IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACEUTICALS, INC.,

a Georgia corporation, 6015 Unity Drive, Norcross, Georgia 30071,

and

JARED WHEAT, 6015 Unity Drive, Norcross, Georgia 30071,

Plaintiffs,

v.

NORMAN E. SHARPLESS, M.D., as Commissioner of the United States Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993,

and

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

and

ALEX M. AZAR, II, as Secretary of the Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201,

and

UNITED STATES DEPARTMENT

COMPLAINT

Civil Action No. _____

OF HEALTH AND HUMAN SERVICES,)
200 Independence Avenue, S.W.)
Washington, D.C. 20201)
)
)
Defendants.)
)
_____)

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

COMES NOW, the plaintiffs Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), and Jared Wheat (collectively "Plaintiffs") by and through the undersigned counsel of record, and for their Complaint against defendants Norman E. Sharpless, M.D. ("Sharpless"), the United States Food and Drug Administration ("FDA"), Alex M. Azar, II ("Azar"), and the United States Department of Health and Human Services ("HHS") state 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 2-Aminoisopheptane HCI, also known as, 1,5 DMHA, 2-amino-6-methylheptane, 2-amino-5methylheptane, 1,5-Dimethylhexylamine, 2-Isooctyl amine, and Octodrine, but most commonly referred to as "DMHA". DMHA is found in the walnut tree

(*Juglans regia)*, one of the oldest tree foods known to man, and can also be synthetically produced much like a vitamin or amino acid.

2. As set forth herein, the FDA has long chaffed at the statutory/regulatory structure for dietary supplements, which does not require pre-market approval and puts the onus on the FDA to establish that a particular dietary supplement or ingredient is unsafe. Under the guise of "modernizing" this regulatory structure, the FDA has embarked on a campaign to drive certain dietary ingredients/supplements from the marketplace by simply declaring, without evidence or rule making, that certain dietary ingredients/supplements are not in fact dietary ingredients but rather unapproved food additives, deemed adulterated by statute. In the case of DMHA containing products, which pose no danger to consumers, the FDA has simply declared them, via a posting to its website, to be "adulterated" because DMHA is allegedly not a dietary ingredient marketed before October 15, 1994. *See* FDA Website Post, attached hereto as Exhibit 1. This has been accompanied by a campaign of intimidation against dietary supplement companies like Hi-Tech who include this ingredient in their products. For Hi-Tech and several of its competitors, this has taken the form of warning letters and pressure by the FDA to remove and destroy DMHA containing products. See, April 10, 2019 Warning Letter to Hi-Tech, attached hereto as Exhibit 2.

3. For Plaintiff Jared Wheat, the President and Chief Executive Officer of Hi-Tech, the stakes are even higher. Mr. Wheat is subject to an unrelated criminal prosecution for various fraud and other charges regarding dietary supplements set forth in a superseding indictment that was returned on September 28, 2017. See *United States v. Jared Wheat, et al.,* 1:17-cr-00229-AT-CMS, Northern District of Georgia, Doc. 7. Shortly after the superseding indictment was unsealed, Mr. Wheat posted an appearance bond. Among Mr. Wheat's bond conditions is the requirement that he not manufacture, distribute or sell "adulterated foods or misbranded drugs." *United States v. Jared Wheat, et al,* 1:17-cr-00229-AT-CMS, Northern District of Georgia, Doc. 22-1. Thus, Mr. Wheat faces the very real threat that the United States Attorney's Office for the Northern District of Georgia could move to revoke his bond based on nothing more than the FDA's assertion, without proof, that Hi-Tech's DMHA containing products are deemed adulterated by statute.

4. The FDA has declined to engage in the rule making process necessary to formally ban DMHA. Thus, there has been no public discussion or comment as to the scientific evidence regarding DMHA and its safety. DMHA, derived from walnuts, has existed in the food supply for many years and certainly before October 15, 1994. Hi-Tech has sold over a million bottles of dietary supplement products containing this ingredient for the past two years without any serious adverse event reports. Upon information and belief, Hi-Tech's competitors have sold millions of

bottles of DMHA containing products for the past five years without any serious adverse event reports. Plaintiffs respectfully request that the FDA's campaign of intimidation be enjoined and that, if the agency has scientific evidence which brings the safety of DMHA into question, that it disclose same and engage in the formal rule making process to ban the ingredient. Furthermore, Plaintiffs seek an express declaration that DMHA is a legitimate dietary ingredient, the presence of which in a dietary supplement product does **not** render that product an "adulterated food."

JURISDICTION AND VENUE

5. 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

6. Plaintiff Hi-Tech 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 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. Hi-Tech also contract manufactures dietary supplement products for other companies and buys and sells raw ingredients for dietary supplement products as well. Several of Hi-Tech's products contain DMHA, including, for example, Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene.

7. Plaintiff Jared Wheat is the President and Chief Operating Officer of Hi-Tech.

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

9. 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.

10. Defendant Azar is the Secretary of HHS. In his official capacity as the Secretary of HHS, Defendant Azar 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 Azar is sued in his official capacity only.

11. 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

12. 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.

13. 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).

14. Furthermore, under DSHEA, dietary supplements are regulated as a subset of foods, rather than drugs, unless the supplement's producer asserts 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).

15. 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).

16. 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. The FDA has recognized the equivalence of natural vs. synthetically produced dietary ingredients in the context of several vitamins and other ingredients.

17. 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).

18. 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 DMHA.

DMHA

19. As mentioned above, DMHA is a natural constituent of walnut trees (*Juglans regia).* Walnuts and the bark of the tree itself have been consumed by humans for many centuries. *Juglans regia* is found in many parts of Asia, Europe, Australia, New Zealand and the United States.

20. While there is a dearth of clinical studies of DMHA itself, there is a significant body of scientific evidence supporting the safety of DMHA for human consumption. For example, animal studies of DMHA showed it to have a very high LD50. "LD50" is the amount of a substance needed to cause the deaths of 50% of animals in a study group. In DMHA's case, a massive dose was required to achieve LD50 in a variety of animals. Similarly, animal studies show the effects of DMHA to be relatively benign. For example, in one animal study, DMHA's ability to increase blood pressure was only 1/500 to 1/1,000 that of epinephrine, a drug/hormone used to treat allergic reactions to food.

21. DMHA has an extensive history of use in dietary supplements. Plaintiffs have retained a leading dietary supplement scientist/regulatory expert to look at the issue of DMHA's classification as a dietary ingredient and its safety.

22. That expert concluded—after reviewing the relevant scientific literature on DMHA—that DMHA should be considered a dietary ingredient under DSHEA because it is found in multiple plants, each of which have a long history as part of the human diet.

23. In order to analyze the safety of DMHA, the expert reviewed, among other things, data from FDA's adverse event data base for 2014 to 2018 using the various synonyms for DMHA. No record of a single serious adverse event was found. A similar search of Canada's comparable data base also revealed no adverse

events for DMHA. Coupled with Hi-Tech's lack of any serious adverse event reports, this evidence supported the expert's conclusion that there is no reason to question the safety of DMHA.

24. Further support for the safety of DMHA can be found in the scientific research regarding another challenged dietary ingredient, DMAA, the status of which under DSHEA is currently pending before the Eleventh Circuit Court of Appeals. According to Plaintiffs' expert, while DMAA is not the chemical equivalent of DMHA, it does have a very similar structure and thus, the two ingredients could be expected to produce similar effects in humans. Multiple clinical studies of DMAA containing products found the ingredient to induce no harmful effects in humans. Most importantly, an extensive case control study of DMAA conducted by the Department of Defense found no link between DMAA consumption and adverse medical events.

THE FDA'S "CRACKDOWN" ON DIETARY SUPPLEMENTS

25. The FDA's action against DMHA is not the first time the agency has acted in an arbitrary and capricious manner, attempting to remove dietary ingredients/supplements from the marketplace without appropriate rule making or procedure. Regarding the similarly structured DMAA, in April 2012 the FDA effectively removed this dietary ingredient from the marketplace by sending out a series of warning letters to dietary supplement companies alleging, among other

things, that DMAA elevated blood pressure which could lead to heart attacks and that the ingredient was synthetically produced and therefore not a dietary ingredient. *See United States v. Undetermined quantities of all articles of finished and in-process foods, etc., et al.*, 1:13-cv-03675-WBH-JCF, Northern District of Georgia, Doc. 108-5. The agency brazenly admitted that it chose this truncated approach to the removal of DMAA, rather than formally banning the ingredient, because "The law requires FDA to follow certain lengthy steps before the agency can ban dietary supplements containing DMAA." See *United States v. Undetermined quantities of all articles of finished and in-process foods, etc., et al.*, 1:13-cv-03675-WBH-JCF, Northern District of Georgia, Doc. 108-6.

26. The FDA's warning letter campaign against DMAA was undertaken with the express purpose of circumventing the legal procedures outlined in DSHEA. The appropriateness of this approach is currently before the Eleventh Circuit.

27. Perhaps emboldened by its at least preliminary success regarding DMAA, the FDA has expanded its tactic of removing dietary ingredients/supplements of which it disapproves from the marketplace, regardless of the requirements of DSHEA. On April 16, 2019, under the guise of "modernizing the FDA's oversight of the dietary supplement industry" the agency announced the promulgation of a "Dietary Supplement Ingredient Advisory List" which lists ingredients that, according to the FDA, "do not appear to be lawful" and that dietary

supplement companies "**may wish** to avoid selling, making or distributing" products containing the ingredients. *See* FDA Statement and Advisory List attached hereto as Exhibit 3.

28. No public comment or input was solicited in creating the FDA's advisory list nor were any hearings held regarding the creation of same. The agency has not released any scientific or legal documentation supporting the inclusion of ingredients on this list other than prior warning letters. On information and belief, several of the ingredients on the FDA's Advisory List have been used by dietary supplement companies for decades, consumed by millions of consumers without serious adverse events, or other negative consequences.

29. At the same time of the announcement of its Advisory List, the FDA again trumpeted the warning letters issued regarding DMHA, alleging it was an unsafe food additive. *See* Exhibit 3. In essence, the FDA's expanded, aggressive approach to dietary supplement regulation has turned DSHEA on its head, attempting to shift to dietary supplement companies the burden of proving a dietary supplement ingredient is safe and lawful, rather than what is clearly called for by DSHEA, namely that dietary ingredients are foods which are presumed safe and that the FDA has the burden to demonstrate that they are unsafe and/or unlawful.

30. By issuing the warning letter regarding DMHA attached hereto as Exhibit 2, the FDA seeks to "expand the envelope" and further broaden its authority

over dietary supplements in direct contravention of DSHEA. It departs dramatically in form and substance from prior warning letters regarding dietary ingredients/supplements. Unlike many prior warning letters, the DMHA warning letter makes no specific claim that the ingredient is unsafe and describes no potential adverse consequences from consuming the ingredient. There is no allegation that DMHA is synthetically produced. There is no citation to any scientific study or literature. There is no allegation that Hi-Tech (or other companies) have made inappropriate or unsubstantiated claims regarding DMHA. In other words, the FDA has taken the unprecedented position that its assertion, without more, that an ingredient was not in the food supply before the effective date of DSHEA (October 15, 1994) is enough in and of itself to deem a product/ingredient unlawful and/or adulterated.

THE EFFECT OF THE FDA'S ACTION ON PLAINTIFFS

31. The warning letter sent to Plaintiffs demands that Wheat/Hi-Tech "immediately cease distribution" of any and all DMHA containing products. Moreover, as noted above, Mr. Wheat's release conditions in his unrelated criminal case forbid him from distributing "adulterated foods."

32. Based on the foregoing, there exists an actual controversy between the Plaintiffs Hi-Tech/Wheat and the Defendants regarding the FDA's circumvention of DSHEA and attempt to "ban" DMHA without an appropriate legal and scientific

review. Moreover, there is little doubt that the FDA will continue this inappropriate pattern of conduct against other companies that market or manufacture DMHA containing products. For Mr. Wheat personally there is the specter of incarceration absent a declaratory judgment.

33. 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 DMHA.

34. 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 DMHA. Additionally, the existing inventory of Hi-Tech's DMHA containing products is worth millions and the products have a limited shelf life.

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

36. Accordingly, Plaintiffs Hi-Tech and Jared Wheat seek declaratory and injunctive relief against the Defendants prohibiting them from circumventing DSHEA by using warning letters against DMHA containing products which have not been established to be either unsafe or "adulterated" or from seeking Mr. Wheat's incarceration for the sale/distribution of same.

CAUSES OF ACTION

A. Declaratory Relief Regarding the FDA's Action Against DMHA Containing Products.

37. Plaintiffs adopt and reallege the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

38. As described herein, there exists an actual controversy of a justiciable nature between Plaintiffs and the Defendants. Pursuant to 28 U.S.C. §§ 2201-2202, Plaintiffs are entitled to a declaratory judgment declaring Plaintiffs' rights as follows:

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

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

c. Unless and until there has been a proper rule making procedure pursuant to DSHEA regarding the legality of DMHA, Defendants are estopped from claiming in any court that DMHA containing products are adulterated or misbranded.

WHEREFORE, the Plaintiffs demand judgment against the Defendants as follows:

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

b. Forbidding the Defendants from claiming in any court that DMHA containing products are adulterated or misbranded;

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

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

e. Awarding Plaintiffs attorneys' fees and costs for this action; and

f. Granting Plaintiffs such other and further relief as may be just and proper.

B. Defendants Violated DSHEA and the APA by Attempting to Improperly Shadow-Ban DMHA without Engaging in the Proper Rule Making Process.

39. Plaintiffs adopt and reallege the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

40. By proceeding against DMHA containing products via intimidating letters which lack supporting allegations and evidence, the Defendants have circumvented the statutory requirements of DSHEA. Moreover, they have improperly shifted the burden of proof as to the safety and lawfulness of DMHA containing products to the manufacturers and producers of dietary supplements containing DMHA.

41. Defendants have further indicated that Plaintiffs will be required to cease manufacturing, producing, marketing, distributing and selling DMHA

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.

42. 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.

43. 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.

44. Defendants' actions have and will continue to cause irreparable harm and injury to Plaintiffs.

45. 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, Plaintiffs demand judgment against the Defendants as follows:

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

b. Forbidding the Defendnats from claiming in any court that DMHA containing products are adulterated or misbranded;

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

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

e. Awarding Plaintiffs attorneys' fees and costs for this action; and

f. Granting Plaintiffs such other and further relief as may be just and proper.

C. Under DSHEA, DMHA is Presumed to be a Safe Dietary Ingredient, and Defendants Violated DSHEA and the APA by Attempting to Shift the Burden on this Issue to Plaintiffs.

46. Plaintiffs adopt and reallege the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

47. Under DSHEA, the Defendants have the burden to demonstrate that DMHA 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).

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

49. By proceeding against Hi-Tech and other manufacturers/marketers of DMHA containing products via warning letters without sufficient evidence, 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.

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

51. 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 DMHA.

52. 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 DMHA as required by DSHEA.

53. 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 DMHA is adulterated.

54. In issuing warning letters against DMHA, 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 DMHA 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.

55. The conduct of the Defendants in making their determinations in issuing warning letters, is 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.

56. 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.

57. Defendants' actions have and will continue to cause irreparable harm and injury to Plaintiffs.

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

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows:

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

b. Forbidding the Defendants from claiming in any court that DMHA containing products are adulterated or misbranded;

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

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

e. Awarding Plaintiffs attorneys' fees and costs for this action; and

f. Granting Plaintiffs 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.

59. Plaintiffs adopt and reallege the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

60. Defendants' actions as described herein constitute actions designed to deprive Plaintiffs of their due process rights under the Fifth Amendment to the Constitution of the United States.

61. Specifically, the Defendants' actions requiring Plaintiffs to cease manufacturing, producing, marketing, distributing and selling their DMHA containing dietary supplement products, deprive Plaintiffs of their 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).

62. Defendants' actions have injured and will continue to injure and will cause irreparable harm to Plaintiffs.

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows:

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

b. Forbidding the Defendants from claiming in any court that DMHA containing products are adulterated or misbranded;

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

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

e. Awarding Plaintiffs attorneys' fees and costs for this action; and

f. Granting Plaintiffs such other and further relief as may be just and proper.

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

63. Plaintiffs adopt and reallege the allegations contained in all prior paragraphs of the Complaint as if set forth at length herein.

64. The Defendants have failed to meet their burden of proof under DSHEA to demonstrate that Hi-Tech's DMHA 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).

65. Defendants have failed to meet their burden under DSHEA to prove that Hi-Tech's DMHA 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).

66. 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 DMHA.

67. By seeking to prevent Plaintiffs from marketing or selling dietary supplements containing DMHA 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 Plaintiffs.

68. 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 Plaintiffs.

69. Consequently, the Defendants' enforcement actions against Plaintiffs including, but not limited to, the issuance of a warning letter, 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 Plaintiffs.

70. Defendants' actions have and will continue to cause irreparable harm and injury to Plaintiffs.

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows:

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

b. Forbidding the Defendants from claiming in any court that DMHA containing products are adulterated or misbranded;

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

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

e. Awarding Plaintiffs attorneys' fees and costs for this action; and

f. Granting Plaintiffs such other and further relief as may be just and proper.

Respectfully submitted,

/s/ Jack Wenik
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Exhibit 1

FDA Statement

FDA Statement from Deputy Commissioner for Food Policy and Response Frank Yiannas on new steps to protect consumers from unlawful ingredients in dietary supplements

For Immediate Release

April 16, 2019

Statement

Taking a dietary supplement – like vitamins, minerals, or herbs – has become a daily routine for many Americans. The $40 billion a year supplement industry reaches 170 million Americans, offering between 50,000 and 80,000 different products that claim to help maintain or improve health. For many, dietary supplements are a key part of their efforts to make healthy choices. To be able to make those choices with respect to dietary supplements, consumers need to have access to safe, well-manufactured, and appropriately labeled products.

While many dietary supplements meet the FDA's standards, there are some companies who knowingly distribute and sell dangerous or otherwise illegal products that put consumers at risk. As the agency entrusted with the oversight of dietary supplements, we will not stand by and allow these companies to compromise the health of the very people who are seeking out supplements to aid in their well-being.

Earlier this year, we **announced new efforts (/NewsEvents/Newsroom/PressAnnouncements/ucm631065.htm)** to strengthen the regulation of dietary supplements by modernizing our regulatory framework to meet the demands of this growing industry. Today, as part of those efforts, we are announcing an important new step and a new action to better protect consumers from potentially unlawful dietary supplements.

The FDA is launching a new tool to quickly alert the public when we become aware of ingredients that appear to be unlawfully marketed in dietary supplements. This Dietary Supplement Ingredient Advisory List will be housed on the **FDA website (/Food/DietarySupplements/ProductsIngredients/ucm636081.htm)**. Consumers may wish to avoid buying and using dietary supplements containing ingredients on the List and industry may wish to avoid making or selling dietary supplements containing ingredients on the List. Ingredients will be added to the List following an initial FDA assessment indicating the ingredient may not lawfully be in dietary supplements. This could be for reasons including the ingredient does not fit the definition of a dietary ingredient or the ingredient requires a pre-market notification that was not submitted; however, inclusion of an ingredient on this List is not necessarily an indication of safety concerns. The FDA will continue to communicate separately and clearly any time we identify safety concerns about dietary ingredients or dietary supplements.

As the dietary supplement marketplace has grown, the introduction of new ingredients often raises complex questions involving science, policy, and the law. In the time it takes the FDA to make a final determination, consumers and industry might mistakenly conclude that a lack of action by the FDA indicates that these ingredients are lawful. This List is intended to get information to both consumers and industry more quickly. It also provides an opportunity for stakeholders to share information with us that they think might be relevant to our determination.

While we will aim to communicate about these suspect ingredients as quickly as possible, it is important to note that the List is not exhaustive; it will always be a work in progress. Additionally, we expect the List will evolve as new ingredients are identified and others are removed. Consumers can **sign up (https://updates.fda.gov/subscriptionmanagement)** to receive the most recent updates and changes to the List, and all stakeholders can **submit additional feedback (mailto:odsp@fda.hhs.gov?subject=)** that may support or refute the FDA's preliminary assessment regarding the ingredients on the List.

The Dietary Supplement Ingredient Advisory List adds to our ability to inform and educate people in determining which ingredients might not be lawfully included in dietary supplements. We will continue to use our traditional enforcement tools as part of our overall strategy regarding dietary supplements.

To that end, we continue to take action against those bad actors who seemingly ignore the legal requirements for dietary supplements. Today, we are also announcing that the agency has **warned (/Food/NewsEvents/ConstituentUpdates/ucm636082.htm)** eight companies for marketing dietary supplements containing **DMHA (/Food/DietarySupplements/ProductsIngredients/ucm636032.htm)**. These products are considered

adulterated because the FDA has determined that DMHA is either a "new dietary ingredient" for which the FDA has not received the required New Dietary Ingredient notification or that DMHA is an unsafe food additive. The agency also issued warnings to three companies for marketing dietary supplements containing **phenibut (/Food/DietarySupplements/ProductsIngredients/ucm636077.htm)**. These products are misbranded because they label phenibut as a dietary ingredient when phenibut does not meet the statutory definition of a dietary ingredient. The products identified in the warning letters include Lean Pills, Chaos Unleashed, Triple X Pre-Workout Stimulator, Simply Skinny Pollen, Synedrex, E.S.P. Extreme, Ultimate Orange, HydroxyElite, Lipodrene Elite, Synadrene, Enrage Extreme, Pre-Workout Relentless V1, Kavinace, Sleep Walker, Red Dawn Liquid, and Limitless.

These companies have 15 business days from receipt of the warning letter to inform the FDA of specific steps they will take to bring their products into compliance with the law. This could include a company's decision to recall, reformulate, discontinue sale or products, or other actions.

We take these violations very seriously and stand ready to take enforcement action without further notice if the companies do not immediately cease distribution of the products. We are firmly committed to ensuring that products sold as dietary supplements meet the law's requirements for dietary supplements, and most importantly, do not put consumers at unnecessary risk. Further, other companies marketing similar illegal products should take note—we will continue to take the necessary steps to protect the American public from ingredients that aren't allowed in dietary supplements.

Today's actions are part of the FDA's overall efforts to strengthen the agency's regulation in a manner that strikes the right balance between preserving consumer access to lawful dietary supplements while also protecting Americans from the potential dangers of products that don't meet the agency's standards for dietary supplements. Just last week, we **announced (/Food/NewsEvents/WorkshopsMeetingsConferences/ucm632939.htm)** a public meeting to discuss responsible innovation in the dietary supplement industry. We're excited to hear from all of our stakeholders in this arena and look forward to an in-depth conversation on May 16 to discuss ideas for facilitating responsible innovation in the dietary supplement industry while preserving the FDA's ability to protect the public from unsafe, misbranded, or otherwise unlawful dietary supplements.

We remain committed to advancing the important work of modernizing the FDA's oversight of the dietary supplement industry and bringing greater assurance to Americans who rely on dietary supplements on a regular basis.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

Lindsay Haake (mailto:Lindsay.Haake@fda.hhs.gov)
301-796-3007

Consumers

888-INFO-FDA

Follow FDA

Follow @US_FDA (https://twitter.com/US_FDA) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
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Follow @FDAmedia (https://twitter.com/FDAMedia) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

More In Press Announcements (/NewsEvents/Newsroom/PressAnnouncements/default.htm)

2017 (/NewsEvents/Newsroom/PressAnnouncements/2017/default.htm)

2016 (/NewsEvents/Newsroom/PressAnnouncements/2016/default.htm)

Exhibit 2

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

5001 Campus Drive
College Park, MD 20740

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

April 10, 2019

Jared Wheat, CEO & Founder
Hi-Tech Pharmaceuticals, Inc.
6015 B Unity Drive
Norcross, GA 30071-3575 US

Re: 560788

Dear Mr. Wheat:

This letter concerns your products Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene, which are labeled and/or offered for sale as dietary supplements. The Supplement Facts panel on your product labels declares 2-Aminoisoheptane HCl as a dietary ingredient. This ingredient is also called, among other names, 1,5-DMHA, 2-amino-6-methylheptane, 2-amino-5methylheptane, 1,5-Dimethylhexylamine, 2-Isooctyl amine, and Octodrine, and will be referred to hereinafter as DMHA.

The term "dietary supplement" is defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(ff)]. Given that you have declared DMHA as a dietary ingredient in the labeling of your product, we assume you have a basis to conclude that DMHA is a "dietary ingredient" under section 201(ff)(1) of the Act [21 U.S.C. § 321(ff)(1)]. If you have a basis to conclude that DMHA is a "dietary ingredient," it would also be a "new dietary ingredient" (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) under section 413(d) of the Act [21 U.S.C. § 350b(d)].

Under section 413 of the Act [21 U.S.C. § 350b], a dietary supplement that contains a new dietary ingredient shall be deemed adulterated under section 402(f) of the Act [21 U.S.C. § 342(f)] unless it meets one of two requirements:

1. The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or
2. There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days

> before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

To the best of FDA's knowledge, there is no information demonstrating that DMHA was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has not been chemically altered. Assuming DMHA is a dietary ingredient, in the absence of such information, DMHA would be subject to the notification requirement in section 413(a)(2) of the Act [21 U.S.C. § 350b(a)(2)] and 21 CFR 190.6. Products for which the manufacturer or distributor is required to submit a new dietary ingredient notification under section 413(a)(2) and 21 CFR 190.6, but for which the required notification has not been submitted, are adulterated under sections 402(f) and 413(a) of the Act [21 U.S.C. §§ 342(f) and 350b(a)].

Even if a new dietary ingredient notification had been submitted under section 413(a)(2) and 21 CFR 190.6, we know of no evidence that would establish that DMHA could be lawfully marketed as a new dietary ingredient in your Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene products. In the absence of a history of use or other evidence of safety establishing that DMHA, when used under the conditions recommended or suggested in the labeling as a dietary ingredient, will reasonably be expected to be safe, dietary supplements containing DMHA as a new dietary ingredient are adulterated under sections 402(f) and 413(a) of the Act because there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under sections 301(a) and (v) of the Act [21 U.S.C. § 331(a) and (v)]. To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that DMHA will reasonably be expected to be safe when used as a dietary ingredient.

We also note that we have questions about whether DMHA is, in fact, a dietary ingredient. If DMHA were not a dietary ingredient under section 201(ff)(1) of the Act, it would be an unsafe food additive. If a substance is not generally recognized as safe (GRAS) by qualified experts for its intended use in food and does not qualify for any of the other exemptions from the food additive definition, it is a food additive.[1] Food additives require premarket approval based on data demonstrating safety. Any food additive that has not been approved for its intended use in food is deemed to be unsafe and causes the food to be adulterated under section 402(a)(2)(C)(i) of the Act [21 U.S.C. § 342(a)(C)(i)]. Adulterated foods cannot be legally imported or marketed in the United States.

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[1] Under section 201(s) of the Act [21 U.S.C. § 321(s)], the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food; (2) pesticide chemicals; (3) color additives; (4) substances used in accordance with a "prior sanction" (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the Act, the Poultry Products Inspection Act, or the Meat Inspection Act); (5) new animal drugs; and (6) dietary ingredients in or intended for use in a dietary supplement.

Section 201(s) of the Act [21 U.S.C § 321(s)] exempts dietary ingredients used in dietary supplements from the food additive definition. However, non-dietary ingredients intended for use in dietary supplements are not exempt from the food additive definition and must meet the same requirements as substances added to conventional foods. In other words, a non-dietary ingredient added to a dietary supplement must be used in accordance with a food additive regulation or be GRAS for its intended use, unless it qualifies for another exception to the food additive definition.

DMHA it is not generally recognized as safe under its conditions of use in your dietary supplement products. If DMHA is not a dietary ingredient under section 201(ff)(1) of the Act, dietary supplements containing DMHA would be adulterated under section 402(a)(2)(C)(i) of the Act because they would contain an unsafe food additive.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations addressed in this letter, as well as any other violations associated with your Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene products or other dietary supplement products marketed by your firm, including any that contain DMHA. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered. Failure to immediately cease distribution of your products Ultimate Orange, HydroxyElite, Lipodrene Elite, and Synadrene, and any other products you market that contain DMHA, could result in enforcement action by FDA without further notice. Sections 302 and 304 of the Act provide for seizure of violative products and injunction against the manufacturers and distributors of violative products [21 U.S.C. §§ 332 and 334].

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your written reply should be directed to Mr. Rob Genzel Jr., Compliance Officer, United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, you may also contact Mr. Genzel at rob.genzel@fda.hhs.gov.

Sincerely,

William A. Correll
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

Exhibit 3

Dietary Supplement Ingredient Advisory List

The ingredients listed below do not appear to be lawful ingredients in dietary supplements. Consumers may wish to avoid purchasing or consuming dietary supplements that include these ingredients:

Andarine also known as:

- GTx 007
- GTX-007
- Propanamide, 3-(4-(acetylamino)phenoxy)-2-hydroxy-2-methyl-N-(4-nitro-3-(trifluoromethyl)phenyl)-, (2S)-
- SARM S-4
- S-3-(4-acetylaminophenoxy)-2-hydroxy-2-methyl-N-(4-nitro-3-trifluoromethylpheanyl)propionamide
- S-4 cpd

Higenamine also known as:

- Isoquinolin-6,7-diol, 1,2,3,4-tetrahydro-1-[4-hydroxybenzyl]-
- DL-DEMETHYLCOCLAURINE
- Norcoclaurine
- (+-)-Norcoclaurine
- (+-)-Demethylcoclaurine
- (+-)-O-Demethylcoclaurine
- (R)-Higenamine
- (R,S)-Norcoclaurine
- 1-(4-hydroxybenzyl)-1,2,3,4-tetrahydroisoquinoline-6,7-diol
- 1-[(4-hydroxyphenyl)methyl]-1,2,3,4-tetrahydroisoquinoline-6,7-diol
- 1-(p-hydroxybenzyl)-6,7-dihydroxy-1,2,3,4-tetrahydroisoquinoline
- 1-(4-Hydroxybenzyl)-1,2,3,4-tetrahydro-6,7-isoquinolinediol
- 6,7-Isoquinolinediol, 1,2,3,4-tetrahydro-1-((4-hydroxyphenyl)methyl)-, (+-)-
- 6,7-dihydroxy-1-(4-hydroxybenzyl)-1,2,3,4-tetrahydroisoquinoline
- 6,7-Dihydroxy-1-[(4-hydroxyphenyl)methyl]-1,2,3,4-tetrahydroisoquinoline
- (+-)-1,2,3,4-Tetrahydro-1-((4-hydroxyphenyl)methyl)-6,7-isoquinolinediol

Hordenine also known as:

- anhaline
- eremursine
- N,N-dimethyltyramine
- peyocactine
- p-hydroxy-N,N-dimethylphenethylamine
- 4-[2-(Dimethylamino)ethyl]phenol

1,4-DMAA also known as:

- 1,4 dimethylamylamine
- 1,4 dimethylpentylamine

Retailers, manufacturers, and other businesses may wish to avoid selling, making, or distributing dietary supplements that include any of the above ingredients.

The FDA **Dietary Supplement Ingredient Advisory List** is intended to quickly alert the public when the FDA identifies ingredients that do not appear to be lawfully included in products marketed as dietary supplements. Inclusion on the **Dietary Supplement Ingredient Advisory List** does not necessarily indicate that the FDA has determined that the ingredient is unsafe. The FDA will continue to communicate separately at any time it identifies safety concerns about ingredients in dietary supplements.

Ingredients are added to the **Dietary Supplement Ingredient Advisory List** based on a preliminary evaluation by the FDA. This preliminary evaluation indicates that an ingredient may not lawfully be in dietary supplements for reasons including:

1. the ingredient appears to be excluded from use in a dietary supplement;
2. the ingredient does not appear to be a dietary ingredient and does not appear to be either an approved food additive or generally recognized as safe for use; and/or
3. the ingredient appears to be subject to the requirement for pre-market notification, but the requirement has not been satisfied.

Although this list reflects ingredients for which the FDA has made a preliminary assessment, it is not an exhaustive list of ingredients that may or may not be lawfully included in dietary supplements. Ingredients may be added to or removed from this list as the FDA continues its evaluation.

The FDA welcomes additional feedback and information, including information that may support or refute the FDA's preliminary assessment regarding the ingredients on the **Dietary Supplement Ingredient Advisory List**. You may submit such information to the **FDA's Office of Dietary Supplement Programs (mailto:ODSP@fda.hhs.gov)**.

Consumers who have experienced a health – related reaction or illness (also known as an adverse event) after consuming any dietary supplement should contact their medical professional. It is important for consumers, health care professionals, and industry members to report adverse events to the FDA, so we can act to protect the public from unsafe products. You can report adverse events to the FDA by visiting the **How to Report a Problem (/Food/DietarySupplements/ReportAdverseEvent/default.htm)** page.

The FDA encourages consumers with questions about dietary supplements to **Submit An Inquiry (https://cfsan.secure.force.com/Inquirypage)**, or to visit www.fda.gov/fcic for additional information.

Sign up for email updates (https://updates.fda.gov/subscriptionmanagement) to receive the most recent updates and changes to the **Dietary Supplement Ingredient Advisory List**.

More in Products & Ingredients (/Food/DietarySupplements/ProductsIngredients/default.htm)

- **Dietary Supplement Ingredient Advisory List (/Food/DietarySupplements/ProductsIngredients/ucm636081.htm)**
- **DMHA in Dietary Supplements (/Food/DietarySupplements/ProductsIngredients/ucm636032.htm)**
- **Phenibut in Dietary Supplements (/Food/DietarySupplements/ProductsIngredients/ucm636077.htm)**
- **Acacia rigidula in Dietary Supplements (/Food/DietarySupplements/ProductsIngredients/ucm489921.htm)**
- **BMPEA in Dietary Supplements (/Food/DietarySupplements/ProductsIngredients/ucm443790.htm)**
- **DMAA in Products Marketed as Dietary Supplements (/Food/DietarySupplements/ProductsIngredients/ucm346576.htm)**
- **DMBA in Dietary Supplements (/Food/DietarySupplements/ProductsIngredients/ucm444719.htm)**
- **Methylsynephrine in Dietary Supplements (/Food/DietarySupplements/ProductsIngredients/ucm493282.htm)**
- **Picamilon in Dietary Supplements (/Food/DietarySupplements/ProductsIngredients/ucm472881.htm)**
- **Pure and Highly Concentrated Caffeine (/Food/DietarySupplements/ProductsIngredients/ucm460095.htm)**
- **Tianeptine in Dietary Supplements (/Food/DietarySupplements/ProductsIngredients/ucm626152.htm)**
- **Vinpocetine in Dietary Supplements (/Food/DietarySupplements/ProductsIngredients/ucm518478.htm)**

CIVIL COVER SHEET

JS-44 (Rev. 6/17 DC)

I. (a) PLAINTIFFS
HI-TECH PHARMACEUTICALS, INC., a Georgia corporation, and JARED WHEAT

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF Gwinnett, GA
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS
NORMAN E. SHARPLESS, M.D., as Commissioner of the United States Food and Drug Administration; the UNITED STATES FOOD AND DRUG ADMINISTRATION;

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Jack Wenik, Esq.
Epstein Becker & Green, PC
1227 25th Street, N.W., 7th Floor, Wash., D.C. 20037
(973-639-5221)

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	◉ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	◉ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ **A. *Antitrust***
- ☐ 410 Antitrust

○ **B. *Personal Injury/ Malpractice***
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

◉ **C. *Administrative Agency Review***
- ☐ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☒ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ **D. *Temporary Restraining Order/Preliminary Injunction***

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ **E. *General Civil (Other)*** **OR** ○ **F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ **G. *Habeas Corpus/ 2255***	○ **H. *Employment Discrimination***	○ **I. *FOIA/Privacy Act***	○ **J. *Student Loan***
☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ **K. *Labor/ERISA (non-employment)***	○ **L. *Other Civil Rights (non-employment)***	○ **M. *Contract***	○ **N. *Three-Judge Court***
☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

APA (5 U.S.C. § 702) and Declaratory Judgment Act (28 U.S.C. § 2201) matter challenging Agency Action

VII. REQUESTED IN COMPLAINT CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** **JURY DEMAND:** Check YES only if demanded in complaint **YES** ☐ **NO** ☐

VIII. RELATED CASE(S) IF ANY (See instruction) **YES** ☐ **NO** ☒ If yes, please complete related case form

DATE: 5/1/19 **SIGNATURE OF ATTORNEY OF RECORD** s/ Jack Wenik

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

HI-TECH PHARMACEUTICALS, INC., a Georgia corporation, and JARED WHEAT, *Plaintiff(s)* v. NORMAN E. SHARPLESS, M.D., as Commissioner of the United States Food and Drug Administration, et al., *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* NORMAN E. SHARPLESS, M.D.
Commissioner of the United States Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jack Wenik
Epstein Becker & Green, PC
1227 25th Street, N.W.
7th Floor
Washington, D.C. 20037

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

HI-TECH PHARMACEUTICALS, INC., a Georgia corporation, and JARED WHEAT,

Plaintiff(s)

v.

NORMAN E. SHARPLESS, M.D., as Commissioner of the United States Food and Drug Administration, et al.,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* JESSIE K. LIU, ESQ.
U.S. Attorney for the District of Columbia
555 4th Street, N.W.
Washington, D.C. 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jack Wenik
Epstein Becker & Green, PC
1227 25th Street, N.W.
7th Floor
Washington, D.C. 20037

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

HI-TECH PHARMACEUTICALS, INC., a Georgia corporation, and JARED WHEAT, *Plaintiff(s)* v. NORMAN E. SHARPLESS, M.D., as Commissioner of the United States Food and Drug Administration, et al., *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jack Wenik
Epstein Becker & Green, PC
1227 25th Street, N.W.
7th Floor
Washington, D.C. 20037

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

HI-TECH PHARMACEUTICALS, INC., a Georgia corporation, and JARED WHEAT,

Plaintiff(s)

v.

NORMAN E. SHARPLESS, M.D., as Commissioner of the United States Food and Drug Administration, et al.,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* UNITED STATES FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Ave.
Silver Spring, MD 20993

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jack Wenik
Epstein Becker & Green, PC
1227 25th Street, N.W.
7th Floor
Washington, D.C. 20037

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

HI-TECH PHARMACEUTICALS, INC., a Georgia corporation, and JARED WHEAT,

Plaintiff(s)

v.

NORMAN E. SHARPLESS, M.D., as Commissioner of the United States Food and Drug Administration, et al.,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* WILLIAM BARR, ESQ.
Attorney General for the United States
U.S. Deptartment of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jack Wenik
Epstein Becker & Green, PC
1227 25th Street, N.W.
7th Floor
Washington, D.C. 20037

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

HI-TECH PHARMACEUTICALS, INC., a Georgia corporation, and JARED WHEAT,

Plaintiff(s)

v.

NORMAN E. SHARPLESS, M.D., as Commissioner of the United States Food and Drug Administration, et al.,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ALEX M. AZAR, II
Secretary of the United States Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Jack Wenik
Epstein Becker & Green, PC
1227 25th Street, N.W.
7th Floor
Washington, D.C. 20037

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACEUTICALS, INC., a Georgia corporation, and JARED WHEAT, Plaintiffs, v. NORMAN E. SHARPLESS, M.D., as Commissioner of the United States Food and Drug Administration, *et al.*, Defendants.	)	Civil Action No. _____

DISCLOSURE STATEMENT PURSUANT TO FRCP 7.1 AND LCvR 26.1

Pursuant to Federal Rule of Civil Procedure 7.1 and Local Rule 26.1, and to enable Judges and Magistrate Judges to evaluate possible disqualification or recusal, the undersigned counsel for Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") in the above-captioned matter, certifies that Hi-Tech is a non-public Georgia corporation with Jared Wheat as a 95% shareholder and Dave Nelson as a 5% shareholder.

Respectfully submitted this 1st day of May, 2019.

Respectfully submitted,

/s/ Jack Wenik
Jack Wenik (D.C. Bar No. 406362)
Epstein, Becker & Green
1227 25th Street, N.W., Suite 700
Washington, DC 20037-1175
(973) 639-5221

Counsel for Plaintiffs
Hi-Tech Pharmaceuticals, Inc. and Jared Wheat