IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

NATURAL PRODUCTS ASSOCIATION, Plaintiff, v. LETITIA JAMES, in her official capacity as New York Attorney General, Defendant.	)	JURY DEMANDED Case No. _____

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

Plaintiff, Natural Product Association ("NPA"), by and through the undersigned counsel, hereby files this Complaint for Declaratory Judgement and Injunctive Relief against Defendant, New York Attorney General Letitia James, in her official capacity, respectfully showing the Court as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiff is a Delaware non-profit corporation having a principal place of business in Washington, DC.

2. Defendant, Letitia James, is the Attorney General of New York. As the Attorney General of New York, she has been expressly delegated with the authority of enforcing Assembly Bill A5610 (to be enacted as NY Gen. Bus. Law § 391-oo, collectively referred to herein as the "Act"), which specifically states "[w]henever there shall be a violation of [the Act], an application may be made *by the attorney general in the name of the people of the state of New York*, to a court or justice having jurisdiction by a special proceeding to issue an injunction, and upon notice to the

defendant of not less than five days, to enjoin and restrain the continuance of such violation." NY Gen. Bus. Law § 391-oo (emphasis added).

3. The Defendant is subject to the personal jurisdiction of this Honorable Court pursuant to Fed. R. Civ. P. 4(k)(1).

4. This Honorable Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, as it arises under 21 U.S.C. § 301, also known as the Federal Food, Drug, and Cosmetic Act ("FDCA"), thus raising a federal question.

5. This Court has jurisdiction under 28 U.S.C. § 1343(a)(3) because this action, authorized by 42 U.S.C. § 1983, seeks to redress the deprivation, under color of the laws, statutes, ordinances, regulations, customs, and usages of the State of New York and political subdivisions thereof, of rights, privileges, or immunities secured by the United States Constitution and Acts of Congress.

6. Defendant is being sued in her official capacity as Attorney General and, at all relevant times, will be acting under the color of state law. Accordingly, this Court has authority under the doctrine of *Ex Parte Young*, 209 U.S. 123, 28 S. Ct. 441, 52 L. Ed. 714 (1908) to enjoin enforcement of the Act and to grant declaratory relief and injunctive relief pursuant to §§ 2201-02 and 5 U.S.C. §§ 705-06 on the grounds that the Act is unconstitutional because it causes, or will imminently cause, ongoing violations of federal law because it (i) is directly or indirectly preempted by federal law; (ii) is void for vagueness and thus violates the Due Process Clauses; and (iii) violates the Dormant Commerce Clause.

7. Defendant works at and performs her official duties as the Attorney General of New York at the New York State Capitol located on State Street and Washington Avenue, Albany, New York, 12224.

8. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b)(1) because the majority of Plaintiff's New York members' business locations are located within this District.

9. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a) and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02 and 5 U.S.C. §§ 705-06.

PLAINTIFF'S STANDING

10. Founded in 1936, Plaintiff is the nation's largest and oldest nonprofit organization dedicated to advocating for the rights of consumers to have access to safe products that will maintain and improve their health and for the rights of retailers and suppliers to sell such products.

11. Plaintiff represents over 700 member organizations, accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. Plaintiff unites a diverse membership, from the smallest health food store to the largest dietary supplement manufacturer.

12. Plaintiff's members will be adversely affected by the Act.

13. Plaintiff advocates before Congress, the Food and Drug Administration ("FDA"), the Federal Trade Commission, and other federal and state agencies, legislatures, state attorneys' general and courts. Additional information about NPA and its work is available at https://www.npanational.org/.

14. The FDCA directly applies to and affects Plaintiff's members by regulating and prosecuting the sale of dietary supplements.

15. Consequently, Plaintiff has standing to bring this action on behalf of its members in its representative capacity.

BACKGROUND FACTS

16. The manufacture, use and sale of dietary supplements in the United States is regulated by the FDCA.

17. The FDCA defines explicitly what types of products are considered dietary supplements. *See, e.g.*, 21 USC § 321(ff).

18. The FDCA includes an express preemption provision that precludes states from imposing, directly or indirectly, any requirement as to the labeling of dietary supplements. *See, e.g.*, 21 USC § 342-1(a)(5).

19. Further, § 343-1(a)(5) preempts state-law requirements for claims about dietary supplements that differ from the FDCA's requirements.

20. The FDCA also prohibits the private enforcement of any of the provisions of FDCA and "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 USC § 337(a).

21. Section 349 of the New York General Business Law provides citizens with the right to bring a private right of action, stating that "[in] addition to the right of action granted to the attorney general pursuant to this section, any person who has been injured by reason of any violation of this section may bring an action in his own name to enjoin such unlawful act or practice, an action to recover his actual damages or fifty dollars, whichever is greater, or both such actions."

22. Thus, § 349 violates 21 USC § 337(a)'s grant of exclusive enforcement authority to FDA by allowing for private causes of action.

23. On October 25, 2023, New York Governor Kathy Hochul signed Assembly Bill A5610 banning the sale (including internet sales) of over-the-counter weight-loss and sports

nutrition supplements to any person under the age of eighteen (18). The legislation is set to take effect in April 2024 as NY Gen. Bus. Law § 391-oo (collectively defined as the "Act").

24. Section 1(a) of the Act defines a dietary supplement as a class of dietary supplements as defined in NY Gen. Bus. Law § 391-o, and is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building.

25. NY Gen. Bus. Law § 391-o definition of dietary supplements differs from the language of § 321(ff) of the FDCA.

26. The Act does not contain the same requirements contained in § 321(ff)(2)(ii) through § 321(ff)(3) of the FDCA.

27. Section 6 of the Act sets forth several factors to determine whether "an over-the-counter diet pill or dietary supplement is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building."

28. Specifically, Section 6 of the Act states the "court shall consider, but is not limited to, the following factors: (a) whether the product contains: (i) an ingredient approved by the federal Food and Drug Administration for weight loss or muscle building; (ii) a steroid; or (iii) creatine, green tea extract, raspberry ketone, garcinia cambogia, green coffee bean extract; (b) whether the product's labeling or marketing bears statements or images that express or imply that the product will help: (i) modify, maintain, or reduce body weight, fat, appetite, overall metabolism, or the process by which nutrients are metabolized; or (ii) maintain or increase muscle or strength; (c) whether the product or its ingredients are otherwise represented for the purpose of achieving weight loss or building muscle; or (d) whether the retailer has categorized the dietary supplement for weight loss or muscle building by: (i) placing signs, categorizing, or tagging the supplement with statements described in paragraph (b) of this subdivision; (ii) grouping the supplements with

other weight loss or muscle building products in a display, advertisement, webpage, or area of the store; or (iii) otherwise representing that the product is for weight loss or muscle building."

29. The above factors are not considered in the manner specified by the Act when determining whether a product is a dietary supplement pursuant to the FDCA.

30. The preceding factors also conflict with provisions of the FDCA and its definition of dietary supplements because the factors could include prescription drugs that are neither dietary supplements nor over-the-counter drugs pursuant to the rubric of the FDCA.

31. The Act does not define "weight loss" or "muscle building," or explain how these terms relate to the dietary supplements and over-the-counter diet pills to allow retailers, consumers, or other actors to make sense of the law, particularly in light of the aforementioned conflicts with the provisions of the FDCA.

32. Yet Section 5 of the Act provides a procedure allowing the Defendant to bring a cause of action against a retailer who sells an "over-the-counter diet pill or dietary supplement [that] is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building" as defined by the Act to anyone under the age of eighteen (18). The Act states that "[w]henever there shall be a violation of [the Act], an application may be made *by the attorney general in the name of the people of the state of New York*, to a court or justice having jurisdiction by a special proceeding to issue an injunction, and upon notice to the defendant of not less than five days, to enjoin and restrain the continuance of such violation." NY Gen. Bus. Law § 391-oo (emphasis added).

33. Moreover, to the extent the New York legislature passed the Act in an effort to reduce the likelihood of the incidence of eating disorders in consumers of the products covered by the Act, it is likely that FDA would treat the incidence of eating disorders arising from the use of

those products as an adverse event under FDCA. The regulation and oversight of adverse events left exclusively to FDA.

34. Additionally, the NY legislature has not established a correlation, let alone a basis for causation, between the likelihood of developing an eating disorder as a result of using weight loss products. Regardless, there is also no substantiation that placing dietary supplements behind the counter could reduce the incidence of eating disorders. Thus, there appears to be no rational basis for implementation of the Act.

35. Thus the Act should be struck down for at least several reasons: (i) enforcement of the Act is preempted by the FDCA; (ii) the Act's definitions conflict with those in the FDCA; (iii) the Act, in combination with other provisions of New York's General Business Law, improperly allows for private causes of action, which are exclusively in the purview of the FDA; and (iv) the provisions of the Act that conflict with the FDCA are left undefined (e.g., "weight loss" and "muscle building") will inevitably lead to improper arbitrary and capricious application of the law by Defendant.

COUNT ONE – VIOLATION OF THE SUPREMACY CLAUSE

36. The preceding paragraphs are incorporated and re-alleged here.

37. The Supremacy Clause is the source of the preemption doctrine which invalidates state laws that are contrary to federal statutes.

38. The FDCA expressly sets forth the definition of what is legally considered a dietary supplement and the labeling requirements for the same. *See* 21 USC § 321(ff) and 21 USC § 343(r). As such, by redefining how to determine whether or not a product is a dietary supplement based on how the product is "labeled, marketed, or otherwise represented", the Act expressly conflicts with the FDCA.

39. Since the FDCA and the Act are in direct conflict, the FDCA preempts the Act and the Act is unconstitutional.

40. Moreover, the FDCA expressly preempts any state law that establishes "any requirement respecting any claim of the type described in § 343(r)(1) . . . made in the label or labeling of food that is not *identical* to the requirements of § 343(r) of this title." 21 U.S.C. § 343-1(a)(5) (emphasis added).

41. The FDCA also expressly forbids private rights of action.Yet the Act specifically creates a private right of action permitting the Defendant to sue on behalf of its citizens for purported violations regarding the sale of dietary supplements and permits the recovery of monetary damages. This is in direct conflict with Congress's delegation of exclusive enforcement of the FDCA, thereby further demonstrating the Act's preemption by the FDCA.

42. The FDCA expressly preempts the Act in multiple instances. The Act should, therefore, be declared unconstitutional, and its enforcement should be enjoined because it threatens Plaintiff with irreparable injury for which there is no adequate remedy at law.

COUNT TWO – IMPLIED PREEMPTION

43. The preceding paragraphs are incorporated and re-alleged here.

44. In addition to express preemption, a state law may be impliedly preempted where it stands as an obstacle to the accomplishment of the Congressional purpose or objective.

45. The federal statutory scheme of the FDCA grants the FDA exclusive enforcement authority to categorize, oversee, and regulate products that fall under the FDCA. The FDA is granted the exclusive enforcement power to punish and deter the use of harmful ingredients in dietary supplements and monitor the same. Thisthe FDA uses this authority to achieve a somewhat delicate balance of statutory objectives. This balance of statutory objectives would be irreparably

disrupted and stymied if state officials pass legislation to determine when a dietary supplement is considered dangerous or what makes a product a dietary supplement—just as the Act improperly does here.

46. The Act conflicts with, or inevitably will conflict with, the FDA's responsibility to police the manufacture, sale, and distribution of dietary supplements in a way consistent with the judgment and objectives set forth in the FDCA. Accordingly, the FDCA impliedly preempts the Act.

47. Since the Act is implicitly preempted, it should be declared unconstitutional, and its enforcement should be enjoined because it threatens Plaintiff with irreparable injury for which there is no adequate remedy at law.

COUNT THREE – VIOLATION OF THE DORMANT COMMERCE CLAUSE

48. The preceding paragraphs are incorporated and re-alleged here.

49. The Commerce Clause, as set forth in Article I, Section 8 of the United States Constitution, expressly grants Congress the power "[t]o regulate commerce with foreign Nations, among the several States, and with the Indian Tribes."

50. The "Dormant" Commerce Clause is inherent in the power granted to Congress under the Commerce Clause and provides that, even if federal law is silent on an area of interstate commerce, states may not enact legislation that directly regulates, discriminates against, and/or impermissibly burdens interstate commerce.

51. The Dormant Commerce Clause prohibits a state from regulating commerce that takes place wholly outside of the state's borders and from punishing a defendant for engaging in conduct that is lawful where it occurs.

52. State laws that are facially neutral violate the Dormant Commerce Clause if their practical effect is to impermissibly burden interstate commerce.

53. To that end, states may not enact legislation that renders unlawful a transaction that occurred wholly out of state, or that controls commerce occurring wholly outside their borders.

54. By regulating the online sale of dietary supplements by any vendor "including online retailers", the Act, burdens interstate commerce in violation of the Dormant Commerce Clause.

55. Specifically, the Act seeks to regulate the conduct of any vendors who may be located outside of the State of New York and sell dietary supplements online to buyers located in New York. Thus, making otherwise lawful conduct unlawful in New York. Theoretically, if other states were to enact laws similar to the Act, it would require dietary supplement vendors to comply with the strictest state restrictions (assuming compliance is even possible), regardless of federal law or the law of the individual state of operation, or face liability. This would allow individual states to establish a national regulatory scheme in violation of the Constitution's delegation of the power to do so to Congress, just as the Act does here.

56. The Act therefore discriminates, both facially and in effect, against out-of-state dietary supplement vendors and buyers in violation of the Dormant Commerce Clause.

57. Further, the Act creates improper anticompetitive harms because it requires stores to check the identification of consumers when they purchase the diet pills in person in the state of New York, but it does not require the same compliance for e-merchants at the time of purchase. On the one hand, it favors e-merchants that themselves do not ship or deliver products that the Act deems an "over-the-counter diet pill or dietary supplement [that] is labeled, marketed, or otherwise represented for the purpose of achieving weight loss or muscle building" because those e-merchants are not tasked with ensuring compliance with the Act. On the other hand, it imposes

restrictions on brick-and-mortar retailers that are physically located in New York by requiring them to, among other things, rearrange their stores to restrict access to the Act's covered products, retrain employees, and face fines at the Defendant's discretion. The Act also favors large businesses that may circumvent the Act's enforcement simply by changing their labels, whereas smaller entities may lack the resources to do so.

58. The Act is also void for vagueness because of its usage of product definitions that conflict with definitions contained in the FDCA. Moreover, the definitions contained in the Act itself, such as but not limited to "muscle loss" and "weight building," are unclear and will lead to arbitrary and capricious enforcement of its provisions as a result.

59. Accordingly, the Act should be declared unconstitutional, and its enforcement should be enjoined because it threatens Plaintiffs with irreparable injury as stated herein and for which there is no adequate remedy at law.

INJURY

60. The Act imposes penalties for noncompliance. Any retail seller who fails to comply with the Act is subject to a penalty of up to Five Hundred Dollars ($500) per sale.

61. The Act requires brick-and-mortar retailers located in New York to incur undefined amounts of cost and risk to take preventative measures, including, among other things, rearranging their stores to restrict access to the Act's covered products, retrain employees, and face fines at the Defendant's discretion.

62. The Act allows for private causes of action against purported violators of the Act, thereby subjecting parties to frivolous and numerous lawsuits, unjustly requiring them to defend themselves against claims, whether justified or not.

63. If the Act is not enjoined, Plaintiff's industry members who were previously able to sell products online in the State of New York will be forced to choose between halting all online sales to the State of New York or expending extreme costs in ensuring all products are hand-delivered to New York customers.

64. The Act will cause irreparable economic harm to supplement manufacturers, formulators, and distributors if the cost of attempting to comply with the Act's improper terms and provisions exceed the benefit of marketing those products in the state of New York.

PRAYER FOR RELIEF

Wherefore, Plaintiff respectfully requests judgment against the Defendant and further Plaintiff prays for:

a. A declaratory judgment that the Act is unconstitutional on its face or, alternatively, as applied to Plaintiffs, because it expressly conflicts with, and is thus preempted by, the FDCA in violation of the Supremacy Clause;

b. A declaratory judgment that the Act is unconstitutional because it discriminates against interstate commerce in violation of the Dormant Commerce Clause, Article I, § 8 of the United States Constitution;

c. An injunctive order restraining Defendant and her officers, agents and employees from enforcing or otherwise bringing suit under the Act;

d. An award of attorneys' fees and costs of suit herein pursuant to 42 USC § 1988, or any other appliable law; and

e. All other, further, and different legal and equitable relief against the Defendant as necessary and appropriate to effectuate the Court's rulings and judgment, and/or as the Court otherwise deems just and equitable.

Respectfully submitted this 4th day of December 2023.

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