IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACEUTICALS, INC., a Georgia Corporation,
6015-B Unity Drive, Norcross, GA 30071

Plaintiff,

v.

MARGARET A. HAMBURG, M.D., as Commissioner of the United States Food and Drug Administration,
10903 New Hampshire Avenue,
Silver Spring, MD 20993

UNITED STATES FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue,
Silver Spring, MD 20993

KATHLEEN SEBELIUS, as Secretary of the Department of Health and Human Services,
200 Independence Avenue, SW,
Washington, DC 20220

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW,
Washington, DC 20220

Defendants.

COMPLAINT

Civil Action No.1:13-cv-1747

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

COMES NOW, the plaintiff Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech" or "Plaintiff"), by and through the undersigned counsel of record, and for its Complaint against defendants Margaret A. Hamburg, M.D. ("Hamburg"), United States Food and Drug Administration ("FDA"), Kathleen Sebelius ("Sebelius"), and the United States Department of Health and Human Services ("HHS") states as follows:

PRELIMINARY STATEMENT

1. This Action is one for declaratory and injunctive relief against the FDA and related defendants for their arbitrary and capricious action, without observance of procedure required by law, regarding the dietary supplement ingredient 1, 3 Dimethylamylamine, commonly known as "DMAA". DMAA is found in the geranium plant and can also be synthetically produced much like a vitamin or amino acid.

2. Under the pretext that DMAA containing products pose a danger to consumers, the FDA has engaged in a campaign of intimidation against dietary supplement companies like Hi-Tech who include this ingredient in their products. For some companies this has taken the form of warning letters and pressure by the FDA to remove and destroy DMAA containing products. In the case of Hi-Tech, the FDA has issued an administrative detention order against numerous proprietary

dietary supplement products without notice, essentially removing millions of dollars in goods from the marketplace.

3. By its own admission, the FDA has declined to engage in the rule making process necessary to formally ban DMAA. Thus, there has been no public discussion or comment regarding the scientific evidence regarding DMAA and its safety. DMAA has existed in the food supply for many years. Hi-Tech has sold over a million bottles of dietary supplement products containing this ingredient without any adverse event reports. Upon information and belief, DMAA containing products continue to be sold by major United States retailers. As just one example, GNC continues to sell such products and has sold over 440 million doses of DMAA with only a single adverse event report. Hi-Tech respectfully requests that the FDA's campaign of intimidation be enjoined and that, if the agency has scientific evidence which brings the safety of DMAA into question, that it disclose same and engage in the formal rule making process to ban the ingredient.

JURISDICTION AND VENUE

4. This case arises under the United States Constitution and the laws of the United States and presents a federal question within this Court's jurisdiction under Article III of the United States Constitution and 28 U.S.C. § 1331. The Court also has jurisdiction under the Administrative Procedures Act ("APA"), 5

U.S.C. § 702. The Court has authority to grant declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* Venue is proper in this district under 28 U.S.C. § 1391(e).

PARTIES

5. Plaintiff Hi-Tech Pharmaceuticals, Inc., is a Georgia corporation with its principal place of business in the State of Georgia. Hi-Tech is one of the largest manufacturers and distributors of dietary supplements, including weight loss products, in the United States. Hi-Tech sells its products to more than 100,000 retail locations including: GNC, CVS, Walgreen's, Wal-Mart, K-Mart, Kroger and convenience stores nationwide. Hi-Tech also sells directly to consumers, healthcare practitioners, and food and dietary supplement companies. Several of Hi-Tech's products contain DMAA, including, for example, Black Widow, Lipodrene, Yellow Scorpion, Fastin XR, Stimerex-ES and Geranium Powder.

6. Defendant Hamburg is the Commissioner of the FDA. In her official capacity as the Commissioner, Defendant Hamburg is in whole or in part directly responsible for the decisions that are at issue in this lawsuit. Defendant Hamburg is sued in her official capacity only.

7. Defendant FDA is an agency within HHS and has direct responsibility for implementing the Dietary Supplement Health and Education Act (hereinafter

"DSHEA"). Pub. L. No. 103-417, 108 Stat. 4325 (1994). FDA is responsible for enforcement of the various provisions of DSHEA in compliance with federal law.

8. Defendant Sebelius is the Secretary of HHS. In her official capacity as the Secretary of HHS, Defendant Sebelius is responsible for ensuring that agencies within the control of HHS, including the FDA, are in compliance with federal law and is in whole or in part directly responsible for the decisions at issue in this lawsuit. Defendant Sebelius is sued in her official capacity only.

9. Defendant HHS is an agency of the United States Government. HHS is responsible for ensuring that agencies within the control of HHS, including the FDA, remain in compliance with federal law.

THE LEGAL FRAMEWORK FOR THE REGULATION OF DIETARY SUPPLEMENTS

10. Dietary supplements, including those manufactured, produced, marketed, distributed and sold by Plaintiff Hi-Tech, are regulated pursuant to DSHEA, which amended the Federal Food, Drug and Cosmetic Act ("FFDCA") in 1994.

11. Under DSHEA, a dietary supplement is deemed "adulterated" if it presents a "significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(A).

12. Furthermore, under DSHEA, dietary supplements are regulated as a subset of foods, rather than drugs, unless the supplement producers assert disease claims that bring the supplement within the definition of a drug under the FFDCA. *See* 21 U.S.C. §§ 321(ff) (defining "dietary supplement"), (g)(1) (defining "drug"). *See also* 21 U.S.C. § 343(r)(6) (identifying claims which may be made by dietary supplement manufacturers and those claims which are prohibited).

13. Because dietary supplements are classified as foods, manufacturers and producers are **not** required to provide evidence of product safety or efficacy before marketing dietary supplement products. Dietary supplements are legally presumed to be safe. In any proceeding under DSHEA, the "United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated." 21 U.S.C. § 342(f)(1). Defendants thus have the burden of proof in showing adulteration. Before commencing an action, the FDA must provide the responding party "appropriate notice and opportunity to present views" regarding the matter. 21 U.S.C. § 342(f)(2).

14. DSHEA covers "dietary ingredients." A dietary ingredient is defined as a "vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any dietary ingredient [from the preceding categories]." 21 U.S.C. § 321(ff)(1). Dietary

ingredients include both naturally occurring and synthetically produced versions of the same ingredient. FDA has recognized the equivalence of natural vs. synthetically produced dietary ingredients in the context of several vitamins and other ingredients.

15. The above statutory framework applies generally to dietary ingredients marketed in the United States prior to October 15, 1994. Dietary ingredients introduced into the marketplace after that date, i.e. "new dietary ingredients" require notification to the FDA at least 75 days prior to the marketing of the ingredient with information regarding the ingredient's safety. 21 U.S.C. § 350b(a)(2).

16. The effect of the above requirements is that, typically, the FDA only regulates and/or prevents the sale of "adulterated" dietary supplements on a "product-by-product basis" rather than on a "class basis." To date, there has been only a single occasion in which the FDA has taken action against an entire class of dietary supplements through the above referenced procedures. *See Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk.* 69 Fed. Reg. 6788 (February 11, 2004), codified at 21 C.F.R. § 119.1. The FDA has **not** followed this procedure regarding dietary supplements that contain DMAA.

DMAA

17. DMAA is a natural constituent of the geranium plant, *Pelargonium graveolens.* Geraniums (which contain DMAA) have been marketed in the United States since before October 15, 1994. The plant's leaves are used in salads and its oil as a flavoring. No less than four published, peer-reviewed scientific studies have confirmed the presence of DMAA in the geranium plant. Large, established reputable laboratories such as Cantox Health Sciences International have confirmed the presence of DMAA in the geranium plant.

18. DMAA has been the subject of at least a dozen peer-reviewed scientific studies, making it one of the most studied botanical products in the United States. Two of these studies, commissioned and paid for by Hi-Tech, were of Hi-Tech products that contained DMAA. One of those products has been "detained" by the FDA. None of the scientific studies regarding DMAA have raised any issues regarding its safety. As mentioned above, DMAA containing products have been used by consumers millions of times virtually without incident.

THE FDA'S CAMPAIGN AGAINST DMAA

19. Beginning in April 2012, the FDA began sending warning letters to dietary supplement companies that marketed DMAA containing products. Without citing any scientific studies or data, the FDA declared that DMAA containing products were "adulterated" and therefore unsafe. The FDA took the position that, because DMAA "may be produced synthetically," it was not a "dietary ingredient"

under DSHEA. The FDA further asserted that DMAA had not been marketed prior to October 15, 1994 and that, because a new dietary ingredient notification had not been submitted to the FDA, DMAA containing products were "adulterated." The FDA demanded that the dietary supplement companies cease distribution of any products containing DMAA.

20. The FDA's warning letter campaign was undertaken with the express purpose of circumventing the legal procedures outlined in DSHEA. In a Q&A posted on the FDA's website regarding the DMAA warning letter campaign the agency noted that it had taken this approach because: "[I]n order for FDA to ban a compound in a dietary supplement, FDA is required under the statute [DSHEA] to undertake a series of lengthy scientific and legal steps." In short, rather than meet its burden of proof and allow public comment in a rule making procedure regarding DMAA, the FDA preferred to informally intimidate dietary supplement makers who marketed these products.

21. The FDA's efforts were largely successful. Ten of the eleven companies that received the FDA's warning letters capitulated and quickly removed their DMAA containing products from the stream of commerce. One entity, USPlabs, responded to the April 2012 warning letter by providing the FDA with scientific studies supporting the safety of DMAA. It took the FDA almost a year to review this information (in the interim the supposedly dangerous DMAA

containing products continued to be sold to consumers) and tell USPlabs that it disagreed with the data provided and still wanted the products removed from commerce. In July of 2013, under continuing FDA pressure, USPlabs "voluntarily" destroyed $8 million worth of DMAA containing products.

THE FDA'S ACTION AGAINST HI-TECH

22. Hi-Tech was not a recipient of an FDA warning letter and has sold DMAA containing products without incident for several years. Spurred on by a journalist, on November 1, 2013, FDA investigators conducted an inspection of Hi-Tech facilities in Norcross, Georgia. The investigators discovered substantial inventories of dietary supplement products that contain DMAA. The FDA issued an administrative Detention Order against these goods. The agency has demanded that Hi-Tech cease manufacturing/marketing DMAA containing goods and "voluntarily" destroy existing stocks of such products.

23. Based on the foregoing, there exists an actual controversy between the Plaintiff Hi-Tech and the Defendants regarding the FDA's circumvention of DSHEA and attempt to "ban" DMAA without an appropriate legal and scientific review. Moreover, there is little doubt that the FDA will continue this inappropriate conduct against other companies that market or manufacture DMAA containing products.

24. Hi-Tech has an established and respected business reputation in the dietary supplement industry from the production, marketing, distribution and selling of dietary supplement products, including those with DMAA.

25. Hi-Tech stands to suffer immediate and irreparable harm to its business reputation should it be forced to cease the manufacturing, production, marketing, distribution and sales of dietary supplement products containing DMAA. Additionally, the goods detained by the FDA are worth millions.

26. Hi-Tech also will suffer immediate and irreparable harm to its business reputation if it is forced to recall DMAA containing products which are lawfully in the marketplace.

27. Accordingly, Plaintiff Hi-Tech seeks declaratory and injunctive relief against the Defendants prohibiting them from circumventing DSHEA by using warning letters, detention orders and seizures against DMAA containing products which have not been established to be either unsafe or "adulterated."

CAUSES OF ACTION

A. Declaratory Relief Regarding the FTC's Action Against DMAA Containing Products.

28. Plaintiff adopts and realleges the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

29. As described herein, there exists an actual controversy of a justiciable nature between Hi-Tech and the Defendants. Pursuant to 28 U.S.C. § 2201-2202,

Plaintiff Hi-Tech is entitled to a declaratory judgment declaring Plaintiff Hi-Tech's rights as follows:

a. Unless and until there has been a proper rule making procedure pursuant to DSHEA, Hi-Tech may continue to market and manufacture DMAA containing products.

b. Unless and until there has been a proper rule making procedure pursuant to DSHEA, Defendants may not detain DMAA containing products marketed or manufactured by Hi-Tech.

WHEREFORE, the Plaintiff Hi-Tech demands judgment against the Defendants as follows:

a. Declaring Defendants' actions against DMAA containing products unlawful and in violation of DSHEA and the APA;

b. Setting aside the Detention Order against Hi-Tech's DMAA containing products;

c. Declaring the Defendants' actions against Hi-Tech as unlawful and in violation of DSHEA and the APA;

d. Granting Hi-Tech preliminary and permanent injunctive relief prohibiting the Defendants from detaining or seizing DMAA containing products absent proper rule making proceedings pursuant to DSHEA;

e. Awarding Hi-Tech attorneys' fees and costs for this action; and

f. Granting Hi-Tech such other and further relief as may be just and proper.

B. Violation of DSHEA and the APA.

30. Plaintiff adopts and realleges the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

31. By proceeding against DMAA containing products via intimidating letters, detention orders and seizure orders, the Defendants have circumvented the statutory requirements of DSHEA. Moreover, they have improperly shifted the burden of proof as to the safety of DMAA containing products to the manufacturers and producers of dietary supplements containing DMAA.

32. Defendants have further indicated that Hi-Tech will be required to cease manufacturing, producing, marketing, distributing and selling DMAA containing products. They have also indicated that Hi-Tech may have to recall DMAA containing products. Defendants continue to disregard their statutory obligations under DSHEA by making these demands without formal rule making, the presentation of scientific evidence, or an opportunity for public review and comment. By such agency action, the Defendants are acting in a manner that is contrary to the established law, in violation of Section 706(2)(a) of the APA.

33. Furthermore, in taking the actions described above, the Defendants are acting in a manner in excess of the statutory authority and jurisdiction granted to the Defendants by Congress in violation of DSHEA and Section 706(2)(c) of the APA.

34. Finally, in taking the actions described above, the Defendants are acting in a manner inconsistent with DSHEA and thus, not in observance of the procedures required by law in violation of Section 706(2)(d) of the APA.

35. Defendants' actions have and will continue to cause irreparable harm and injury to Hi-Tech.

36. As a consequence of the above, the Defendants' actions are unlawful and must be set aside and prohibited under Sections 706(2)(a), (c) and (d) of the APA.

WHEREFORE, the Plaintiff Hi-Tech demands judgment against the Defendants as follows:

a. Declaring Defendants' actions against DMAA containing products unlawful and in violation of DSHEA and the APA;

b. Setting aside the Detention Order against Hi-Tech's DMAA containing products;

c. Declaring the Defendants' actions against Hi-Tech as unlawful and in violation of DSHEA and the APA;

d. Granting Hi-Tech preliminary and permanent injunctive relief prohibiting the Defendants from detaining or seizing DMAA containing products absent proper rule making proceedings pursuant to DSHEA;

e. Awarding Hi-Tech attorneys' fees and costs for this action; and

f. Granting Hi-Tech such other and further relief as may be just and proper.

C. Violation of DSHEA and the APA.

37. Plaintiff adopts and realleges the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

38. Under DSHEA, the Defendants have the burden to demonstrate that DMAA containing dietary supplements "present an unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(A).

39. Defendants completely failed to meet this high burden in order to declare dietary supplements containing DMAA "adulterated" under DSHEA.

40. By proceeding against Hi-Tech and other manufacturers/marketers of DMAA containing products via warning letters, detention orders and seizure orders, the Defendants distorted federal law and disregarded the Congressional mandate that placed the burden of proof upon the Defendants in connection with the prohibition of dietary supplements under DSHEA.

41. Specifically, the Defendants shifted the burden of proof to the manufacturers and producers of DMAA containing dietary supplements by implementing a "risk/benefit" analysis unauthorized by Congress. Under this impermissible analysis, a manufacturer or producer of dietary supplements containing DMAA must establish that the benefits of such products outweigh the risks associated with the use of such products.

42. Moreover, under this unauthorized concept of "risk/benefit," the Defendants simply have to show an extremely slight risk in order to justify the prohibition on the sale of dietary supplements containing DMAA.

43. In addition, the Defendants have further violated federal law by failing to reach a "dose-specific" determination of the presence of risk associated with the use of dietary supplements containing DMAA as required by DSHEA.

44. Under DSHEA, the Defendants have an affirmative duty to demonstrate a "significant or unreasonable" risk at a particular dose level in order to support a finding that a dietary supplement containing DMAA is adulterated.

45. In issuing warning letters, detention orders and seizure orders against DMAA, the Defendants have ignored the express intent of Congress and simply relied upon an unfounded presumption that a safe level could not be determined. By failing to do so, the Defendants improperly placed the burden upon manufacturers and producers of dietary supplements containing DMAA to demonstrate that their respective products are safe at their recommended or suggested dosage levels. Such action by the Defendants is directly contrary to the statutory language placing the burden of proof on the government and to the intent of Congress in regulating dietary supplements as food.

46. The conduct of the Defendants in making their determinations in issuing warning letters, detention orders and seizure orders are in direct violation

of DSHEA and the Defendants are acting in a manner that is contrary to the established law, in violation of Section 706(2)(a) of the APA.

47. In making the determinations described above, the Defendants are acting in a manner in excess of the statutory authority and jurisdiction granted to the Defendants by Congress in violation of DSHEA and Section 706(2)(c) of the APA.

48. Defendants' actions have and will continue to cause irreparable harm and injury to Hi-Tech.

49. Consequently, the Defendants' conduct in issuing warning letters, detention orders and seizure orders regarding DMAA is unlawful and must be set aside under Section 706(2)(a)(c) of the APA.

WHEREFORE, the Plaintiff Hi-Tech demands judgment against the Defendants as follows:

a. Declaring Defendants' actions against DMAA containing products unlawful and in violation of DSHEA and the APA;

b. Setting aside the Detention Order against Hi-Tech's DMAA containing products;

c. Declaring the Defendants' actions against Hi-Tech as unlawful and in violation of DSHEA and the APA;

d. Granting Hi-Tech preliminary and permanent injunctive relief prohibiting the Defendants from detaining or seizing DMAA containing products absent proper rule making proceedings pursuant to DSHEA;

e. Awarding Hi-Tech attorneys' fees and costs for this action; and

f. Granting Hi-Tech such other and further relief as may be just and proper.

D. Violation of Due Process Under the Fifth Amendment to the United States Constitution.

50. Plaintiff adopts and realleges the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

51. Defendants' actions as described herein constitute actions designed to deprive Hi-Tech's due process rights under the Fifth Amendment to the Constitution of the United States.

52. Specifically, the Defendants' actions requiring Hi-Tech to cease manufacturing, producing, marketing, distributing and selling its DMAA containing dietary supplement products , as well as, in seeking to order Hi-Tech to recall such products currently in the marketplace, deprive Hi-Tech of its due process rights in violation of the Fifth Amendment to the Constitution of the United States and in further violation of 5 U.S.C. § 706(2)(B).

53. Defendants' actions have injured and will continue to injure and will cause irreparable harm to Hi-Tech.

WHEREFORE, the Plaintiff Hi-Tech demands judgment against the Defendants as follows:

a. Declaring Defendants' actions against DMAA containing products unlawful and in violation of DSHEA and the APA;

b. Setting aside the Detention Order against Hi-Tech's DMAA containing products;

c. Declaring the Defendants' actions against Hi-Tech as unlawful and in violation of DSHEA and the APA;

d. Granting Hi-Tech preliminary and permanent injunctive relief prohibiting the Defendants from detaining or seizing DMAA containing products absent proper rule making proceedings pursuant to DSHEA;

e. Awarding Hi-Tech attorneys' fees and costs for this action; and

f. Granting Hi-Tech such other and further relief as may be just and proper.

E. The Defendants' Actions Are Arbitrary and Capricious Under the APA.

54. Plaintiff adopts and realleges the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

55. The Defendants have failed to meet their burden of proof under DSHEA to demonstrate that Hi-Tech's DMAA containing products are not safe when used in accordance with the recommended dosage found on the products' labeling as required by DSHEA. 21 U.S.C. § 342(f)(1)(A).

56. Defendants have failed to meet their burden under DSHEA to prove that Hi-Tech's DMAA containing products "present an unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use." 21 U.S.C. § 342(f)(1)(A).

57. The Defendants have attempted to avoid the high burden of proof placed upon them by resorting to a risk/benefit analysis not authorized by Congress under DSHEA whereby the Defendants simply have to show an extremely slight risk in order to justify the prohibition on the sale of dietary supplements containing DMAA.

58. By seeking to prevent Hi-Tech from marketing or selling dietary supplements containing DMAA without sufficient, credible evidence that demonstrates an "unreasonable risk" with the use of such dietary supplements at their recommended dosage level, the Defendants have acted arbitrarily and capriciously and have abused their discretion with respect to Hi-Tech.

59. Furthermore, by failing to follow the necessary procedural requirements as required by DSHEA, the Defendants have acted arbitrarily and capriciously and have abused their discretion with respect to Hi-Tech.

60. Consequently, the Defendants' enforcement actions against Hi-Tech including, but not limited to, the issuance of a detention order, are unlawful and must be set aside under Section 706(2)(A) of the APA. Furthermore, by failing to meet their statutorily required burden of proof as established by DSHEA, the Defendants are prohibited from taking enforcement action(s) against Hi-Tech.

61. Defendants' actions have and will continue to cause irreparable harm and injury to Hi-Tech.

WHEREFORE, the Plaintiff Hi-Tech demands judgment against the Defendants as follows:

a. Declaring Defendants' actions against DMAA containing products unlawful and in violation of DSHEA and the APA;

b. Setting aside the Detention Order against Hi-Tech's DMAA containing products;

c. Declaring the Defendants' actions against Hi-Tech as unlawful and in violation of DSHEA and the APA;

d. Granting Hi-Tech preliminary and permanent injunctive relief prohibiting the Defendants from detaining or seizing DMAA containing products absent proper rule making proceedings pursuant to DSHEA;

e. Awarding Hi-Tech attorneys' fees and costs for this action; and

f. Granting Hi-Tech such other and further relief as may be just and proper.

Respectfully submitted,

/s/ Jack Wenik
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