UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACEUTICALS, INC., 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. 1:19-cv-1268 Hon. Reggie B. Walton

MEMORANDUM OF LAW BY PLAINTIFFS HI-TECH PHARMACEUTICALS, INC., AND JARED WHEAT IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE COMPLAINT PURSUANT TO FED. R. CIV. P. 12(b)(1) and 12(b)(6)

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PRELIMINARY STATEMENT

Plaintiffs Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") and Jared Wheat (collectively, "Plaintiffs") submit this memorandum of law in opposition to the motion of Defendants United States Food & Drug Administration ("FDA"), Commissioner Norman E. Sharpless, M.D., the Department of Health & Human Services ("HHS"), and Secretary Alex Azar (collectively, "Defendants") to dismiss Plaintiffs' complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6). Defendants' moving papers reflect a strategy similar to their strategy in dealing with DMHA, the dietary ingredient at issue in this lawsuit – they overlook relevant facts and make broad, unsupported claims regarding the scope of the FDA's authority to regulate dietary supplements and ingredients.

Defendants claim that this Court lacks subject-matter jurisdiction to hear Plaintiffs' challenge to the FDA's attempted end-run around the statutory requirements of DSHEA by arguing that the DMHA warning letter does not constitute final agency action and that Plaintiffs are barred from pre-enforcement judicial review of the FDA's actions. The Court should reject this position because this case is not about precluding or circumscribing the FDA's enforcement authority. Rather, this case is about whether the FDA has acted arbitrarily and capriciously by taking actions against an entire class of products, all of which contain a particular dietary ingredient – DMHA. It is also about whether the FDA will be required to comply with the requirements that Congress has imposed as part of the Dietary Supplement Health and Education Act before the FDA can take such action against DMHA. Moreover, the impacts of the FDA's actions are not theoretical: Mr. Wheat's freedom is threatened by the FDA's assertion that DMHA is not a lawful dietary ingredient, as is Hi-Tech's ability to serve its customers. These are ripe and justiciable issues that require the Court's attention now.

STATEMENT OF FACTS

The following facts are based on the factual allegations of Hi-Tech's complaint, which must be accepted as true for purposes of this motion.

A. Parties

Hi-Tech is a Georgia corporation with its principal place of business in Georgia. Hi-Tech is one of the largest manufacturers and distributors of dietary supplements in the United States. Hi-Tech sells its products through more than 100,000 retail locations including, for example: 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. Compl. at ¶ 6. Plaintiff Jared Wheat is the President and Chief Operating Officer of Hi-Tech. *Id*. at ¶ 7.

Defendants are the FDA, an agency within HHS, HHS, Norman E. Sharpless, the commissioner of the FDA, and Alex Azar, the Secretary of HHS (the individual defendants are sued in their official capacities only). *Id.* at ¶¶ 7-10.

B. DMHA

Several of Hi-Tech's products contain 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". *Id.* at ¶¶ 1, 19. 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. *Id*. at ¶ 19. 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. *Id*.

A leading dietary supplement scientist/regulatory expert retained by Plaintiffs concluded–

–after reviewing the relevant scientific literature on DMHA—that DMHA should be considered a dietary ingredient under the Dietary Supplement Health and Education Act (hereinafter "DSHEA"). Pub. L. No. 103-417, 108 Stat. 4325 (1994), because it is found in multiple plants, each of which have a long history as part of the human diet. *Id.* at ¶ 22.

Moreover, DMHA is safe to use as directed. Although 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. *Id.* at ¶ 20. For example, animal studies of DMHA showed it to have a very high LD50. *Id.*[1] In DMHA's case, a massive dose was required to achieve LD50 in a variety of animals. *Id.* Similarly, animal studies have shown the effects of DMHA to be relatively benign. *Id.* 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. *Id.*

Plaintiffs' expert further confirmed the safety of DMHA by reviewing FDA's adverse event data base for 2014 to 2018 using the various synonyms for DMHA. *Id.* at ¶ 23. No record of a single serious adverse event was found. *Id.* A similar search of Canada's comparable data base also revealed no adverse events for DMHA. *Id.* 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.

There is also a strong reason to believe that DMHA is safe because another challenged similar dietary ingredient, DMAA—the status of which under DSHEA is currently pending before the Eleventh Circuit—is safe. *Id.* at ¶ 24. According to Plaintiffs' expert, while DMAA is not the chemical equivalent of DMHA, it does have a very similar structure and thus, the two

[1] "LD50" is the amount of a substance needed to cause the deaths of 50% of animals in a study group. *Id.*

ingredients could be expected to produce similar effects in humans. *Id.* Multiple clinical studies of DMAA containing products found the ingredient to induce no harmful effects in humans. *Id.* 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. *Id.*

C. Regulation of Dietary Supplements

At least for purposes of this motion, it must be assumed that Hi-Tech's products that contain DMHA are dietary supplements. *See* Def. Br. at 5, 16; ECF 1-2 (FDA Warning Letter, dated April 10, 2019) at 3 (referring to Hi-Tech's products containing DMHA as dietary supplements).

The FDA's authority to regulate food and drugs derives from the Federal Food, Drug, & Cosmetics Act ("FFDCA"), 21 U.S.C. § 301 *et seq.* In 1994, Congress enacted DSHEA, which amended the FFDCA in several respects to specify the FDA's authority to regulate dietary supplements and 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)(A)-(F).

A dietary supplement is defined as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more [dietary ingredients.]" *Id.* Dietary ingredients include both naturally occurring and synthetically produced versions of the same ingredient. The FDA has recognized the equivalence of natural versus synthetically produced dietary ingredients in the context of several vitamins and other ingredients. Compl. at ¶ 16.

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).

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 regarding a dietary supplement/ingredient, the FDA must provide the responding party "appropriate notice and opportunity to present views" regarding the matter. 21 U.S.C. § 342(f)(2).

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. § 350*b*(a)(2). As previously noted, Plaintiffs' Complaint alleges that several plants, including the bark of walnut trees, which contain DMHA, have been sold in this country prior to October 15, 1994. Compl., ¶ 19.

D. The FDA's "Crackdown" on Dietary Supplements

The FDA's decision to *de facto* ban DMHA via a campaign of warning letters is not the first time that the agency has acted in an arbitrary and capricious manner in an attempt to remove dietary ingredients/supplements from the marketplace without appropriate rule making, public comment or procedure.

Regarding the similarly structured DMAA, in April 2012 the FDA attempted to *de facto* ban 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.

Hi-Tech challenged the FDA's illegal attempts to ban DMAA and during that litigation the agency brazenly admitted that it chose to *de facto* ban DMAA via a series of warning letters, rather than formally banning the ingredient, because "[t]he 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. The agency may not want to adhere to its governing regulations and law, but it simply cannot skirt around them, regardless of the motivation.[2]

Seemingly emboldened by its at least preliminary success regarding DMAA, the FDA is again attempting to remove dietary ingredients/supplements which it disapproves of 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* ECF 1-3 (emphasis added).

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

[2] The appropriateness of the FDA's approach is currently pending before the Eleventh Circuit, which heard oral argument on the matter in August 2018. *See USA v. Hi-Tech Pharmaceuticals, Inc., et al.*, 17-13376 (11th Cir.).

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. Although the list does not include DMHA, the posting of such a "list," when there is no legal or scientific basis for it, demonstrates the agency's brazen disregard of its governing statutes and regulations.

E. The FDA Expands Its Crackdown to DMHA

Simultaneous with the announcement of its improper Advisory List, the FDA began sending out warning letters regarding DMHA, alleging it was an unsafe food additive. *See* ECF No. 1-2. 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.

By issuing the warning letter regarding DMHA, the FDA has sought to further broaden its authority over dietary supplements in direct contravention of DSHEA. Moreover, the DMHA warning letter 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. *See* ECF No. 1-2. There is no allegation that DMHA is synthetically produced. *Id.* There is no citation to any scientific study or literature. *Id.* There is no allegation that Hi-Tech (or other companies) have made inappropriate or unsubstantiated claims regarding DMHA. *Id*. 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. This is simply not the law and turns DSHEA on its head by improperly shifting the burden onto Plaintiff to establish DMHA's status as a dietary ingredient.

F. The Impact of FDA's Campaign Against DMHA are Especially Dangerous to Plaintiffs.

The warning letter sent to Plaintiffs demands that they "immediately cease distribution" of any and all DMHA containing products. As such, Hi-Tech stands to suffer immediate and irreparable harm to its business should it be forced to cease the manufacturing, production, marketing, distribution and sales of dietary supplement products containing DMHA. It would also render Hi-Tech's existing inventory of DMHA containing products worthless. These harms create an actual case and controversy between Hi-Tech and Defendants regarding the FDA's circumvention of DSHEA and its attempt to "ban" DMHA without an appropriate legal and scientific review.

The stakes for Plaintiff Jared Wheat are even more severe than those threatened to befall Hi-Tech. 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 market DMAA, an ingredient similar to DMHA, and more generally, that he not manufacture, distribute or sell any "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. To be clear, the bail

condition barring Plaintiffs selling or manufacturing "adulterated foods or misbranded drugs" was specifically sought by the Government/FDA and is not a typical or run-of-the-mill condition.

The FDA's DMHA warning letter is unambiguous in that it considers the continued marketing of DMHA containing dietary supplements "violations" of various provisions of DSHEA and that the products containing DMHA are adulterated. *See* ECF No. 1-2 at 3 ("You should take prompt action to correct the violations addressed in this letter . . . ."). 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 that Hi-Tech's DMHA containing products are deemed adulterated by statute. Mr. Wheat—and Hi-Tech—are therefore compelled to 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.

ARGUMENT

I. THE COURT HAS SUBJECT-MATTER JURISDICTION TO HEAR THIS ACTION UNDER THE ADMINISTRATIVE PROCEDURE ACT.

As an initial matter, Defendants misstate the standards for this Court's review of Plaintiffs' complaint to determine whether it has jurisdiction. They wrongly assert that the Court "must accept as true all *uncontroverted* material factual allegations in the complaint . . . ." Def. Br. at 7 (emphasis added). That position is incorrect and contrary to settled law in this Circuit. "While the district court may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction, . . . the court must still 'accept *all* of the factual allegations in [the] complaint as true.'" *Jerome Stevens Pharm. Inc. v. Food & Drug Admin.*, 402 F.3d 1249, 1253 (D.C. Cir. 2005) (emphasis added); *see, also, Boland v. Fortis Constr. Co.*,

796 F. Supp.2d 80, 86 n.5 (D.D.C. 2011) (describing Defendants' position as "incorrect;" non-presumption of truthfulness applies only if plaintiff's allegations are "fantastic and incredulous" and are "wholly insubstantial or frivolous."). Absent a showing that Hi-Tech's allegations are fantastic, incredulous, insubstantial, or frivolous – which they are not – the Court must presume the truth of all of Plaintiffs' factual allegations, even if Defendants dispute them at this juncture.

A. The Circumstances Surrounding Plaintiffs' Bail Conditions Render Defendants' Actions Ripe for Review.

Defendants go to great lengths to argue that *Holistic Candlers & Consumers' Ass'n v. Food & Drug Admin.*, 664 F.3d 940 (D.C. Cir.), *cert. denied*, 133 S. Ct. 497 (2012), dictates that Plaintiffs' claims under the APA must be dismissed because it held that FDA warning letters do not constitute "final agency action." The Court should reject Defendants' position due to the unique factual circumstances present here, where the Defendants have combined their warning letter with a bond condition in an unrelated criminal matter to produce serious legal consequences for Plaintiffs.

The *Holistic* Court observed that, "[a]s a general matter, two conditions must be satisfied for agency action to be 'final': First, the action must mark the consummation of the agency's decision making process -- it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Holistic*, 664 F.3d at 943 (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)). Defendants have—by (1) affirmatively seeking the bail order currently in place in the Northern District of Georgia, and then (2) taking the unilateral position that DMHA is not a lawful dietary ingredient and that any product containing it is adulterated and therefore "violates" DSHEA—effectively determined "various rights or obligations . . . from which legal consequences will flow."

It is uncontested that Plaintiffs are subject to a unique bail condition that was specifically sought by the Government/FDA that broadly prohibits them from manufacturing or marketing DMAA *and* any "adulterated or misbranded" product. It is further uncontested that the Government now considers Plaintiffs' DMHA containing products to be adulterated. Although the FDA's DMHA warning letter may use various weasel-words to give the impression that the Government has not reached a conclusion on this matter, *see* Def. Br. at 9-13, the Government's lack of open-mindedness is evident from the fact that it has utterly failed to consider the opinion of Plaintiffs' expert as to the status of DMHA under DSHEA. The FDA has been in receipt of that information since May 1, 2019, a total of 117 days as of the filing of this brief (the Government was in receipt of Plaintiffs' expert's conclusions for 89 days prior to filing its motion to dismiss). If the Government were truly interested in determining the status of DMHA under DSHEA, it could have easily done so in the time that it took to respond to this action. Instead, it pressed ahead with the motion to dismiss this action and Plaintiffs remain in danger of violating their bail condition in the Northern District of Georgia. Clearly, the FDA's DMHA warning letter is not interlocutory in nature and legal consequences will flow from the Government's conclusion that DMHA containing products are adulterated.

B. Jurisdiction Is Not Precluded By *Ewing* or Its Progeny Because This Action Does Not Seek Pre-Enforcement Judicial Review.

Defendants incorrectly characterize Hi-Tech's action as seeking pre-enforcement review of FDA's determination that DMHA is not a legal dietary ingredient, and, based on that mischaracterization, argue that the Court lacks jurisdiction over such a claim. Because the Defendants' initial premise is wrong, the entire argument must fall.

This lawsuit is not an attempted end-run around the FDA's attempts to legally regulate DMHA and products containing it. As previously noted, Hi-Tech merely seeks to compel the

FDA to comply with its statutory obligations that Congress imposed on it in DSHEA. If the FDA intends to impose an industry-wide ban on DMHA as an ingredient in dietary supplements, it must engage in fact-finding and rulemaking, and prove that DMHA presents a serious or unreasonable risk of illness or injury. Thus, *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), in which the Supreme Court precluded judicial review of the FDA's finding of probable cause to initiate enforcement proceedings, is inapplicable to this lawsuit.

Rather, this litigation is akin to *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967), in which the Court held there was jurisdiction to hear the plaintiff manufacturer's challenge to regulations promulgated by the FDA regarding prescription drug labeling. As here, the FDA argued that there was no jurisdiction for a pre-enforcement review of the FDA's policy, citing *Ewing. Gardner*, 387 U.S. at 140-47. The Court rejected the argument, holding that the FDA's argument would have cut off the "the well-established jurisdiction of the federal courts to hear, in appropriate cases, suits under the Declaratory Judgment Act and the Administrative Procedure Act challenging final agency action of the kind present here." *Id.* at 148.

Similarly, in *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167 (1967), the Supreme Court held that jurisdiction existed to hear a challenge by a cosmetic manufacturers' association to FDA regulations governing color additives in cosmetics. The Court explained that the regulation presented the manufacturers with an unacceptable choice between defiance or submission:

> On the one hand they can, as the Government suggests, refuse to comply, continue to distribute products that they believe do not fall within the purview of the Act, and test the regulations by defending against government criminal, seizure, or injunctive suits against them. We agree with the respondents that this proposed avenue of review is beset with penalties and other impediments rendering it inadequate as a satisfactory alternative to the present declaratory judgment action.
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> * * *
>
> The price of noncompliance is not limited to these formal penalties. Respondents

> note the importance of public good will in their industry, and not without reason fear the disastrous impact of an announcement that their cosmetics have been seized as "adulterated."
>
> The alternative to challenging the regulations through noncompliance is, of course, to submit to the regulations and present the various ingredients embraced in them for premarketing clearance. We cannot say on this record that the burden of such a course is other than substantial, accepting, as we must on a motion to dismiss on the pleadings, the allegations of the complaint and supporting affidavits as true.

Id. at 172.

Similarly here, even though there has been no formal regulation, as in *Abbott* and *Gardner*, Plaintiffs face a similar "Hobson's choice" regarding its DMHA-containing dietary supplements that are in the marketplace, as well as any future products it makes that contain DMHA. They can continue marketing these products and risk incarceration under the bond condition imposed at the FDA's request, or lose millions of dollars by ceasing the sale of such products. All while the FDA refuses to review and analyze the information submitted by Plaintiffs' expert. Lastly, if the FDA's unilateral action stands, what is to prevent it from alleging an array of Hi-Tech's products are "adulterated" without proof, thus depriving Plaintiffs of resources needed to defend themselves in the unrelated criminal matter. The Court should reject Defendants' premise and conclusion regarding this issue.

II. PLAINTIFFS HAVE STATED A CLAIM UPON WHICH RELIEF CAN BE GRANTED.

A. Any Attempt by Plaintiffs to Pursue Their Administrative Remedies Would Be Futile.

The Court should reject Defendants' argument that Plaintiffs have failed to state a claim because they did not exhaust all of their administrative remedies before filing this action. Def. Br. at 20. As a legal matter, moreover, it makes no difference whether Plaintiffs were or were not able to pursue further administrative remedies. Given the FDA's stated position regarding

DMHA, any attempt by Hi-Tech to pursue its administrative remedies would be futile. In such a case, this Circuit has held that the exhaustion requirement will not preclude review. *Cutler v. Hayes*, 818 F.2d 879, 890-91 (D.C. Cir. 1987) ("The exhaustion requirement is not jurisdictional, however, but rather should be applied 'flexibly, with an eye toward its underlying purposes . . . . Since the doctrine is not linked to the power of the court to entertain actions, but instead implicates prudential considerations, the exhaustion requirement may be waived by the agency, or disregarded by the court when application of the doctrine would be futile.'").

Halbig v. Sebelius, No. 13-0623 (PLF), 2014 U.S. Dist. LEXIS 4853 (D.D.C. Jan. 15, 2014) is instructive regarding this issue. *Halbig* was a taxpayer challenge to IRS regulations implementing the premium tax credit provision of the Affordable Care Act where this Court waived the exhaustion requirement, finding that "[a]ny administrative challenge would be futile, as the Secretary of the Treasury can be expected to deny plaintiffs' complaint as contrary to the issued IRS regulations. Abstaining from a decision now would simply kick the can down the road until 2015, after the Secretary of the Treasury reaffirms the view he already has announced." *Id.* at *26. And in *Smoking Everywhere Inc. v. Food & Drug Admin.*, 680 F. Supp.2d 62 (D.D.C. 2010), which involved two electronic cigarette manufacturers' challenge to the FDA's decision to detain shipments of their electronic cigarettes, the district court agreed that, even though the shipments of one of the plaintiffs, NJOY, were detained without a "Refusal of Admission" notice, NJOY was not required to further resort to the administrative process, since to do so would be futile:

> Exhaustion does not apply where it "would be futile because of certainty of an adverse decision." *James v. U.S. Dep't of Health & Human Servs.*, 824 F.2d 1132, 1138, 263 U.S. App. D.C. 152 (D.C. Cir. 1987) (internal quotation marks and emphasis omitted). "Resort to administrative remedies is 'futile' and adverse action certain," if the agency "has evidenced a strong position on the issue together with an unwillingness to reconsider." *Id.* at 1139.

* * *

> Given FDA's refusal to allow entry of Smoking Everywhere's products, given its unwavering position in this litigation (even after passage of the Tobacco Act), and given the manner in which NJOY has marketed its electronic cigarettes, there is no reason to believe that FDA would treat NJOY's products any differently than Smoking Everywhere's products.

Id. at 68-69 n.7.

Given the FDA's refusal to date to even examine or review the scientific information submitted by Plaintiffs, it is beyond argument that the FDA will not change its stated position, making administrative proceedings futile.

B. Hi-Tech Has Stated a Claim Based on Well-Pleaded Factual Allegations That Must Be Assumed True for Purposes of This Motion.

Defendants' argument that Hi-Tech has failed to state a claim because it did not exhaust all of its administrative remedies again incorrectly focuses on the warning letter it sent Plaintiffs. Rather, this action seeks relief for a much broader problem, *i.e.*, the FDA's refusal to comply with the requirements of DSHEA and its unilateral decision to declare all DMHA-containing dietary supplements "adulterated" and "illegal" without satisfying its statutorily imposed burden of proof.

Defendants fault Plaintiffs' complaint for "attack[ing] a legal theory not asserted by FDA" as a basis for declaring Hi-Tech's DMHA-containing dietary supplements to be "adulterated." Def. Br. at 22. But that is the very purpose of Hi-Tech's complaint; the FDA is ignoring the statutory provisions it is required to follow.

Defendants assert that Plaintiffs' claims are misdirected because they are based on the requirements of 21 U.S.C. § 342(f)(1)(A) – the statutory provision setting forth the conditions that the FDA must prove in order to find that a dietary supplement is "adulterated." Instead,

Defendants assert that the FDA sent the DMHA warning letter because DMHA is an "unapproved food additive." Def. Br. at 16. It is that very position of the FDA which Plaintiffs challenge. Plaintiffs' products are dietary supplements; the Defendants' motion as well as the FDA's warning letter both concede as much. Section 342(f) sets forth the conditions for a finding that a "dietary supplement" is "adulterated." In addition, that section puts the burden of proof on the FDA to prove that those conditions are met, and further provides for *de novo* review by this Court, thus giving no deference to any determination made by the FDA. *See* 21 U.S.C. § 342(f)(1). That may be a difficult burden for the FDA to meet, but that is the burden that Congress imposed. The FDA cannot circumvent these requirements by simply declaring, without proof, that a dietary ingredient is an unapproved food additive. If the FDA intends to ban a dietary ingredient, it cannot ignore its statutory obligations merely because it is required to take a series of lengthy scientific and legal steps.

Defendants' assertion – made without any supporting citation – that it can effectively ban a dietary ingredient through enforcement proceedings using the statutory provisions governing "food additives" ignores the very definition of "food additives." That definition specifically excludes any dietary ingredient in, or intended for use in, a dietary supplement. *See* 21 U.S.C. § 321(s)(6). Assuming the truth of Plaintiffs' allegations that DMHA is an extract of the walnut tree that has been marketed in the United States since before October 15, 1994—which the Court must do on this motion to dismiss—the FDA's unilateral declaration of DMHA as an illegal food additive is arbitrary and capricious and in violation of the requirements of DSHEA, and its actions taken in reliance on that unlawful act are similarly in violation of the law. In other words, the entire basis for the FDA's campaign against DMHA must fall.

CONCLUSION

For the foregoing reasons, Plaintiffs Hi-Tech Pharmaceuticals, Inc., and Jared Wheat request that the Defendants' motion to dismiss be denied.

Respectfully submitted,

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