

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION**

STEVE AUDELO, on behalf
of themselves and all other
similarly situated,

Plaintiff,

vs.

JOHNSON & JOHNSON
CONSUMER INC. and PROCTER
& GAMBLE;

Defendants.

Case No. 3:23-cv-24250

CLASS ACTION COMPLAINT

Steve Audelo (“Plaintiff”), on behalf of himself and all others similarly situated, file this Class Action Complaint (“CAC”) against Defendants Johnson & Johnson Consumer Inc. (“J&J” or “Defendant”) and Procter & Gamble (“P&G” or “Defendant”), and in support states the following:

NATIURE OF THE ACTION

1. This is a class action lawsuit brought under Florida’s consumer protection laws by Plaintiff, and others similarly situated, who purchased the

following over-the-counter (“OTC”) decongestant products containing phenylephrine: (1) Sudafed PE, (2) Vicks NyQuil, and (3) Benadryl Allergy Plus Congestion (collectively the “Products”). These Products are manufactured, sold and distributed by Defendants and have been found by the U.S. Food and Drug Administration (“FDA”) to lack efficacy. The Products’ lack of efficacy in was not disclosed to Plaintiff prior to Plaintiff’s purchase of the Products and Plaintiff would not have purchased the Products had he known they did not work as advertised. Plaintiff and the putative class suffered economic damages due to Defendants’ misconduct (as set forth below) and they seek injunctive relief and restitution for the full purchase price of the Products they purchased. 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.

JURISDICTION AND VENUE

2. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$5,000,000 and is a class action in which there are in excess of 100 class members and Plaintiff is a citizen of a state different from Defendants.

3. This Court has jurisdiction over each Defendant because both

Defendants are authorized to conduct and do business in Florida. Defendants have marketed, promoted, distributed, and sold the Products in Florida and Defendants have sufficient minimum contacts with this State and/or sufficiently avail themselves of the markets in this State through promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.

4. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred while he resided in this judicial district. Venue is also proper under 18 U.S.C. §1965(a) because Defendants transact substantial business in this District.

THE PARTIES

5. Plaintiff Steve Audelo is a citizen and resident of Escambia County, and at all times relevant hereto, has been a resident of Escambia County. Within the class period define defined below, Plaintiff purchased Sudafed PE, Vicks NyQuil, and Benadryl Allergy Plus Congestion in Escambia County. During that time, based on the false and misleading claims by Defendants, Plaintiff was unaware that Defendants' Products were not an effective remedy for congestion and/or cold symptoms. Plaintiff purchased the Defendants' Products on the assumption that the labeling of the Products was accurate and that the Products worked as advertised. Plaintiff would not have purchased Defendants' Products had he known they were not effective and lacked efficacy. As a result, Plaintiff suffered injury in fact when

he spent money to purchase Products he would not otherwise have purchased absent Defendants' misconduct, as alleged herein.

6. Defendant Johnson & Johnson Consumer Inc., a McNeil Consumer Healthcare Division, is a New Jersey corporation with its headquarters and principal place of business at 199 Grandview Road, Skillman, New Jersey, 08558. J&J manufactures, markets, advertises, labels, distributes and sells Sudafed PE and Benadryl Allergy Plus Congestion. J&J may be served via its registered agent, C T Corporation System, 100 Biscayne Blvd., Miami, FL 33132.

7. Defendant Procter & Gamble is an Ohio corporation with its headquarters and principal place of business at One Procter & Gamble Plaza, Cincinnati, Ohio 45202. Procter & Gamble manufactures, markets, advertises, labels, distributes and sells Vicks NyQuil. Procter & Gamble may be served via its registered agent, C T Corporation System, 1200 South Pine Island Rd., Plantation, FL 33324.

INTRODUCTION

8. Defendant, J&J, is a corporation engaged in the manufacture, marketing, and sale of various OTC pharmaceutical products, including Sudafed PE and Benadryl Allergy Plus Congestion.

9. Defendant, Procter & Gamble, is a corporation engaged in the manufacture, marketing, and sale of various OTC pharmaceutical products,

including Vicks NyQuil.

10. Collectively, Defendants J&J and Procter & Gamble marketed and sold the Products to consumers in Florida and across the United States as an effective nasal decongestant.

11. The main active ingredient in the Products is phenylephrine hydrochloride, or “PE.” In 1994, the FDA issued a final monograph establishing conditions under which OTC nasal decongestant drug products are generally recognized as safe and effective (“GRASE”) and not misbranded. Phenylephrine is included in the final monograph as an OTC oral nasal decongestant. Defendants marketed PE as an effective decongestant that should be used to relieve nasal congestion and sinus pressure associated with colds, allergies, and other respiratory conditions.

12. According to Defendants, phenylephrine works by constricting blood vessels in the nasal passages, which reduces swelling and congestion.

13. Over the years, Defendants made the following claims in their marketing materials concerning the efficacy of their Products,

14. For example, for Sudafed PE, these claims include:

- Relief from Nasal Congestion: Sudafed PE products provide relief from nasal congestion associated with colds, allergies, or sinus congestion.
- Fast-Acting: Some Sudafed PE products are fast-acting and provide rapid relief from congestion symptoms.

- 24-Hour Relief: Sudafed PE provide up to 24 hours of relief from congestion symptoms, reducing the need for frequent dosing.
- Sinus Pressure Relief: Sudafed PE's is highly effective in relieving sinus pressure in addition to congestion.
- Sudafed PE offers relief from multiple cold and allergy symptoms, such as nasal congestion, sinus pressure, sneezing, and runny nose.

15. For Benadryl Allergy Plus Congestion, these claims include:

- Allergy Relief you can trust and fast congestion relief.
- Relief of: Runny nose, sneezing, itchy, watery eyes, itchy throat or nose, sinus congestion, stuffy nose.
- Benadryl Allergy Plus Congestion relieves allergy and cold symptoms such as: sneezing, itchy, watery eyes, runny nose, itchy throat or nose, sinus congestion.
- Powerful allergy relief with fast congestion relief.

16. For Vicks NyQuil, these claims include:

- The congestion, pressure & pain, clear your head, medicine.
- Fast Relief- Clear your head with fast acting nighttime relief.
- Powerful congestion, pressure and pain relief.
- Maximum strength sinus relief.
- Fast, powerful cold and congestion relief.

17. In 2007, the consumer advocacy group Public Citizen filed a petition with the U.S. Food and Drug Administration (FDA) regarding phenylephrine. The petition requested that the FDA re-evaluate the safety and efficacy of phenylephrine as a nasal decongestant and take regulatory action.

18. Public Citizen expressed concerns that phenylephrine, the active ingredient in many OTC decongestant products, was not as effective as another decongestant called pseudoephedrine.

19. The petition argued that the switch from pseudoephedrine to phenylephrine in many cold and allergy medications had not been supported by adequate scientific evidence demonstrating the latter's effectiveness in relieving nasal congestion.

20. Public Citizen also raised concerns about the potential side effects and safety of phenylephrine, suggesting that its use might lead to increased blood pressure in some individuals.

21. The FDA reviewed the concerns raised by the Public Citizen petition regarding the safety and efficacy of phenylephrine as a nasal decongestant. The FDA concluded that, based on the available data at the time of its review in 2007, phenylephrine could be considered effective as a nasal decongestant when used at the recommended doses.

22. Thus, in 2007, the FDA concluded that orally administered PE was Generally Recognized as Safe and Effective (GRASE).

23. The FDA's GRASE determination allowed Defendants to market the Products as an OTC or "over-the-counter" medication. This was an important designation to Defendants as it allowed them to market the Products to consumers without requiring a doctor's prescription, making it more accessible for self-treatment, and allowing Defendants to make billions of dollars in OTC sales.

24. However, on September 11th and 12th, 2023, the FDA issued a new report detailing its updated review of the efficacy of phenylephrine, based on the studies it initially reviewed in 2007 and additional studies obtained since its initial review. A copy of the FDA's report is attached as Exhibit A.

25. The FDA's findings are based on rigorous scientific research and evaluation.

26. At its initial 2007 Nonprescription Drugs Advisory Committee ("NDAC") meeting and review, the FDA reviewed clinical effectiveness data for oral doses between 5mg and 40mg in a total of 14 studies, of which 7 reported positive measurable efficacy results.

27. In its re-analysis of these studies in 2023, the FDA found significant problems:

[w]hen considering the studies through a modern drug review lens, all of the studies (both positive and negative)

were highly problematic in both design and methodology. All used a highly variable endpoint (NAR) to study a drug in the setting of a highly variable disease state (the common cold) that is no longer used as a primary endpoint to evaluate congestion in pivotal trials.¹ Further, all the positive studies (and most of the negative studies) were unpublished and therefore never peer-reviewed. Six of the seven positive studies came from a single study center (funded by the manufacturer of Neo-Synephrine), were very small in size, and (except in one instance) the results could not be duplicated at two other study centers (also funded by the same manufacturer) that used a similar study design and methodology. (emphasis added).

Exhibit A.

28. The FDA thus found that the original studies had data integrity issues and that the results from the Elizabeth study site, a study it relied on in 2007, could not be duplicated in at least two other Sterling-Winthrop study sites that used a similar study design and methodology.

29. As noted in the FDA’s re-evaluation of the data, the original studies used to support the GRASE determination in 2007 were based on “equivocal findings.” Exhibit A. Indeed, there were “significant deficiencies” in the “design and conduct of these studies.” *Id.*

¹ The FDA’s Guidance for Industry on Developing Drug Products for Treatment of Allergic Rhinitis recommends use of symptom scores for the primary endpoint in clinical trials. *See* FDA, 2018, Guidance for Industry; Allergic Rhinitis: Developing Drug Products for Treatment, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/allergic-rhinitis-developing-drugproducts-treatment-guidance-industry> (hereafter “FDA Guidance for Industry (2018)”).

30. In light of the methodological and design flaws it found, the FDA now believes that “the original studies evaluated for efficacy” are “unacceptable as continued support for the efficacy of monographed doses or oral PE.” Exhibit A.

31. Since 2007, several additional large clinical trials have been conducted regarding the efficacy of phenylephrine.² Those studies provide evidence of the absence of a decongestant effect from the OTC approved doses of 10 mg.

32. For example, Horak et al (2009) found that PE was not significantly different from placebo in the mean change in subjective nasal congestion scores whereas pseudoephedrine, a positive control in the study, decreased congestion significantly greater than placebo and PE.

33. Day et al (2009) similarly reported no difference between PE and placebo with respect to decreased nasal congestion scores.

² See, e.g., Gelotte, CK and BA Zimmerman, 2015, Pharmacokinetics, safety, and cardiovascular tolerability of phenylephrine HCl 10, 20, and 30 mg after a single oral administration in healthy volunteers, *Clin Drug Investig*, 35(9):547-558; Day, JH, MP Briscoe, JD Ratz, M Danzig, and R Yao, 2009, Efficacy of loratadine-montelukast on nasal congestion in patients with seasonal allergic rhinitis in an environmental exposure unit, *Ann Allergy Asthma Immunol*, 102(4):328-338; Horak, F, P Zieglmayer, R Zieglmayer, P Lemell, R Yao, H Staudinger, and M Danzig, 2009, A placebo-controlled study of the nasal decongestant effect of phenylephrine and pseudoephedrine in the Vienna Challenge Chamber, *Ann Allergy Asthma Immunol*, 102(2):116-120; Meltzer, EO, PH Ratner, and T McGraw, 2015, Oral phenylephrine HCl for nasal congestion in seasonal allergic rhinitis: A randomized, open-label, placebo-controlled study, *J Allergy Clin Immunol Pract*, 3(5):702-708; Meltzer, EO, PH Ratner, and T McGraw, 2016, Phenylephrine hydrochloride modified-release tablets for nasal congestion: a randomized, placebo-controlled trial in allergic rhinitis patients, *Ann Allergy Asthma Immunol*, 116(1):66-71.

34. Gelotte and Zimmerman (2015) likewise reported a lack of local decongestion effect of PE, finding that doses up to three times the labeled OTC for oral phenylephrine are unlikely to be effective as a nasal decongestant.

35. Thus, the results of several studies reported after the initial efficacy determination of the Products in 2007 clearly demonstrate that PE is no more effective than placebo in decreasing nasal congestion and, thus, lacks efficacy.

36. On September 12, 2023, an FDA panel unanimously declared that phenylephrine, the active ingredient in the Products, is an ineffective decongestant.

37. As of 2007, nasal airway resistance (“NAR”) was the principle methodology used to assess the effectiveness of oral PE. This methodology used measurements of airflow and air pressure in the nasal passage to calculate NAR as an indirect measure of the level of nasal congestion.

38. In 2018, however, the FDA issued new guidance for industry as it related to the use of nasal congestion symptom scores to evaluate congestion,³ meaning that NAR was no longer used as a primary endpoint to evaluate congestion in studies.

39. Based on the FDA’s new 2018 guidance, Defendants knew or should have known that their marketing claims regarding the Products’ efficacy were false

³ FDA Guidance for Industry (2018).

and misleading. This is because the primary endpoint for evaluating the efficacy of the Products had changed since the FDA's 2007 NDAC meeting, meaning that the previous data under which the Products were approved as GRASE no longer supported efficacy. There have been no published studies since the FDA's revised 2008 guidance for industry was released that demonstrate the effectiveness of oral phenylephrine as a decongestant. Accordingly, Defendants knew or should have known by at least 2018 that their marketing claims regarding the Products' efficacy were false and misleading.

40. Plaintiff and the class members purchased the Products in reliance on Defendants' false and deceptive marketing claims.

41. As a result of Defendants' false and deceptive marketing, Plaintiff and the class members suffered economic damages, including the cost of purchasing the Products.

CLASS ALLEGATIONS

42. Plaintiff brings this action on behalf of himself and all other similarly situated class members (the "Class" or "Classes") pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class against Defendants for violations of Florida state laws and/or similar laws in other states:

Multi-State Class Action

All consumers who purchased Sudafed PE, Vicks NyQuil, and/or Benadryl Allergy Plus Congestion Products in the United States of America and its territories (excluding California) from September 13, 2018 to the present for personal use or consumption.

Excluded from the Class are individuals who allege personal bodily injury resulting from the use of Sudafed PE, Vicks NyQuil, and/or Benadryl Allergy Plus Congestion Products. Also excluded from this Class are Defendants, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

43. In the alternative, Plaintiff brings this action on behalf of herself and all other similarly situated Florida consumers pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Sub-Classes:

Florida Sub-Class

All consumers who purchased Sudafed PE, Vicks NyQuil, and/or Benadryl Allergy Plus Congestion Products in the State of Florida from September 13, 2018 to the present for personal use or consumption.

Excluded from the Class are individuals who allege personal bodily injury resulting from the use of Sudafed PE, Vicks NyQuil, and/or Benadryl Allergy Plus Congestion Products. Also excluded from this Class are Defendants, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

44. The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is informed and believes that the proposed Class/Sub-Classes contains thousands of purchasers of Defendants' Products who have been damaged by Defendants' conduct as alleged herein. The precise number of Class members is unknown to Plaintiff at this time.

45. Plaintiff's claims are typical to those of all Class members because members of the Class are similarly injured through Defendants' uniform misconduct described above and were subject to Defendants' deceptive marketing claims that accompanied each and every Product. Plaintiff is advancing the same claims and legal theories on behalf of themselves and all members of the Class/Sub-Class.

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

- (a) whether Defendants' Products contained phenylephrine;
- (b) whether Defendants' marketing statements are false, misleading, or objectively reasonably likely to deceive;
- (c) whether the alleged conduct constitutes violations of the laws asserted;

- (d) whether Defendants' alleged conduct violates public policy;
- (e) whether Defendants engaged in false or misleading advertising;
- (f) whether Defendants were unjustly enriched as a result of its labeling, marketing, advertising and/or selling of the Products;
- (g) whether Plaintiff and the Class members are entitled to damages and/or restitution and the proper measure of that loss; and
- (h) whether an injunction is necessary to prevent Defendants from continuing to market and sell Products that lack efficacy.

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

48. A class action is superior to the other available methods for a fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by the Plaintiff and individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. It would thus be virtually impossible for Plaintiff and

Class members, on an individual basis, to obtain meaningful and effective redress for the wrongs done to them. Further, it is desirable to concentrate the litigation of the Class members' claims in one forum, as it will conserve party and judicial resources and facilitate the consistency of adjudications. Plaintiff knows of no difficulty that would be encountered in the management of this case that would preclude its maintenance as a class action.

49. The Class also may be certified because Defendants have acted or refused to act on grounds applicable to the Class, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

50. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent Defendant from engaging in the acts described above, such as continuing to market and sell Products that lack efficacy, and requiring Defendants to provide a full refund of the purchase price of the Products to Plaintiff and Class members.

51. Unless a Class is certified, Defendants will retain monies received as a result of their conduct that were taken from Plaintiff and the Class members. Unless a Class-wide injunction is issued, Defendants will continue to commit the violations alleged and the members of the Class and the general public will continue to be

misled. Indeed, to this day, Defendants continues to market and sell the Products that have been determined by a unanimous FDA panel to lack efficacy.

FIRST CAUSE OF ACTION

Violation of Florida’s Deceptive and Unfair Trade Practices Act

Fla. Stat. §§ 501.201-213

(On Behalf of the Plaintiff and the Florida Sub-Class Against All Defendants)

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

53. Plaintiff brings this Count individually and on behalf of the Florida Sub-Class.

54. The Florida Deceptive and Unfair Trade Practices Act (“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. § 501.204, Fla. Stat.

55. 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.” § 501.202, Fla. Stat.

56. As alleged herein, Plaintiff and the Sub-Class members have suffered injury in fact and lost money as a result of Defendants’ conduct because they

purchased Products from Defendants in reliance on Defendants' representation that the Products were effective.

57. As alleged herein, Defendants' actions are deceptive and in clear violation of FDUTPA, entitling Plaintiff and the Sub-Class to damages and relief under Fla. Stat. §§ 501.201-213.

58. Defendants have engaged, and continue to engage, in conduct that is likely to deceive members of the public. This conduct includes representing in their labels that their Products are effective, which is untrue.

59. Similarly, Defendants have engaged, and continue to engage, in deceptive, untrue, and misleading advertising as described above.

60. By committing the acts alleged above, Defendants have engaged in unconscionable, deceptive, or unfair acts or practices, which constitute unfair competition within the meaning of FDUTPA.⁴

61. Defendants' conduct is substantially injurious to consumers. Consumers are purchasing using Defendants' Products without knowledge that they lack efficacy. This conduct has caused, and continues to cause, substantial injury to consumers because consumers would not have paid for nasal decongestant Products that do not work as advertised but for Defendants' false

⁴ Defendants' conduct violates Section 5 of the Federal Trade Commission ("FTC") Act, 15 U.S.C. § 45, which prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.

labeling, advertising, and promotion. Thus, Plaintiff and the putative Sub-Class 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.

62. Indeed, no benefit to consumers or competition results from Defendants’ conduct. Since consumers reasonably rely on Defendants’ representation that the Products work as advertised, consumers could not have reasonably avoided such injury.

63. Florida Statutes, Section 501.204, makes unfair and/or deceptive trade practices in the conduct of any trade or commerce illegal.

64. Florida Statutes, Section 501.211, creates a private right of action for individuals who are aggrieved by an unfair and/or deceptive trade practice by another person.

65. Florida Statutes, Section 501.2105, provides that the prevailing party in litigation arising from a cause of action pursuant to Chapter 501 shall be entitled to recover attorney’s fees within the limitations set forth therein from the non-prevailing party.

66. Florida Statutes, Section 501.213, provides that any remedies available under Chapter 501 are in addition to any other remedies otherwise available for the same conduct under state or local law.

67. Florida Statutes, Section 501.203 (3)(c), states that a person has violated the FDUTPA if he violates “any law, statute, rule, regulation, or ordinance which proscribes unfair, deceptive, or unconscionable acts or practices.”

68. Defendants are engaged in the practice of manufacturing, marketing, distributing, selling and otherwise placing into the stream of commerce Products which constitutes trade and commerce as defined by Sections 501.203(8) Fla. Stat., and is therefore subject to FDUTPA.

69. As a result of Defendants’ unfair and deceptive trade practices, Plaintiff and the Sub-Class members are entitled to an award of attorney’s fees pursuant to FDUTPA, Florida Statutes, Section 501.2105, if he prevails.

70. Wherefore, Plaintiff, and the Florida Sub-Class, pray for judgement against Defendants, as set forth hereafter. Defendants’ conduct with respect to the labeling, advertising, marketing, and sale of their Products is unfair because Defendant’ conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

71. In accordance with FDUTPA,⁵ Plaintiff and the Florida Sub-Class, seek an order enjoining Defendants from continuing to conduct business through

⁵ Section 501.211(1) allows “anyone aggrieved by a violation of” FDUTPA to seek declaratory or injunctive relief. Fla. Stat. §501.211.

fraudulent or unlawful acts and practices and to commence a corrective advertising campaign. Defendants' conduct is ongoing and continuing, such that prospective injunctive relief is necessary.

72. On behalf of Plaintiff and the Florida Sub-Class, Plaintiff also seeks an order entitling them to recover all monies spent on the Defendants' Products, which were acquired through acts of fraudulent, unfair, or unlawful competition.⁶ In addition, the measure of restitution should be full refund of the purchase price insofar as the Products and their associated labels are worthless. But for Defendants' misrepresentations and omissions, Plaintiff and Sub-Class members would have paid nothing for Products that do not work as advertised. Indeed, there is no discernible "market" for an over-the-counter nasal decongestant that is no more effective than a placebo at decreasing congestion. As a result, the Defendant's Products are rendered valueless.

73. Wherefore, Plaintiff and members of the Florida Sub-Class are entitled to injunctive and equitable relief, and a full refund in the amount they spent on the Products.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly

⁶ Section 501.211(2) provides that "a person who has suffered a loss as a result of a [FDUTPA] violation ... may recover actual damages"

situated, pray for judgment against the Defendants as to each and every count, including:

- A. An order declaring this action to be a proper class action, appointing Plaintiff and his counsel to represent the Class/Sub-Classes, and requiring Defendants to bear the costs of class notice;
- B. An order enjoining Defendants from selling the Products;
- C. An order enjoining Defendants from suggesting or implying that they are effective for human application;
- D. An order requiring Defendants to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief, such as recalling existing Products;
- E. An order awarding declaratory relief, and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendants from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendants' past conduct;
- F. An order requiring Defendants 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;

- G. An order requiring Defendants to disgorge any ill-gotten benefits received from Plaintiff and members of the Class/Sub-Classes as a result of any wrongful or unlawful act or practice;
- H. An order requiring Defendants to pay all actual and statutory damages permitted under the counts alleged herein;
- I. An order awarding attorneys' fees and costs to Plaintiff and the Class/Sub-Classes; and
- J. 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.

DATED: September 13, 2023

By: /s/R. Jason Richards
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