UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

NATURAL PRODUCTS ASSOCIATION, Plaintiff, v. FOOD AND DRUG ADMINISTRATION; DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; and JANET WOODCOCK, M.D., in her official capacity as Acting Commissioner of Food and Drugs, Defendants.	)	Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, Natural Products Association ("NPA"), for its complaint against the defendants, Food and Drug Administration ("FDA"), Department of Health And Human Services ("HHS"), Xavier Becerra, in his official capacity as Secretary of the Department of Health And Human Services, and Janet Woodcock, M.D., in her official capacity as Acting Commissioner of the FDA (collectively referred to as "Defendants"), alleges as follows.

INTRODUCTION

1. NPA brings this action against Defendants for declaratory and injunctive relief. Defendants have concluded that a product called N-acetyl-L-cysteine ("NAC") is excluded from the definition of a dietary supplement under a provision of the Food, Drug, and Cosmetic Act, as amended by the Dietary Supplement Health and Education Act, 21 U.S.C. § 321(ff)(3)(B)(i). Defendants have taken final agency action in their determination that the provision at issue applies

retroactively as a matter of law. There is, however, nothing in the relevant statute that allows for retroactive application.

2. NPA respectfully requests that the Court enter a declaratory judgment and a preliminary and permanent injunction under the Administrative Procedure Act and hold unlawful and set aside FDA's final actions that are arbitrary, capricious, an abuse of discretion, and contrary to law. More particularly, NPA requests that this Court order that FDA cease its unlawful retroactive application of the Food, Drug, and Cosmetic Act, as amended by the Dietary Supplement Health and Education Act.

PARTIES

3. Natural Products Association is a Delaware non-profit corporation that does business as Natural Products Association. It has a principal place of business in Washington, DC.

4. FDA is an agency of the United States government responsible for administering, among other things, the Food, Drug and Cosmetics Act, as amended.

5. HHS is an executive department of the United States government and is responsible for the FDA.

6. Secretary Becerra is the Secretary of HHS. He oversees, among other things, the FDA. He is sued in his official capacity.

7. Dr. Woodcock is the Acting Commissioner of Food and Drugs. She oversees the activities of FDA. She is sued in her official capacity.

JURISDICTION

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1346, and 5 U.S.C. §§ 701-06. 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.

9. Personal jurisdiction over Defendants exists in the State of Maryland because they are engaged in substantial activity here and the FDA is headquartered in the state.

10. Venue in this District is proper under 28 U.S.C. § 1391(e) because the action seeks relief against federal agencies located in this district and a substantial part of the events or omissions giving rise to the claim occurred in this district.

FACTS

I. NPA/STANDING

11. Founded in 1936, NPA is the nation's largest and oldest nonprofit organization dedicated to the natural products industry. Natural products are represented by a wide array of consumer goods that grow in popularity each year. These products include natural and organic foods, dietary supplements, pet foods, health and beauty products, "green" cleaning supplies and more.

12. NPA advocates 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 these products. NPA 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. NPA unites a diverse membership, from the smallest health food store to the largest dietary supplement manufacturer.

13. NPA has standing to bring this action on behalf of itself and its members.

14. NPA advocates before Congress, 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/.

15. Further, NPA has taken a leadership role in promoting quality standards and has developed proactive certification programs for that purpose. NPA was the first organization to offer a third-party good manufacturing practices ("GMP") certification program for the manufacturing of dietary supplements and dietary ingredients. NPA's GMP standard includes all of the FDA GMP requirements of 21 C.F.R. Part 111 as well as certain requirements that exceed Part 111 or reflect best industry practices. NPA's GMP certification is only awarded to companies that meet a high level of compliance with NPA's standard. NPA's certification not only meets, but exceeds, FDA's GMP requirements. NPA's certification is awarded only after companies' satisfaction of NPA's rigorous requirements have been verified through comprehensive third-party inspections of the company's facilities and GMP-related documentation.[1] Any company that receives NPA's GMP certification should be considered to be in compliance with all FDA GMP-related standards. NPA also has "Natural Seal" Standard and Certification programs that dictate whether cosmetic, personal-care-products, and certain home care products can be deemed truly "natural."[2]

16. In addition, NPA's "TruLabel" program is a dietary supplement label registration and random-testing program adopted by NPA in 1990 and subsequently made a requirement for supplier membership in 1995. This internal oversight program has created a high level of confidence with retailers and consumers that products sold in the marketplace under NPA's

[1] *See* https://www.npanational.org/certifications/npa-gmp-certification-program/.
[2] *See* https://www.npanational.org/certifications/natural-seal/.

TruLabel program are accurately labeled; establish an ongoing self-regulatory process within the industry; demonstrate industry maturity to legislators; and provide a comprehensive industry product database. Under the TruLabel program, products are periodically selected for laboratory analysis to confirm the label; in other words, to verify that what is on the label is what is in the product.[3]

17. Another example of industry self-regulation effectuated by NPA's oversight is the Supplement Safety and Compliance Initiative ("SSCI"). SSCI is an industry-driven initiative led by the nation's leading retailers to provide a harmonized benchmark to recognize various safety standards throughout the entire dietary supplement supply chain. SSCI provides enhanced quality assurance for products on retailer shelves. Dietary supplements must meet or exceed the SSCI benchmark to be accepted in participating major retailers, all with the goal of providing quality products and increasing consumer confidence that the products they are consuming are safe.[4]

18. NPA also organized the Natural Products Foundation, a 501(c)(3) entity, to stimulate and support research, education and knowledge regarding dietary supplements, nutritional foods, and related products, with the overall objective of advancing the knowledge of the public, and thereby, improving the public health.

19. NPA played a key role in the passage of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325. This important legislation, discussed further below, struck a balance between the need for consumers to have access to and information about safe and effective dietary supplements while also preserving the

[3] *See* https://www.npanational.org/certifications/trulabel-program/.
[4] *See* http://www.ssciglobal.org/.

government's interest in protecting the public from unsafe products and false and misleading claims.

20. The dietary supplement industry is large. It includes domestic sales likely exceeding $50 billion annually has grown dramatically. In the United States, the market currently exceeds $35 billion and includes thousands of companies – including manufacturers, retailers, and formulators that create and distribute a vast array of products aimed at improving consumer health. While estimates vary, the now former Commissioner of the FDA stated that: "What was once a $4 billion industry comprised of about 4,000 unique products, is now an industry worth more than $40 billion, with more than 50,000 – and possibly as many as 80,000 or even more – different products available to consumers."[5] "The use of dietary supplements, including vitamins, minerals, amino acids, or herbs, has become a routine part of the American lifestyle. Three out of every four American consumers take a dietary supplement on a regular basis. For older Americans, the rate rises to four in five. And one in three children take supplements, either given to them by their parents or, commonly in teens, taking them on their own."[6] Indeed, physicians frequently recommend a supplement regimen in addition to medical intervention.

21. As the natural product industry has grown, increased internal oversight, innovated, and become more sophisticated in increased compliance and internal oversight as well as innovation of new products and methods of use, consistent and applicable legal and regulatory enforcement has been lacking. In some instances, FDA has taken illogical actions to preclude products from the market without justification on the one hand, or simply refused to enforce its

[5] *Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight* (Feb. 11, 2019), available at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary.
[6] *Id*.

own statutes and regulations on the other hand. For example, under the Food, Drug, and Cosmetic Act, FDA is required to review a distributor's basis for concluding that a "new dietary ingredient" ("NDI") is reasonably expected to be safe prior to that distributor putting that NDI into commerce. Although it has been conservatively estimated that there have been tens of thousands of new dietary ingredients introduced into the market since DSHEA, FDA has reviewed the basis for safety of less than 900 unique ingredients. FDA's enforcement of its enabling statutes and promulgated regulations has been slipshod at best, despite organizations like NPA striving to advocate for and provide oversight and compliance programs for safe dietary ingredients and products for consumers.

22. With specific reference to NAC, the actions by FDA impairs NPA's ability to carry out its mission and commitment to consumer safety and access to natural health ingredients. NPA and its members have spent significant time and money to respond to FDA's new position, discussed below, that the exclusion provision of DSHEA known as the "drug preclusion" or "race to market clause" is to be given *retroactive* effect and that, as such, now suddenly bars NAC from the supplement market. Were FDA properly interpreting and applying DSHEA, NPA would not have been forced to take action in response, including: discussions and written communications with regulators and third parties, preparation and submission of a Citizen Petition, submission of Freedom of Information Act requests, responses to media inquiries and the preparation and filing of this action. NPA's members have suffered harm as a direct and proximate result of FDA's recent final agency actions concluding that the drug exclusion provision of DSHEA applies retroactively to NAC. NPA members who have been selling NAC for years, if not decades, have seen their sales dry up as result of having to preemptively pull products from the shelves by virtue of FDA's unlawful decisions.

23. As discussed further below, in 2020, Amazon.com implemented its take-down policy requiring sellers on their platform to remove NAC-containing products that would violate FDA's recent final agency actions determining that the ingredient could not be used in products marketed as dietary supplements. In many instances, companies that are NPA members were forced to proactively remove their products from Amazon to avoid harm to their brands, which was a direct result of FDA's final agency decisions and statements aimed at removing NAC from the supplement market. NPA's members have lost and will continue to lose significant revenue because Amazon, among other online retailers, will no longer allow companies to sell NAC.

24. Further, FDA has recently denied export certificates sought by NPA members for products that contain NAC. By denying export certificates, FDA has taken another final agency action that works to preclude U.S. distributors from selling NAC-containing products in overseas markets due to its misplaced position on DSHEA's drug exclusion provision.

II. REGULATION OF DIETARY SUPPLEMENTS

25. Asserting that "improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government" and that "the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies," DSHEA became law on October 25, 1994 as an amendment to the Food, Drug, and Cosmetic Act. DSHEA represented a victory for the millions of consumers of dietary supplements who felt that FDA advocated unreasonable regulatory guidelines prior to the passage of DSHEA. The language of DSHEA addressed the aforementioned consumer concern by stating that "the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers" and that "dietary supplements are safe within a broad range of intake, and safety

problems with the supplements are relatively rare." DSHEA § 2. DSHEA further established that "consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements." *Id.* § 2(8).

26. DSHEA was introduced to counteract "unnecessarily stringent" federal intervention into the manufacturing, sale, labelling of dietary supplements and government overregulation. 103 CONG. REC. S4577 (daily ed. Apr. 7, 1993) (statement of Sen. Hatch); 103 CONG. REC. S17049 (daily ed. Nov. 23, 1993) (statement of Sen. Hatch). The legislation concluded that consumer well-being is improved when there is greater access to dietary supplements. 103 CONG. REC. S4577 (daily ed. Apr. 7, 1993) (statement of Sen. Hatch). Supplement producers and related companies should be free from intervention as long as "the labelling and advertising are truthful, non-misleading, and there exists a reasonable scientific basis for products claims." *Id*.

27. Section 201(ff) of the Food, Drug, and Cosmetic Act, as amended by DSHEA, specifically defined what it means to be a "dietary supplement." In relevant part, the term is defined as:

> a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following ingredients:
>
> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;
> (D) an amino acid;
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
> (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

21 U.S.C. § 321(ff)(1). Section 201(ff)(3)(B) of DSHEA goes on to exclude from the definition of dietary supplement:

> (i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or
>
> (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,
>
> which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

21 U.S.C. § 321(ff)(3)(B). The first exception, the one most relevant to this case, means that companies may not market in products labeled as dietary supplements an article that has been approved as a new drug unless the article was marketed as a dietary supplement or as a food before it obtained approval as a drug. Significantly, DSHEA did not include any provision indicating that any of its regulations, including the drug exclusion provision was intended to operate retroactively.

28. Particularly, the legislative history of DSHEA actually contradicts any notion that the drug provision has retroactive effect:

> On occasion, a substance that is properly included as a dietary ingredient in a dietary supplement (food) product may also function as an active ingredient in a drug product. There is nothing particularly surprising about this fact.
>
> As an example, the dietary substance L-carnitine may properly be used as an ingredient in a dietary supplement (as FDA itself has acknowledged), although it is also the active ingredient in a drug product that has been approved by FDA for a particular prescription-only usage. Similarly, the substance caffeine is a natural component offered in products such as coffee and tea; it is used as an added ingredient in foods, including carbonated beverages, and it has also been approved by FDA as a drug.

Sen. Rept. 103-410 (Oct. 8, 1994).

29. The near-ubiquitous ingredient L-carnitine is an oft-discussed example of what could be excluded from the food supply under FDA's interpretation of the drug exclusion clause of DSHEA that it has applied to NAC. L-carnitine was marketed as both a dietary ingredient and an approved drug prior to the passage of DSHEA. This is an example of exactly why Congress logically intended for supplements and food ingredients that were in the relevant markets prior to DSHEA to continue to be marketed as dietary ingredients (even if those ingredients could simultaneously be marketed as drugs under DSHEA's rubric) after the effective date of DSHEA, October 15, 1994.

30. Under DSHEA, dietary supplement labels cannot claim to treat, cure, prevent, or mitigate a disease, but may include statements or claims of nutritional support, in which "the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient . . . ." 21 U.S.C. § 343(r)(6)(A). An example of a structure/function claim is the popular dietary supplement St. John's Wort, which a seller may claim to be a "mood-brightener" but not a cure for depression, which is a specific disease. *See, e.g.*, J. Beisler, DIETARY SUPPLEMENTS AND THEIR DISCONTENTS: FDA REGULATION AND THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994, 31 Rutgers L.J. 511, 517 n.29 (2000).

31. DSHEA also requires that a statement of nutritional support must have "substantiation that such statement is truthful and not misleading" and contain a disclaimer that

the "statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 343(r)(6)(B)-(C).

32. The FDA has recognized that "DSHEA's purpose [is] to broaden the scope of labeling claims that may be made for dietary supplements without subjecting them to regulation as drugs." 65 Fed. Reg. 1000-01, 2000 WL 4559, *1024. Consistent with that purpose, substantiation of structure/function claims under DSHEA requires that manufacturers have "competent and reliable scientific evidence," which has been defined by the FDA and the Federal Trade Commission to include "tests, analyses, research, studies, or other evidence . . . ." Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide (Criterion 8). Under DSHEA, dietary supplement manufacturers are not required to conduct clinical trials or efficacy testing. *See* FDA Comment Request, *Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act*, 76 Fed. Reg. 51988-01, 2011 WL 3624830 (2011).

III. NAC

33. The scientific name for NAC is N-acetylcysteine (also known as N-acetyl-cysteine or N-acetyl-l-cysteine). The naturally occurring amino acid L-cysteine is a precursor to NAC. NAC is naturally metabolized to the antioxidant glutathione. L-cysteine is a semi-essential amino acid. It is considered semi-essential because the human body produces it from two other amino acids, methionine and serine. It becomes essential only when the dietary intake of methionine and serine is suboptimal or deficient. Two other amino acids - glutamine and glycine are used with NAC to make and replenish glutathione. NAC is most notably found in plants of the *Allium* species, especially in the onion *(Allium cepa,* 45 mg NAC/kg) along with animal tissue, including chicken skin. The mercapturic acid pathway is a metabolic route for the processing of glutathione conjugates to mercapturic acid (N-acetylcysteine conjugates).

34. NAC satisfies the definition of dietary ingredient under Section 201(ff)(1)(F) of the Food, Drug, and Cosmetic Act in that it is a metabolite and constituent of other articles (as noted above) that themselves satisfy the definition of a dietary ingredient under Sections 201(ff)(1)(C), 201(ff)(1)(D), and 201(ff)(1)(E) of the Food, Drug, and Cosmetic Act.

35. Acetylcysteine was allegedly approved as a mucolytic drug in 1963. It was approved for use solely as an inhalant. An inhalation drug is inhaled as compared to a dietary supplement, which is ingested by humans.

36. Among other things, the term dietary supplement means a product that is intended for ingestion. *See* Section 201(ff)(2) of the Food, Drug, and Cosmetic Act.

37. NAC was allegedly approved as a drug as an oral formulation in 1985. This approval was strictly limited to a use as an antidote for acetaminophen poisoning (*i.e.*, as a drug to counteract overdoses of drugs like Tylenol®).

38. Despite NAC's limited applications for which it was approved as a drug, NAC was marketed and sold as a dietary ingredient and a dietary supplement for human ingestion before October 1994. Ex. 1 reflects true and correct copies of evidence that NAC was being marketed and sold as a dietary ingredient and a dietary supplement for ingestion before October 1994. FDA's own document proves that NAC was marketed and sold as a dietary ingredient and a dietary supplement before July 1993. *See* Ex. 2, Department of Health and Human Services, Public Health Service, Food and Drug Administration, *Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace*, July 1993, at page 85 (excerpt referencing a Cell Defense Formula X11 product that contained NAC). Thus, NAC was continuously sold for many years as a food ingredient, dietary ingredient, or dietary supplement after NAC delivery forms

were approved as a drug (*e.g.*, as an inhalation product) and before the passage of DSHEA in 1994. In fact, those sales of NAC proceeded unabated until FDA's very recent objection.

39. Hundreds of popular dietary supplement products containing the dietary ingredient NAC have been on sale in the United States to consumers who have come to rely on them.

40. NAC is safe to use. There is no evidence in the public record that NAC is harmful or injurious to consumers when the supplement is used as directed. Certainly, the FDA has never suggested that NAC is an unsafe product. In fact, the National Institute of Health has noted that NAC has been sold as a drug and supplement and that NAC is safe. *See* Ex. 3.

IV. THE FDA HAS IMPROPERLY DECIDED THAT DSHEA'S DRUG EXCLUSION PROVISION MUST BE RETROACTIVELY APPLIED WITH RESPECT TO NAC.

41. The FDA has represented to the public—and a member of Congress—that it has not made any final decision on the regulatory status of NAC. *See, e.g.*, Exs. 4-8. However, FDA has definitively interpreted DSHEA to mean and require that, among other things, the drug exclusion provision has retroactive effect, and that interpretation and application by the FDA is final agency action on the issue as it applies to NAC.

A. *Blackstone* Case

42. FDA and the Department of Justice have interpreted DSHEA and its drug provision to apply retroactively to NAC in a criminal action in the U.S. District Court for the Southern District of Florida, captioned *United States v. Braun, et al*., Case No. 19-80030-CR. The docket in that case is available on Pacer.gov and is incorporated by reference in its entirety.

43. On February 3, 2017, the government applied for search warrants for Blackstone Labs, LLC and VBS Laboratories, LLC, supported by an affidavit of Kelly McCoy, a Special Agent with FDA's Office of Criminal Investigations. Agent McCoy swore under oath that products containing NAC are excluded from the definition of dietary supplements:

> The Blackstone website also lists for sale other products that violate the FDCA, including products named "Gear Support" and "PCTV." The website includes images of each product and their labels. According to the products' labels, Gear Support and PCTV contain N-Acetyl-Cysteine ("NAC") and are described as dietary supplements.
>
> Products that contain NAC are excluded from the definition of dietary supplement under 21 U.S.C. § 321(ff)(3)(B)(i) because FDA approved NAC as a "new drug" in 1985 and FDA does not have any information that indicates that NAC was marketed as a dietary supplement or as a food prior to its approval as a "new drug."

Ex. 9 ¶¶ 106-07. Agent McCoy concluded that there was probable cause to believe that Blackstone introduced unapproved "new drug" products into interstate commerce in violation of 21 U.S.C. § 331(d). *Id*. ¶ 111. The search warrants were approved and executed.

44. On March 7, 2019, Blackstone and others were indicted for, among other things, violating § 331(d) based on sales of products containing the "new drug" NAC. *See* Ex. 10 (counts 1 and 2). On September 19, 2021, the defendants moved to suppress evidence obtained during the execution of the search warrants. The motion specifically challenged the allegations in Special Agent McCoy's affidavit. *See* Ex. 11. The government's opposition to the motion argued that the affidavit was not misleading in describing NAC as a drug. *See* Ex. 12 at 13. Defendants filed a reply that contested the government's arguments. *See* Ex. 13 at 9-10. The Court denied the motion to suppress on October 21, 2021.

45. Should the FDA seek to assert that it has not reached a final agency action in its determination as to NAC's categorization as dietary ingredient that is excluded from the definition of a dietary supplement because it was marketed as a drug before it was marketed in a food or in a dietary supplement, this is belied by FDA's actions and determinations in the *Blacksone* case. If FDA attempts to assert that it has not yet reached any final agency actions or determination as to whether NAC is a lawful ingredient in dietary supplements and what potential regulatory action FDA might take regarding NAC-containing products, these representations or assertions would be

contradicted by the statements made to the Court in the pending criminal case cited above. The FDA has repeatedly taken the position that NAC is a new drug and cannot fall within the definition of a dietary supplement, most recently in the opposition to the defendant's motion to suppress filed October 4, 2021. The FDA cannot continue to claim that it has not yet formulated a determination of NAC's regulatory status – and taken final agency actions based on it, when NPA's members have sought clarity on this issue. In fact, the FDA has taken final agency action as evidenced by its unambiguous representations to the Court in the *Blackstone* case, thereby establishing FDA's final agency action ripe for review under the Administrative Procedure Act.

B. FDA Warning Letters

46. On or about July 23, 2020, FDA sent warning letters to four companies regarding their sale of certain products that included NAC as a dietary ingredients. Exs. 14-17.

47. The warning letters concluded that:

> [Y]our product could not be a dietary supplement, because it does not meet the definition of dietary supplement under section 201(ff) of the Act [21 U.S.C. § 321(ff)]. FDA has concluded that NAC products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(i) of the Act [21 U.S.C. § 321(ff)(3)(B)(i)]. Under this provision, if an article (such as NAC) has been approved as a new drug under section 505 of the Act [21 U.S.C. § 355], then products containing that article are outside the definition of a dietary supplement, unless before such approval that article was marketed as a dietary supplement or as a food. NAC was approved as a new drug under section 505 of the Act [21 U.S.C. § 355] on September 14, 1963. FDA is not aware of any evidence that NAC was marketed as a dietary supplement or as a food prior to that date.

Id.

48. These four warning letters all concluded that the drug exclusion provision of DSHEA was applicable to NAC and subject to retroactive effect.

C. Amazon

49. Members of NPA and other companies have been selling their dietary supplement products, including those containing NAC, through Amazon and other outlets for many years

without consumer harm or interference from FDA. For many of these companies, sales through Amazon alone represent all or a substantial part of their supplement business.

50. On information and belief, after issuing four warning letters in July 2020 as discussed above asserting NAC was a drug and not a supplement, one or more FDA employees contacted Amazon. FDA alerted Amazon to the recent warning letters.

51. When informing Amazon about the July 2020 NAC warning letters, FDA also explained its position that the DSHEA drug exclusion provision applied retroactively to NAC. FDA also indicated that there was no evidence of pre-1963 marketing of NAC as a dietary supplement or food and that NAC could not legally be sold.

52. By at least May 2021, Amazon began acting on FDA's verbal communication and assertions and began removing NAC products sold by Amazon.[7]

53. Amazon has informed retailers of NAC products, including members of NPA, that their NAC products can no longer be sold through Amazon. As a direct and proximate result, NPA members and other retailers have lost and continue to lose substantial revenue.

D. Congressional Letters And Citizen Petitions

54. On July 27, 2021, Sen. Mike Lee sent a letter to FDA's Acting Commissioner, Dr. Woodcock, regarding NAC and requested that the FDA hold a hearing on the matter pursuant to 21 C.F.R. Part 15. Ex. 4. FDA responded to Sen. Lee in two letters dated August 19, 2021 and September 29, 2021. Exs. 5. 6. In denying Sen. Lee's request for a hearing, both responses made clear FDA's determination that DSHEA's drug exclusion provision was to be applied to NAC retroactively. The only open issue for FDA was whether there was evidence that NAC was

[7] Josh Long, *Amazon confirms plans on removing NAC supplements*, Natural Products Insider (May 6, 2021), available at https://www.naturalproductsinsider.com/regulatory/amazon-confirms-plans-removing-nac-supplements.

marketed as a dietary supplement or food before September 1963, the date of the alleged new drug approval.

55. On August 18, 2021, NPA submitted a Citizen Petition to FDA on NAC. Ex. 7. The Citizen Petition argued that FDA's position on NAC was legally erroneous because, among other things, the drug exclusion provision of DSHEA was not entitled to be applied retroactively. As further alleged below, it is canonical that statutes are not to be applied retroactively unless the statute or, in limited circumstances, the legislative history unambiguously dictates such a result. There is no provision in DSHEA or any indication in its legislative history to overcome the presumption against statutory retroactivity. Here, the legislative history shows that the drug exclusion provision was not intended to apply retroactively.

56. NPA is not alone in its understanding that DSHEA does not apply retroactively. Another trade association, American Herbal Products Association, submitted comments to FDA on NPA's Citizen Petition on NAC and agreed that the drug exclusion provision should not be given retroactive effect. Ex. 18.

57. On November 24, 2021, FDA issued what it called a "tentative response" to NPA's Citizen Petition. Ex. 8. FDA again reiterated its decision that DSHEA's drug exclusion provision was retroactively effective as to NAC. There is no indication that FDA's decision on retroactivity as a matter of law was being reconsidered or that FDA would change its mind on that point. FDA only sought additional information as to whether NAC was marketed as a drug or food before the alleged 1963 new drug application approval.

E. Export Certificate

58. One or more members of NPA recently requested that FDA issue an export certificate covering a NAC product. FDA denied NPA's request in November 2021 on the ground

that because of the drug exclusion provision of DSHEA, the product did not meet the statutory definition of a dietary supplement in 21 U.S.C. § 321(ff) and thus cannot be marketed as a dietary supplement. FDA concluded that § 321(ff)(B)(i) applied retroactively.

59. Accordingly, FDA's determination that the drug provision of DSHEA applies retroactively is shown in the *Blackstone* criminal case, the July 2020 warning letters, communications with Amazon, responses to Sen. Lee's letter, response to NPA's Citizen Petition, and its denial of export certificates.

CLAIM I
(Declaratory/Injunctive Relief – 5 U.S.C. § 706)

60. The foregoing allegations are incorporated here by reference.

61. As a federal agency, FDA has no power to act unless and until Congress confers that power. Actions that are unauthorized by Congress or inconsistent with Congressional direction are *ultra vires* and must be strictly established by statute.

62. FDA has taken final agency action to determination that the drug provision of DSHEA is to be applied retroactively.

63. FDA's determination is legally erroneous, contrary to DSHEA and exceeds FDA's statutory authority.

64. FDA's position on NAC was legally erroneous because, among other things, the drug provision of DSHEA was not entitled to be applied retroactively.

65. Statutes are not to be applied retroactively unless the statute or, in limited circumstances, the legislative history, unambiguously dictates such a result. See, e.g., *Landgraf v. USI Film Products*, 511 U.S. 244, 270 (1994) ("Since the early days of this Court, we have declined to give retroactive effect to statutes burdening private rights unless Congress had made clear its intent."); *United States v. Heth*, 7 U.S. (3 Cranch) 399, 413 (1806) ("Words in a statute ought not

to have a retrospective operation, unless they are so clear, strong, and imperative, that no other meaning can be annexed to them, or unless the intention of the legislature cannot be otherwise satisfied.").

66. There was no provision in DSHEA or its legislative history to overcome the presumption against statutory retroactivity. Congress expressed no clear intent in the text of DSHEA or its legislative history to support FDA's erroneous legal determination. The legislative history shows that the drug provision was not intended to apply retroactively.

67. Further, the purpose of that provision was to incentivize the development of new drugs after DSHEA's enactment. Drug development would not be incentivized by precluding the sale of an ingredient that has been sold both as a drug and as a dietary supplement for many years before DSHEA was enacted.

68. Section 201(ff)(3)(B)(i) only applies to articles that were approved as new drugs by FDA after October 26, 1994.

69. FDA's actions with respect to applying the drug provision of DSHEA retroactively is not in accordance with law, exceeds its statutory authority and limitations, and is arbitrary and capricious under 5 U.S.C. § 706(2). As such, the FDA's determination as to NAC should be vacated and set aside.

REQUEST FOR RELIEF

NPA requests the following relief:

a. judgment in its favor on all claims against Defendants;

b. a declaratory judgment pursuant to 28 U.S.C. § 2201(a) in favor of NPA and against Defendants declaring that the drug exclusion in 21 U.S.C. § 321(ff)(3)(B) does not retroactively apply to the dietary supplement NAC;

c. a preliminary and permanent injunction prohibiting Defendants from taking any regulatory action against manufacturers, sellers, or distributors of NAC based on the claim that the drug exclusion in 21 U.S.C. § 321(ff)(3)(B) is retroactive and applies to NAC;

d. reasonable attorneys' fees as allowed by law;

e. costs pursuant to Fed. R. Civ. P. 54(d) or otherwise provided by law; and

f. such other relief as the Court deems just and appropriate under the circumstances

Dated: December 6, 2021

Respectfully submitted,

/s/ Micah Kanters

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