and defines "inhalation, skin absorption, ingestion, skin and/or eye contact" as exposure routes or paths.[21]

34. The Environmental Protection Agency ("EPA") similarly recognizes the cancer risks of benzene, noting that "Benzene is classified as a 'known' human carcinogen (Category A) under the Risk Assessment Guidelines of 1986."[22] "[B]enzene is characterized as a known human carcinogen for all routes of exposure based on convincing human evidence as well as supporting evidence from animal studies."[23]

35. EPA has set 0.0005 ppm as the maximum permissible level of benzene in drinking water, with a stated goal of "zero."[24]

36. In its review of non-cancer adverse health effects of benzene, the EPA cited

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[17] https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs.
[18] Hudspeth, A., et al., Independent Sun Care Product Screening for Benzene Contamination, Environmental Health Perspectives, 130:3, Online Publication 29 March 2022.
[19] *Valisure Detects Benzene in Sunscreen*, VALISURE BLOG (May 25, 2021), https://www.valisure.com/blog/valisure-news/valisure-detects-benzene-in-sunscreen/.
[20] *Facts About Benzene,* CENTERS FOR DISEASE CONTROL AND PREVENTION, https://emergency.cdc.gov/agent/benzene/basics/facts.asp.
[21] *NIOSH Pocket Guide to Chemical Hazards - Benzene*, THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH), https://www.cdc.gov/niosh/npg/npgd0049.html.
[22] https://cfpub.epa.gov/ncea/iris2/chemicallanding.cfm?substance_nmbr=276.
[23] *Id*.
[24] https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations.

epidemiologic evidence that "support a threshold of benzene hematotoxicity[25] in humans in the 5-19 ppm range[.]"[26] As noted in the EPA's review, "[c]learly, if a significantly elevated risk of benzene poisoning is an indication of hematotoxicity, then certainly exposures to benzene at 5-19 ppm are hematotoxic."[27]

## III. Discovery of Benzene in the BPO Product

37. On March 5, 2024, Valisure LLC ("Valisure") submitted a public citizens petition to the FDA requesting a recall and suspension of sales of benzoyl peroxide from the U.S. market. The petition was based on Valisure's findings that numerous BPO Product contained elevated levels of benzene, a known human carcinogen.[28]

38. "Valisure operates an analytical laboratory that is accredited under International Organization for Standardization ('ISO/IEC') 17025:2017 standards for chemical testing (PJLA Accreditation Number 94238)," and it "is registered with the Drug Enforcement Administration (License # RV0484814)."[29] As an industry leader in independent chemical testing of medications, Valisure works with large private health care systems like Kaiser Permanente and governmental healthcare systems like the Military Health System through the U.S. Department of Defense.[30]

39. In its citizens petition, Valisure reported its testing results for benzene in various types of BPO drug products, mostly utilizing gas chromatography and detection by mass

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[25] The term "hematotoxic" means "poisonous to the blood and to the organs and tissues involved in the production of blood, such as the bone marrow." https://clinicalinfo.hiv.gov/en/glossary/hematotoxic.
[26] EPA, Toxicological Review of Benzene (Noncancer Effects) (October 2002), at 38. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0276tr.pdf.
[27] *Id*.
[28] https://assets-global.website-files.com/6215052733f8bb8fea016220/65e8560962ed23f744902a7b_Valisure%20Citizen%20Petition%20on%20Benzene%20in%20Benzoyl%20Peroxide%20Drug%20Products.pdf.
[29] *Id.*
[30] Valisure Signs Agreement with Department of Defense to Independently Test & Quality Score Drugs. (August 8, 2023). PR Newswire. (https://www.prnewswire.com/newsreleases/valisure-signs-agreement-with-department-of-defense-to-independently-test--quality-score-drugs301895301.html).

spectrometry ("GC-MS") instrumentation that allows mass spectral separation and utilizing selected ion chromatograms, along with Selected Ion Flow Tube-Mass Spectrometry ("SIFT-MS") for detection of benzene released into the air around certain BPO Product. Valisure also used other orthogonal approaches for confirmation of a few select products.[31]

40. GC-MS "is generally considered one of the most accurate analyses available."[32] Indeed, the FDA used the same method to test for impurities like benzene in hand sanitizers.[33]

41. "The GC-MS method described in [Valisure's] petition utilized body temperature (37°C) for oven incubation. 40°C has been previously used for benzene analysis from liquid pharmaceuticals and beverages, and reduced false positive results compared with higher-temperature incubation."[34]

42. As reported, Valisure analyzed 66 different BPO containing drug products, both prescription and over-the-counter ("OTC") for the presence of benzene. Valisure acquired the products and incubated the products at 50°C[35] for 18 days, with samples measured at day 0, 4, 10, 14, and 18. These BPO containing products represented creams, lotions, gels, washes, liquids, and bars. As demonstrated below, results from this 50°C stability showed that every one of the 66 products contained some level of benzene ranging from a maximum of 2,000 ppm to 1.8 ppm.[36]

43. Valisure's findings with respect to its benzene testing of the BPO Product has been

[31] *Id.* at 10.
[32] *GC/MS Analysis*, Element, https://www.element.com/materials-testing-services/chemical-analysis-labs/gcms-analysis-laboratories.
[33] *Direct Injection Gas Chromatography Mass Spectrometry (GC-MS) Method for the Detection of Listed Impurities in Hand Sanitizers*, FDA (Aug. 24, 2020), https://www.fda.gov/media/141501/download.
[34] *Valisure Citizen Petition* at 10-11 (citations omitted).
[35] "50°C (122°F) is not only a reasonable temperature that 'the product may be exposed to during distribution and handling by consumers' but is an accepted incubation temperature used by the pharmaceutical industry for performing accelerated stability studies with a duration of at least 3 months." *Id.* at 18-19 (citations omitted).
[36] *Id*. at 16-18.

published in peer-reviewed literature.[37]

44. As noted above, independent testing conducted on Plaintiff's BPO Product in particular also revealed benzene levels far above of the maximum set by FDA guidelines, thus rendering the BPO Product harmful to human health and illegal to sell.

45. The BPO Products are not designed to contain benzene. Further, although Defendant lists benzoyl peroxide as the active ingredient on the BPO Products' labels, Defendant fails to disclose on the Products' labeling or anywhere in its marketing that the BPO Products contains benzene or can degrade to form benzene.

46. Despite its knowledge that its BPO Products contain benzene, Defendant has failed to issue a voluntary recall of the BPO Products.

## IV. Benzene Contamination Renders the BPO Product Adulterated, Misbranded, and Illegal to Sell

47. The BPO Product is a "drug" used to treat acne (i.e., *acne vulgaris*), formulated with a chemical called benzoyl peroxide, along with other inactive ingredients, to make acne treatment creams, washes, scrubs, and bars. Before being sold to the public, the BPO Product must be made in conformity with current good manufacturing practices and must conform to quality, safety, and purity specifications. Under the FDCA, a drug is adulterated "if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding do not confirm to or are not operated or administered in conformity with current good manufacturing practice…."[38]

48. Benzene is restricted by the FDA to 2 ppm where its use in manufacturing "is

[37] Kucera K, Zenzola N, Hudspeth A, Dubnicka M, Hinz W, Bunick CG, Dabestani A, Light DY. Benzoyl Peroxide Drug Products Form Benzene. Environ Health Perspect. 2024 Mar;132(3):37702. doi: 10.1289/EHP13984. Epub 2024 Mar 14. PMID: 38483533; PMCID: PMC10939128.
[38] 21 U.S.C. § 351(a)(2)(B).

unavoidable in order to produce a drug product with a significant therapeutic advance."[39] Except in such "limited cases," Class 1 solvents such as benzene should not be employed in the manufacture of drug substances or drug products "because of their unacceptable toxicity."[40] Defendant's BPO Product do not meet this safe harbor exception. This is because the use of benzene in the manufacture of the BPO Product is not "unavoidable," nor does the use of benzene in BPO Product provide a "significant therapeutic advance." Hence, in December 2022, the FDA issued a statement alerting manufacturers to the risk of benzene contamination and warned that any drug product containing more than 2 ppm benzene was adulterated and should be recalled. This statement was updated on December 27, 2023, and still provides that drug manufacturers "should not release any drug product batch that contains benzene above 2 ppm," and further provides, "[i]f any drug product batches with benzene above 2 ppm are already in distribution, the manufacturer should contact FDA to discuss the voluntary initiation of a recall[.]"[41]

49. It is therefore illegal under federal law to manufacture and distribute drug products in the United States that contain benzene above 2 ppm.[42] Hence, within the past three years alone, the FDA has announced over a dozen recalls of various drug and cosmetic products identified as containing "low levels" or even "trace levels" of benzene, including certain hand sanitizers and

[39] 2018 ICH Q3C guidance, at p. 5. US FDA, June 2017 (available at https://www.fda.gov/media/71737/download).
[40] *Reformulating Drug Products That Contain Carbomers Manufactured With Benzene*; Guidance for Industry – Final Guidance. US FDA, December 27, 2023 (citing 2018 ICH Q3C guidance at p. 5) (available at https://www.regulations.gov/document/FDA-2023-D-5408-0002).
[41] https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs. The FDA cannot force a drug manufacturer to recall a contaminated or adulterated drug. https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp ("While FDA cannot force a company to recall a drug, companies usually will recall voluntarily or at FDA's request").
[42] 21 U.S.C. § 351(a)(2)(B).

aerosol drug products like sunscreens and antiperspirants.[43]

50. It is also illegal to distribute benzene contaminated drug products under New York state law. For example, in New York, "[a] drug … shall be deemed to be adulterated: (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."[44]

51. A drug shall also be deemed to be adulterated: "If it purports to be, or is represented as, a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium[,]"[45]

52. Because all of Defendant's BPO Products contain benzene above 2 ppm, the BPO Products, among other things, (1) consist of a filthy, putrid, and/or decomposed substance, (2) have been prepared, packed, or held under unsanitary conditions or whereby it has been contaminated with benzene and rendered injurious to health, and (3) have a purity or qualify that falls below that which it purports or is represented to possess. As a result, it is illegal under New York law for Defendant to distribute any of its BPO Products in the State of New York.

53. As alleged herein, Defendant's BPO Products contain more than 2 ppm benzene and have been distributed to residents of the state of New York, including to Plaintiff.

54. The manufacture of any misbranded or adulterated drug is prohibited under federal

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[43] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/johnson-johnson-consumer-inc-issues-voluntary-recall-specific-neutrogenar-and-aveenor-aerosol; https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/edgewell-personal-care-issues-voluntary-nationwide-recall-banana-boat-hair-scalp-sunscreen-due-0; https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pg-issues-voluntary-recall-specific-old-spice-and-secret-aerosol-spray-antiperspirants-and-old-spice#:~:text=The%20Procter%20%26%20Gamble%20Company%20(NYSE,level%20due%20to%20the%20presence.

[44] N.Y Education Law §6815(1)(a).

[45] N.Y. Education Law §6815(1)(b).

law[46] and New York state law.[47]

55. Among the ways a drug may be misbranded under New York law include:

> a. If its labeling is false or misleading in any particular.[48] …
>
> f. Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users…;[49] or
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> i. If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.[50]

56. Defendant could have avoided any potential for benzene contamination in the BPO Products by changing the manufacturing process or raw ingredients, and the BPO Products could have been sold with absolutely no benzene in them. Specifically, benzoyl peroxide as a raw material is known to be thermally stable at purities as high as 75% up to temperatures of 98°C.[51] Valisure also evaluated pure BPO reference powder in its GC-MS analytical system and found no evidence of the instability and formation of benzene seen in formulated final products of BPO containing acne treatments.[52] Thus, if BPO is inherently stable as a pure, crystalline powder, a reformulated product that focuses on substantially reducing or entirely preventing the degradation of BPO into benzene could potentially be developed.[53]

57. The levels of benzene in the BPO Products renders the Products adulterated, misbranded, and illegal to sell. As such, the BPO Products have no economic value and are worthless. Worse, as manufactured, the levels of benzene contained in the BPO Product render

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[46] 21 U.S.C. §331(g).
[47] N.Y. Education Law § 6811(9)-(11)
[48] N.Y. Education Law §6815(2)(a).
[49] N.Y. Education Law §6815(2)(f).
[50] N.Y. Education Law §6815(2)(i).
[51] *Valisure Citizens Petition* at 25 (citation omitted).
[52] *Id.*
[53] *See id.* at 25-26.

them "dangerous to health" under the conditions of use prescribed in the labeling and advertising.[54]

58. As the FDA's July 2021 Health Hazard Evaluation concluded, serious adverse effects, including potential for "life-threatening" issues or "permanent impairment of a body function" were "likely to occur" at benzene exposure levels between 11.2 to 23.6 ppm.[55] As tested by Valisure and Plaintiff, Defendant's BPO Products meet or exceed these levels.

59. Similarly, in its review of the non-cancer effects of benzene, the EPA cites to studies in the medical literature which "support a threshold of benzene hematotoxicity in humans in the 5-19 ppm range, in broad agreement with the emerging exposure-response range that is apparent from the epidemiologic studies[.]"[56]

60. Defendant engaged in fraudulent, unfair, deceptive, misleading, and/or unlawful conduct stemming from its misrepresentations and omissions regarding benzene in its BPO Products.

61. If Defendant had disclosed to Plaintiff and putative Class members that the BPO Products contain benzene and/or would degrade to form benzene, Plaintiff and putative Class members would not have purchased the BPO Products.

62. As manufacturers, distributors, and sellers of acne treatment products, Defendant had and have a duty to ensure that its BPO Products did not and do not contain excessive levels of benzene, including through regular testing, especially before injecting the BPO Products into the stream of commerce for consumers to use on their skin.[57] This includes testing of raw materials and finished product batches prior to release to ensure they meet appropriate specifications for identity, strength, quality, and purity.[58] But Defendant made no reasonable effort to test its BPO

[54] N.Y. Education Law §6815(2)(f).
[55] https://article.images.consumerreports.org/prod/content/dam/CRO-Images-2021/Health/12Dec/FDA_Benzene_in_Sunscreen_Assessment.
[56] EPA, Toxicological Review of Benzene (Noncancer Effects) (October 2002), at 38. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0276tr.pdf.
[57] 21 CFR 211.84; 21 CFR 211.160.
[58] 21 CFR 211.165.

Products for the presence of benzene or test whether the Products could degrade to form benzene over the course of the shelf-life of the Products. Nor did Defendant disclose to Plaintiff in any advertising or marketing that its BPO Products contain benzene and/or could degrade to form benzene. To the contrary, Defendant represented that its BPO Products were of merchantable quality, safe to use as prescribed, complied with federal and state law, and did not contain carcinogens or other impurities such as benzene.

## V. Defendant's Knowledge, Misrepresentations, Omissions, and Concealment of Material Facts Deceived Plaintiff and Reasonable Consumers

63. It is well known that BPO degrades to form benzene when exposed to heat over time. This process was first reported in scientific literature as early as 1936.[59]

64. The issue of BPO decomposition into benzene has been previously identified and acted upon in industries other than in the acne treatment product industry.

65. For example, at least one patent application was filed by the chemical company Akzo Nobel N.V. in 1997 which "relates to a method for reducing the rate of free benzene and/or benzene derivative formation in BPO formulations based on organic plasticizers, such as pastes, emulsions, suspensions, dispersions and the like."[60]

66. In the polymer manufacturing industry, BPO's decomposition into benzene has been studied and concern was raised specifically regarding the carcinogenic implications of the presence of benzene. In 1994, a paper was published[61] by researchers at Denmark's Department of Environmental Chemistry titled "Formation of benzene by hardeners containing benzoyl peroxide and phthalates" and stated:

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[59] H. Erlenmeyer and W. Schoenauer, *Über die thermische Zersetzung von Di-acyl-peroxyden,* HELU. CHIM. ACTA, 19, 338 (1936), https://onlinelibrary.wiley.com/doi/10.1002/hlca.19360190153.

[60] Borys F. SchafranBryce Milleville (1997). "Reduction of benzene formation in dibenzoyl peroxide formulations." Akzo Nobel N.V. Worldwide application, WO1997032845A1. (https://patents.google.com/patent/WO1997032845A1/en)

[61] Rastogi SC. Formation of benzene by hardeners containing benzoyl peroxide and phthalates. *Bull Environ Contam Toxicol*. 1994 Nov;53(5):747-52. doi: 10.1007/BF00196949. PMID: 7833612.

> Recently, during the investigation of benzene residues in chemical products (Rastogi 1993a),[62] it was observed that the benzene content in benzoyl peroxide containing hardeners of two component repair-sets (fillers, elastomers) were >2 % (w/w) [20,000 ppm]. Benzene is carcinogenic (IARC 1982), and its use in consumer and industrial products is generally avoided.

67. The study continues with heating of various BPO-containing products at 34°C, 50°C and 80°C, finding substantial benzene formation at elevated temperatures, even exceeding levels found in Valisure's March 2024 public citizens petition. Furthermore, similar to Valisure's results, Rastogi finds that only formulations of BPO are unstable, while BPO alone is relatively stable:

> Even heating of BPO-phthalate mixtures at 50°C produced significant amounts of benzene (approximately 0.3% [3,000 ppm]), while no benzene production was detected when benzoyl peroxide was heated alone at this temperature (Table 2).[63]

68. The referenced 1993 Rastogi article above, titled "Residues of Benzene in Chemical Products," has also been flagged by the EPA as part of its Health & Environmental Research Online ("HERO") system.[64]

69. Chemical evidence of carcinogenicity has been reported since at least 1981.[65] Multiple studies in the 1980s were conducted using animal models that suggested carcinogenic potential of benzoyl peroxide, including the use of commercial drug formulations of BPO like that of the BPO Product at issue.[66]

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[62] Rastogi, S.C. Residues of benzene in chemical products. Bull. Environ. Contam. Toxicol. 50, 794-797 (1993). https://doi.org/10.1007/BF00209940.
[63] *Id.*
[64] US Environmental Protection Agency. Health & Environmental Research Online (HERO). "Residues of Benzene in Chemical Products." HERO ID 2894703 (http://hero.epa.gov/hero/index.cfm/reference/details/reference__id/2894703).
[65] Slaga TJ, Klein-Szanto AJ, Triplett LL, Yotti LP, Trosko KE. Skin tumor-promoting activity of benzoyl peroxide, a widely used free radical-generating compound. Science. 1981 Aug 28;213(4511):1023-5. doi: 10.1126/science.6791284. PMID: 6791284.
[66] Kurokawa Y, Takamura N, Matsushima Y, Imazawa T, Hayashi Y. *Studies on the promoting and complete carcinogenic activities of some oxidizing chemicals in skin carcinogenesis.* Cancer Lett. 1984 Oct;24(3):299-304. doi: 10.1016/0304-3835(84)90026-0. PMID: 6437666; Pelling JC,

70. In 1991, FDA posted an amendment to the monograph for OTC topical acne drug products because, "the agency became aware of a 1981 study by Slage, et al. ([FDA] Ref. 1) that raised a safety concern regarding benzoyl peroxide as a tumor promoter in mice and a 1984 study by Kurokawa, et al. ([FDA] Ref. 2) that reported benzoyl peroxide to have tumor initiation potential," leading FDA to determine that "further study is necessary to adequately assess the tumorigenic potential of benzoyl peroxide."[67]

71. By 2010, FDA published a final monograph on benzoyl peroxide along with summarizing results from further studies on the potential carcinogenicity of benzoyl peroxide and actions of the FDA Advisory Committee. This final monograph stated: "The Committee recommended, by a four-to-three vote (with one abstention), that the known safety data regarding the tumor promoting potential of benzoyl peroxide should be communicated to consumers. Because this data was inconclusive, the Committee unanimously agreed that the word, "cancer" should not be included in the labeling of acne drug products containing benzoyl peroxide. The Committee was concerned that the word "cancer" would cause consumers to avoid using these products (even though the data were inconclusive).[68]

72. Defendant, which markets itself as merchandisers of quality acne treatment products that employs high-level scientists, chemists, and researchers to formulate and/or decide which drug products to label and sell for public use, was aware of the well-known chemical processes that degrade its BPO Product into benzene when exposed to commonly used

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Fischer SM, Neades R, Strawhecker J, Schweickert L. *Elevated expression and point mutation of the Ha-ras proto-oncogene in mouse skin tumors promoted by benzoyl peroxide and other promoting agents*. Carcinogenesis. 1987 Oct;8(10):1481-4. doi: 10.1093/carcin/8.10.1481. PMID: 3115617; 81 O'Connell JF, Klein-Szanto AJ, DiGiovanni DM, Fries JW, Slaga TJ. *Enhanced malignant progression of mouse skin tumors by the free-radical generator benzoyl peroxide.* Cancer Res. 1986 Jun;46(6):2863-5. PMID: 3084079; 82 Iversen OH. *Carcinogenesis studies with benzoyl peroxide (Panoxyl gel 5%)*. J Invest Dermatol. 1986 Apr;86(4):442-8. doi: 10.1111/1523-1747.ep12285787. PMID: 3091706.

[67] Food and Drug Administration. *Proposed Rule: Reclassifies benzoyl peroxide from GRASE to Category III.* (August 7, 1991) Federal Register, 56FR37622. pp 37622 - 37635 (https://cdn.loc.gov/service/ll/fedreg/fr056/fr056152/fr056152.pdf#page=178).

[68] Food and Drug Administration. Final Monograph. (March 4, 2010) Federal Register, 75FR9767. (https://www.gpo.gov/fdsys/pkg/FR-2010-03-04/pdf/2010-4424.pdf).

temperatures and conditions.

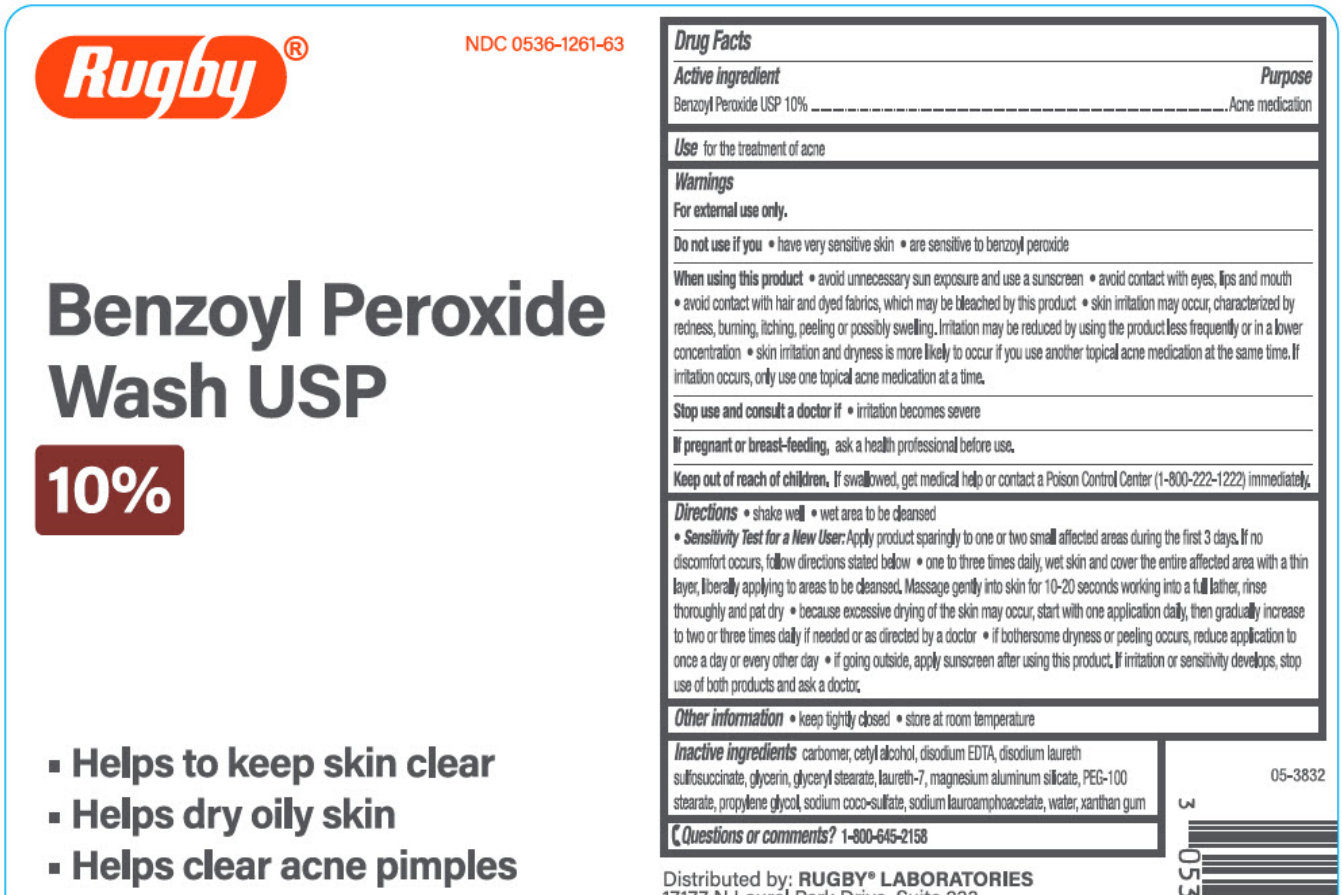
73. Defendant, as a large, sophisticated corporations in the business of manufacturing, distributing, and selling products containing BPO, knew or should have known the BPO Product was contaminated with excess levels of benzene and that testing the BPO Product for benzene was necessary to protect Plaintiff and Class members from harmful levels of benzene exposure.

74. Defendant's use of BPO put it on notice of the potential for excessive levels of benzene in its BPO Product.

75. Notwithstanding this knowledge, Defendant failed to appropriately and adequately test its BPO Products for the presence of benzene to protect Plaintiff and Class members from dangerous levels of benzene exposure.

76. Defendant sold, and continues to sell, the BPO Product during the class period despite its knowledge of benzene contamination.

77. Moreover, benzene is not listed on the BPO Products' labels as an ingredient or inactive ingredient, nor is there any warning about the presence (or even potential presence) of benzene in the BPO Products. The following image shows an example:



78. Plaintiff has standing to represent members of the putative Class because there is sufficient similarity between the specific BPO Product purchased by Plaintiff and the other BPO Products not purchased by Plaintiff.[69] Specifically, each and every one of the BPO Products (i) are marketed in substantially the same way—as an acne treatment—and (ii) fail to include labeling indicating to consumers that the BPO Products contain benzene and/or degrade to form benzene during the shelf-life of the Products. Accordingly, the misleading effect of all the BPO Products' labels are substantially the same.

79. Defendant has engaged in deceptive, untrue, and misleading advertising by making representations by failing to warn about the presence of benzene in the BPO Products.

80. As alleged, the presence of benzene in the BPO Products render the Products misbranded and adulterated and therefore illegal and unfit for sale in trade or commerce. Plaintiff would not have purchased the BPO Product had it been truthfully and accurately labeled.

81. Had Defendant adequately tested its BPO Products for benzene and other carcinogens and impurities, it would have discovered its Products contain benzene and/or degrade to form benzene at levels above 2 ppm, making the BPO Products illegal to market, distribute, or sell as drugs in the United States.

[69] Other BPO Products manufactured and sold by Defendant include Rugby Benzoyl Peroxide Wash USP 5%, Rugby Acne Medication Benzoyl Peroxide Gel USP 5%, Rugby Acne Medication Benzoyl Peroxide Gel USP 10%, and Rugby Acne Medication Benzoyl Peroxide Gel USP 2.5%.

82. Accordingly, Defendant knowingly, recklessly, or at least negligently, introduced the contaminated, adulterated, and misbranded BPO Products into the U.S. market.

83. Defendant's concealment was material and intentional because people are concerned with what is contained in the products they are putting onto and into their bodies. Consumers such as Plaintiff and Class members make purchasing decisions based on the representations made on the BPO Products' labeling, including the Products' contents.

## VI. Injuries to Plaintiff and Class Members

84. When Plaintiff purchased Defendant's BPO Product, Plaintiff did not know, and had no reason to know, that Defendant's BPO Product contained benzene and/or would degrade to form benzene. Not only would Plaintiff not have purchased Defendant's BPO Product had he known the Product contained benzene and/or would degrade to form benzene, he would not have been capable of purchasing it if Defendant had done as the law required and tested the BPO Product for benzene and other carcinogens and impurities.

85. Consumers lack the ability to test or independently ascertain or verify whether a product contains unsafe substances, such as benzene, especially at the point of sale, and therefore must rely on Defendant to truthfully and honestly report on the BPO Product packaging and labeling what the Product contains.

86. Further, given Defendant's position as a leader in the acne treatment market, Plaintiff and reasonable consumers trusted and relied on Defendant's representations and omissions regarding the presence of benzene in the BPO Product.

87. Defendant's false and misleading omissions and deceptive misrepresentations regarding the presence of benzene in the BPO Product is likely to continue to deceive and mislead reasonable consumers and the public, as it has already deceived and misled Plaintiff and the Class

members.

88. Plaintiff and Class members bargained for products free of contaminants and dangerous substances. Plaintiff and Class members were injured by the full purchase price of the BPO Product because the Product is worthless, as it is adulterated, contains harmful levels of benzene, and illegal to sell, and Defendant failed to warn consumers of this fact. Such illegally sold products are worthless and have no value.

89. As a proximate result thereof, Plaintiff and Class members are entitled to statutory and punitive damages, attorneys' fees and costs, and any further relief this Court deems just and proper.

90. All conditions precedent to the prosecution of this action have occurred, and/or have been performed, excused, or otherwise waived. Specifically, on August 8, 2024, Plaintiff provided notice via certified mail to Defendant of its alleged breaches of implied warranty with respect to its BPO Products as required under New York Uniform Commercial Code Section 2-607(3)(a).

## CLASS ALLEGATIONS

91. Plaintiff, individually and on behalf of all others similarly situated, bring this class action pursuant to Fed. R. Civ. P. 23.

92. Plaintiff seeks to represent classes defined as:

> **New York Class**
>
> All persons who purchased Rugby® Laboratories' branded BPO Products in the State of New York for personal, family or household use within the applicable limitations period.

93. Excluded from the Class are: (1) any Judge or Magistrate presiding over this action and any members of their families; (2) Defendant, Defendant's subsidiaries, parents, successors, predecessors, and any entities in which Defendant or its parent and any entities in which Defendant

has a controlling interest and its current or former employees, officers, and directors; and (3) individuals who allege personal bodily injury resulting from the use of the BPO Products.

94. Plaintiff reserves the right to modify, change, or expand the definitions of the Class based upon discovery and further investigation.

95. *Numerosity*: The Class is so numerous that joinder of all members is impracticable. The Class likely contains tens of thousands of members based on publicly available data. The Class is ascertainable by records in Defendant's possession, receipts and/or packaging in the possession of Plaintiff and other Class members, as well as the affidavits of purchase.

96. *Commonality*: Questions of law or fact common to the Class include:

a. Whether the BPO Products contain benzene;

b. Whether a reasonable consumer would consider the presence of benzene in the BPO Products to be material;

c. Whether Defendant knew or should have known that the BPO Products contained benzene and/or could degraded to form benzene;

d. Whether Defendant misrepresented that the BPO Products contained and/or degrade to form benzene;

e. Whether Defendant failed to disclose that the BPO Products contain and/or degrade to form benzene;

f. Whether Defendant concealed that the BPO Products contain and/or degrade to form benzene;

g. Whether Defendant engaged in unfair or deceptive trade practices;

h. Whether Defendant violated the state consumer protection statutes alleged herein; and

i. Whether Plaintiff and Class members are entitled to damages.

97. *Typicality*: Plaintiff's claims are typical of the claims of Class members. Plaintiff and Class members were injured and suffered damages in substantially the same manner, have the same claims against Defendant relating to the same course of conduct, and are entitled to relief under the same legal theories.

98. *Adequacy*: Plaintiff will fairly and adequately protect the interests of the Class and has no interests antagonistic to those of the Class. Plaintiff has retained counsel experienced in the prosecution of complex class actions, including actions with issues, claims, and defenses similar to the present case. Counsel intends to vigorously prosecute this action.

99. *Predominance and superiority*: Questions of law or fact common to Class members predominate over any questions affecting individual members. A class action is superior to other available methods for the fair and efficient adjudication of this case because individual joinder of all Class members is impracticable and the amount at issue for each Class member would not justify the cost of litigating individual claims. Should individual Class members be required to bring separate actions, this Court would be confronted with a multiplicity of lawsuits burdening the court system while also creating the risk of inconsistent rulings and contradictory judgments. In contrast to proceeding on a case-by-case basis, in which inconsistent results will magnify the delay and expense to all parties and the court system, this class action presents far fewer management difficulties while providing unitary adjudication, economies of scale and comprehensive supervision by a single court. Plaintiff is unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

100. Accordingly, this class action may be maintained pursuant to Fed. R. Civ. P.

23(b)(3).

**COUNT I**
**Violation of the New York False Advertising Act, New York Gen. Bus. Law § 350**
**(On Behalf of Plaintiff Kouyate and the New York Class)**

103. Plaintiff Kouyate incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

104. Plaintiff Kouyate brings this Count individually and on behalf of the New York Class against Defendant.

105. Defendant was and is engaged in the "conduct of business, trade or commerce" within the meaning of N.Y. Gen. Bus. Law §350.

106. The New York False Advertising Act ("New York FAA") prohibits "[f]alse advertising in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law §350. False advertising includes "advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect," taking into account "the extent to which the advertising fails to reveal facts material in the light of . . . representations [made] with respect to the commodity." N.Y. Gen. Bus. Law §350-a(1).

107. Defendant had a duty to disclose that the BPO Products contained benzene and/or degraded into benzene because it had superior—indeed exclusive—knowledge of the material fact that benzoyl peroxide could produce benzene and/or degrade to form benzene. Nevertheless, Defendant made representations that its BPO Products were safe and fit to be used for the treatment of acne.

108. Defendant caused to be made or disseminated through New York and the United States, through advertising, marketing, and/or other publications, statements that were untrue or misleading, and which were known, or which by the exercise of reasonable care should have been

known to Defendant, to be untrue and misleading to consumers, including Plaintiff and other Class members.

109. In the course of its business, Defendant, directly or through their agents, employees, and/or subsidiaries, violated the New York FAA by knowingly and intentionally misrepresenting, omitting, concealing, and/or failing to disclose material facts regarding BPO Products as detailed above.

110. Defendant's BPO Products are not safe or fit for their intended use because the Products contain benzene and/or degrade to form benzene at levels which render them dangerous to human health when used as directed and thus illegal to sell.

111. Specifically, by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose the material fact that its BPO Products contain benzene and/or degrade to form benzene and were (and are) not fit to be used for its intended purpose, as detailed above, Defendant engaged in one or more unfair or deceptive acts or practices in the conduct of trade or commerce in violation of the New York FAA.

112, Defendant's unfair or deceptive acts or practices, including its misrepresentations, concealments, omissions, and/or suppressions of material facts, as alleged herein, had a tendency or capacity to mislead and create a false impression in consumers' minds and were likely to and, in fact, did deceive reasonable consumers, including Plaintiff and other Class members, about the BPO Products' safety and fitness for their intended purposes, as detailed above.

113. The facts regarding BPO Products that Defendant knowingly and intentionally misrepresented, omitted, concealed, and failed to disclose would be considered material by a reasonable consumer, and they were, in fact, material to Plaintiff and other Class members, who consider such facts to be important to their purchasing decisions with respect to BPO Products.

114. Plaintiff and the other Class members had no way of reasonably discerning that Defendant's representations were false and misleading or otherwise learning the facts that Defendant had concealed or failed to disclose.

115. Defendant had an ongoing duty to Plaintiff and other Class members to refrain from false and misleading practices under the New York FAA in the course of its business. Specifically, Defendant owed Plaintiff and other Class members a duty to disclose all the material facts regarding its BPO Products, including that such products contained benzene and/or degraded into benzene and were (and are) not fit to be used for its intended purpose, as detailed above, because Defendant possessed superior knowledge, intentionally concealed the material facts regarding its BPO Products, and/or it made misrepresentations that were rendered misleading because they were contradicted by withheld facts, including that such Products contained benzene and/or degraded into benzene and were (and are) not fit to be used for their intended purpose.

116. Plaintiff and other Class members were aggrieved by Defendant's violations of the New York FAA because they suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's knowing and intentional misrepresentations, omissions, concealments, and failures to disclose material facts regarding BPO Products, including that such products contained benzene and/or degraded into benzene and not fit to be used for its intended purpose. Specifically, Plaintiff and other Class members purchased BPO Products in reliance on Defendant's misrepresentations, omissions, concealments, and/or failures to disclose material facts regarding BPO Products. Had Defendant not engaged in the deceptive acts and practices alleged herein, Plaintiff and Class members would not have purchased the BPO Products at all, or would have paid less for them, and, thus, they did not receive the benefit of the bargain and/or suffered out-of-pocket loss.

117. Defendant's violations present a continuing risk to Plaintiff and other Class members, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

118. As a result of Defendant's violations of the New York FAA, as alleged herein, Plaintiff and other Class members seek to recover their actual damages or $500, whichever is greater. Because Defendant acted willfully or knowingly, Plaintiff and other Class Members are entitled to recover three times actual damages, up to $10,000. Plaintiff and other Class members seek an additional civil penalty of $10,000 per elderly person sixty-five years of age or older because Defendant's conduct was in willful disregard of the rights of elderly persons. N.Y. Gen. Bus. Law § 349-C(2)(b). Plaintiff and other Class members also seek an order enjoining Defendant's false advertising, attorneys' fees, and other relief that this Court deems just and appropriate.

**COUNT II**
**Fraud/Misrepresentation**
**(On Behalf of Plaintiff Kouyate and the New York Class)**

119. Plaintiff Kouyate incorporates by reference and re-allege each and every allegation contained above, as though fully set forth herein.

120. Plaintiff Kouyate brings this Count individually and on behalf of the New York Class against Defendant.

121. Defendant intentionally and knowingly falsely concealed, suppressed and/or omitted material facts including as to the standard, quality or grade of the BPO Product.

122. Defendant intended to defraud Plaintiff and the other Class members.

123. Due to Defendant's fraudulent conduct, Plaintiff and the other Class members have suffered actual damages.

124. Defendant knew or should have known that its BPO Products contain benzene and/or degrade into benzene when used as directed.

125. Defendant knew or should have known that its concealment and suppression of material facts was false and misleading and knew the effect of concealing those material facts.

126. Defendant acted with malice, oppression, and fraud.

127. Defendant knew or should have known of the dangers associated with benzene in its BPO Product based on regulatory studies and regulatory guidance.

128. Defendant was obligated to inform Plaintiff and the other Class members of the dangers associated with benzene in the BPO Products due to its exclusive and superior knowledge of the Products.

129. Plaintiff and other Class members also expressly reposed a trust and confidence in Defendant because of its dealings as a healthcare entity and with Plaintiff and other Class members as their customers.

130. Plaintiff and the other Class members would not have purchased the BPO Products but for Defendant's omissions and concealment of material facts regarding the nature and quality of the Products, or would have paid less for the Products.

131. Plaintiff and Class members were justified in relying on Defendant's misrepresentations and/or omissions.

132. As alleged herein, Plaintiff and the Class members have suffered injury in fact and lost money as a result of Defendant's conduct because they purchased BPO Products from Defendant in reliance on Defendant's misrepresentations that the BPO Products were safe to use as directed.

133. Although Defendant is in the best position to know (1) what content it placed on its

website(s), social media sites, and in marketing materials during the relevant timeframe, (2) the knowledge it had regarding the presence of benzene in its BPO Products, and (3) its failure to disclose the existence of excessive levels of benzene in its Products and/or the fact that its Products could degrade to form excessive levels of benzene Plaintiff alleges the following facts with particularity:

a. WHO: Defendant made false statements and material misrepresentations and/or omissions of fact on its BPO Products, labeling, marketing materials and in public statements, which include express and/or implicit representations that its Products were (and are) safe to use as directed and free from excessive levels of benzene.

b. WHAT: Defendant falsely and misleadingly, and through misrepresentations and omissions, led consumers to believe that its BPO Products were (and are) safe to use as directed and free of excessive levels of benzene yet failed to disclose that the Products contain excessive levels of benzene and/or degrade to form excessive levels of benzene. Thus, Defendant's conduct deceived Plaintiff into believing that the Product was created, manufactured, and sold with such qualities. Defendant knew or should have known that this information was material to reasonable consumers, including Plaintiff, in making purchasing decisions about which benzoyl peroxide acne treatment products to purchase and use on their skin, yet Defendant continued (and continues) to pervasively market the Products as possessing qualities they do not possess.

c. WHEN: Defendant made material misrepresentations, false statements and/or omissions both prior to and at the time Plaintiff purchased the BPO Product in approximately 2024.

d. WHERE: Defendant's marketing message was uniform and pervasive, carried through material misrepresentations, false statements and/or omissions on its BPO Products labeling and packaging, website and social medical accounts throughout the United States and in

the State of New York

e. HOW: Defendant made material misrepresentations, false statements and/or omissions regarding the presence of benzene in its BPO Products by making express and/or implicit representations in the above-referenced materials their its Products were safe and by omitting any facts in its marketing, labeling, and/or descriptions of its Products that would inform a consumer as to the presence of excessive levels of benzene and/or that its Product can degrade to form excessive levels of benzene.

f. WHY: Defendant made material misrepresentations, false statements, and/or omissions detailed herein for the express purpose of inducing Plaintiff and Class members to purchase and/or pay for the BPO Products instead of other brands of benzoyl peroxide acne treatment products, the effect of which was that Defendant profited by selling the Products to thousands of consumers.

g. INJURY: Plaintiff purchased Defendant's BPO Product when Plaintiff otherwise would not have, or would have paid less for it, absent Defendant's misrepresentations, false statements, and/or omissions. Plaintiff purchased and used an unsafe and harmful Product that should not be used by anyone and, in fact, is illegal to sell in the United States and under New York state law because it contains excessive levels of benzene and/or degrades to form excessive levels of benzene. As a result, Plaintiff suffered economic harm. As a direct and proximate result thereof, Plaintiff and members of the Class are entitled to a full refund in the amount they spent on the BPO Products and other legal and equitable relief.

**COUNT III**
**Negligence Per Se**
**(On Behalf of Plaintiff Kouyate and the New York Class)**

134. Plaintiff incorporates by reference and re-alleges each and every allegation

contained above, as though fully set forth herein.

135. Plaintiff Kouyate brings this Count individually and on behalf of the New York Class against Defendant.

136. N.Y. Education Law § 6811(9)-(11) states that it is a class A misdemeanor under state law to "manufacture, sell, deliver for sale, hold for sale or offer for sale of any drug . . . that is adulterated or misbranded; "adulterate or misbrand any drug . . ."; or "receive in commerce any drug . . . that is adulterated or misbranded, and to deliver or proffer delivery thereof for pay or otherwise". .

137. Plaintiff and the Class members are members of the general public who purchased and used Defendant's adulterated, contaminated, and misbranded BPO Products in the State of New York. As such, they are among the class of people these state statutes are meant to protect. .

138. Moreover, the creation of a private right of action is consistent with the overall legislative purpose of these statutes because each of the aforementioned regulations are intended to protect the consuming public from contaminated, misbranded, and adulterated drugs and insure that such drugs will not be sold to consumers.

139. As alleged herein, Defendant violated New York state law because it manufactured and sold adulterated and misbranded Products that contain benzene and/or degrade to form benzene, then introduced such adulterated and misbranded Products into the stream of commerce. Further, as alleged, the levels of benzene detected in the Products render the Products dangerous to health when used as prescribed and illegal to sell under New York state law.[70].

140. Plaintiff and Class members would not have been injured had Defendant not violated New York state law by introducing the adulterated and misbranded Products into the

[70] *See, e.g.* N.Y Education Law §6815(1)(a); §6815(1)(b); §6815(2)(a); §6815(2)(f); and §6815(2)(i).

stream of commerce.

141. As a direct and proximate result thereof, Plaintiff and members of the Class are entitled to a full refund in the amount they spent on the BPO Products and other legal and equitable relief.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of themselves and all others similarly situated, pray for judgment against the Defendant as to each and every count, including:

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

B. An order requiring Defendant to pay restitution/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, untrue or misleading advertising in violation of the above-cited authority, plus pre- and post-judgment interest thereon;

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

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

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

## DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Date: August 16, 2024

Respectfully Submitted,

By: /s/ D. Nicole Guntner
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