UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACEUTICALS, INC., and JARED WHEAT,

Plaintiffs,

v.

NORMAN E. SHARPLESS, M.D.
Acting Commissioner of Food and Drugs
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

UNITED STATES FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

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

and

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, D.C. 20201

Defendants.

Civil Action No. 19-1268

DEFENDANTS' MOTION TO DISMISS
AND MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT THEREOF

Pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure, Defendants U.S. Food and Drug Administration ("FDA" or the "Agency"), Acting Commissioner of Food and Drugs Norman E. Sharpless, U.S. Department of Health and Human Services ("HHS"), and Secretary of HHS Alex M. Azar II (collectively, "Defendants") move to dismiss the Complaint filed by Hi-Tech Pharmaceuticals ("Hi-Tech") and Jared Wheat (collectively, "Plaintiffs") for lack of subject-matter jurisdiction and failure to state a claim.

Plaintiffs sue to challenge an April 2019 FDA Warning Letter, which stated the Agency's view that Plaintiffs' dietary supplements containing a substance known as DMHA were adulterated. Plaintiffs disagree with the letter and, fearing a future enforcement action, seek pre-enforcement injunctive and declaratory relief. But as Plaintiffs themselves acknowledged in a separate court filing made just a few months before they filed the Complaint, FDA's Warning Letters are "informal and advisory" and merely "start a dialogue" between the manufacturer and FDA "about the legality of the subject product."[1] The D.C. Circuit already concluded that FDA's Warning Letters do not constitute final agency action under the Administrative Procedure Act ("APA") in *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 943-44 (D.C. Cir. 2012), a case that is fatal to Plaintiffs' challenges here. Plaintiffs also cannot bring a suit to enjoin future enforcement action because district courts lack jurisdiction to enjoin enforcement

[1] Defs. Jared Wheat & Hi-Tech's Reply Br. in Support of Mot. to Dismiss for Selective Pros., Dkt. No. 223 at 6, *United States v. Wheat*, No. 17-cr-229 (N.D. Ga.) (Jan. 11, 2019) (emphasis added) ("*United States v. Wheat* Reply Br.").

proceedings brought under the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act"). *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950).

For these reasons and as further explained below, Plaintiffs' allegations do not give rise to valid claims justiciable under the APA or the other authorities invoked in the Complaint. Plaintiffs' Complaint must be dismissed.

BACKGROUND

I. FDA's Authority to Regulate Foods, Including Dietary Supplements, and Food Additives

The FDCA authorizes FDA to regulate food, including dietary supplements. *See, e.g.*, 21 U.S.C. § 301 *et seq.* Under the Dietary Supplement Health and Education Act of 1994 ("DSHEA"),[2] which amended the FDCA, dietary supplements are generally deemed to be foods, with limited exceptions not relevant here. *See* 21 U.S.C. §§ 321(ff). A "dietary supplement" is a product other than tobacco that, in addition to other requirements, bears or contains one or more dietary ingredients. *See id.* § 321(ff). If a dietary supplement also contains an ingredient that meets the Act's definition of a "food additive," that dietary supplement is also regulated under the FDCA's food additive provisions.

With certain exceptions, a "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. § 321(s). A food additive generally "shall . . . be deemed to be unsafe" unless FDA has approved its use by regulation and its use conforms to such regulation. *See id.* § 348(a).[3] FDA can "regulate the use

[2] Pub. L. No. 103-417, 108 Stat. 4325 (1994).

[3] This provision was added to the FDCA by the Food Additive Amendments of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958), codified at 21 U.S.C. § 348, which authorized FDA to protect

of substances affecting food *without first determining that they are in fact dangerous*; the method is to require that such substances be established as safe before being used." *Natick Paperboard Corp. v. Weinberger*, 525 F.2d 1103, 1106 (1st Cir. 1975) (emphasis added); *see also United States v. Ewig Bros. Co.*, 502 F.2d 715, 721 (7th Cir. 1974). Dietary supplements that contain unsafe food additives are deemed to be adulterated. 21 U.S.C. § 342(a)(2)(C)(i).

DSHEA carved out an exemption from the FDCA's food additive definition for substances that meet the definition of a "dietary ingredient" in 21 U.S.C. § 321(ff)(1)(A)–(F).[4] *See* 21 U.S.C. § 321(s)(6). A dietary supplement is deemed to be adulterated if, among other things, it contains a "dietary ingredient" that (A) presents a significant or unreasonable risk of illness or injury under ordinary conditions of use, or (B) is a "new dietary ingredient" for which there is inadequate information to provide reasonable assurance that it does not present a significant or unreasonable risk of illness or injury. *Id*. § 342(f)(1). A "new dietary ingredient" is defined as a dietary ingredient not marketed in the United States before October 15, 1994. *Id.* § 350b(d). More specifically, a dietary supplement that contains a "new dietary ingredient" is deemed to be adulterated under 21 U.S.C. § 342(f) unless it either (1) 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

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the public from untested food ingredients. *See, e.g.*, *Ewig Bros.*, 502 F.2d at 721 & n.4 (7th Cir. 1974). The Amendments shifted the burden of proof to manufacturers, requiring that they prove the safety of food components *before* marketing foods containing such components. *See, e.g.*, *Fmali Herb, Inc. v. Heckler*, 715 F.2d 1385, 1391 (9th Cir. 1983); *Continental Chemiste Corp. v. Ruckelshaus*, 461 F.2d 331, 340-41 (7th Cir. 1972).

[4] A "dietary ingredient" is defined as a vitamin; mineral; herb or other botanical; amino acid; 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 of the preceding. 21 U.S.C. § 321(ff)(1).

suggested in the labeling of the dietary supplement will reasonably be expected to be safe, and at least 75 days before prior to distribution, the manufacturer or distributor provides FDA with the information that is the basis on which it has concluded that the dietary ingredient will reasonably be expected to be safe. *Id.* § 350b(a). DSHEA further provides that in any proceeding alleging adulteration under § 342(f), "the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated." *Id.* § 342(f)(1).

Congress provided FDA numerous enforcement authorities in the FDCA to protect the public health, while leaving the choice of enforcement method to FDA's discretion. FDA possesses a general authority to issue regulations for the efficient enforcement of the FDCA, which may be used to formally ban substances by rulemaking proceedings. 21 U.S.C. § 371(a). FDA may also seek to enforce the Act through individual adjudications. For example, FDA may initiate an *in rem* action to seize and forfeit violative products, such as adulterated or misbranded foods or dietary supplements, while in or after their shipment in interstate commerce, *see id.* § 334(a)(1), initiate an action to enjoin violations relating to adulterated and misbranded foods and dietary supplements, *see id.* § 332(a), and order the administrative detention of foods, including dietary supplements, found during an inspection when an FDA investigator has "reason to believe that such article[s are] adulterated or misbranded." *Id.* § 334(h)(1)(A). Contrary to Plaintiffs' contention, nothing in the FDCA or DSHEA requires FDA to conduct rulemaking to prohibit an ingredient in a dietary supplement before action can be taken against an adulterated dietary supplement.

II. FDA's Actions Pertaining to Plaintiffs' Products Containing DMHA

Hi-Tech is a Georgia-based manufacturer and distributer of various dietary supplements. *See* Compl. ¶ 6. Jared Wheat is its President and CEO. *Id.* ¶ 7. Around 2018, FDA investigators learned that Hi-Tech was manufacturing and holding numerous dietary supplements

and bulk raw materials containing an ingredient known as DMHA, 1,5-DMHA, 2-Aminiosoheptane HCl, and various other names.

On April 10, 2019, FDA issued a Warning Letter ("Warning Letter" or "WL") to Wheat and Hi-Tech, explaining that Hi-Tech's dietary supplements containing DMHA were adulterated under 21 U.S.C. § 342, because DMHA was either a new dietary ingredient requiring notification and history of use or other evidence of safety establishing that it will be reasonably expected to be safe when used as a dietary ingredient, or it was an unapproved food additive deemed to be unsafe under 21 U.S.C. § 348(a). Compl. Ex. 2. The Warning Letter further stated that Plaintiffs "should take prompt action to correct the violations in this letter," and if they did not, it "could result in enforcement action by FDA without further notice." *Id.* The Warning Letter requested a response within fifteen working days explaining the remedial actions taken, and further invited, "[i]f you believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration." *Id*. FDA also issued Warning Letters to several other manufacturers of dietary supplements containing DMHA on the same date. *See* Compl. Ex. 1.

Fifteen working days later, on May 1, 2019, Plaintiffs filed the instant action. On the same date, they emailed and sent via U.S. Postal Service a letter to the FDA Compliance Officer identified in the Warning Letter as the person to whom a response was to be sent, explaining that in lieu of formally responding to the Warning Letter, they instead were filing suit challenging it. Plaintiffs appended to their letter a copy of the Complaint and a report written by Dr. Marvin Heuer, Compl. Ex. 3, which sets forth the reasons Dr. Heuer believes DMHA to be a safe and lawful dietary ingredient.

FDA has not taken enforcement action against Plaintiffs' DMHA-containing products.

III. Plaintiffs' Complaint

Plaintiffs allege that FDA has violated the APA, DSHEA, and the Due Process Clause of the Fifth Amendment by "proceeding against DMHA containing products" without first going through formal rulemaking or following supposed statutory requirements of DSHEA for which the government bears the burden of proof. *See id.* ¶¶ 37-70. Plaintiffs seek broad declaratory and injunctive relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the APA, 5 U.S.C. § 706(2). They ask this Court to enjoin Defendants from (1) "claiming in any court that DMHA containing products are adulterated or misbranded"; and (2) "detaining or seizing DMHA containing products absent proper rule making proceedings." Compl. ¶¶ 38, 45, 58, 62, 70.

ARGUMENT

I. Legal Standard

To survive a motion to dismiss under Rule 12(b)(1), a plaintiff bears the burden of proving that a court has subject-matter jurisdiction to hear the claims. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); *U.S. Ecology, Inc. v. U.S. Dep't of Interior*, 231 F.3d 20, 24 (D.C. Cir. 2000).

While the Court may consider materials outside the pleadings in determining whether it has jurisdiction, it must accept as true all uncontroverted material factual allegations in the complaint and "construe the complaint liberally, granting plaintiff the benefit of all inferences that can be derived from the facts alleged." *Am. Nat'l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011); *Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1253 (D.C. Cir. 2005).

To survive a Rule 12(b)(6) motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570

(2007)). Although, again, the Court must construe factual allegations in the light most favorable to the plaintiff and grant the plaintiff all reasonable inferences based on those facts, a complaint may not rest upon mere conclusory allegations, unsupported inferences, legal conclusions, "[t]hreadbare recitals of the elements of a cause of action," or allegations that are "merely consistent with a defendant's liability." *Id.*; *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994).

II. Plaintiffs' Complaint Fails to State a Claim under the APA Due to Lack of Final Agency Action

The APA authorizes judicial review of "final agency action for which there is no other adequate remedy in a court," as well as "[a]gency action made reviewable by statute." 5 U.S.C. § 704. Without finality, a party's APA claims must be dismissed for failure to state a valid cause of action. *See Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 253 (D.C. Cir. 2014); *Reliable Automatic Sprinkler Co. v. CPSC*, 324 F.3d 726, 732 (D.C. Cir. 2003) (dismissing pre-enforcement challenge); *Holistic Candlers,* 664 F.3d at 944-45; *Lannett Co., Inc. v. FDA*, 300 F. Supp. 3d 34, 43 (D.D.C. 2017) (Walton, J.).

The D.C. Circuit has held that FDA Warning Letters — the very same type of letter as Plaintiffs challenge here — are *not* final agency action, and therefore cannot be challenged in court. *Holistic Candlers,* 664 F.3d at 944-45. It has consistently reaffirmed that holding in indistinguishable contexts. *See, e.g.*, *Soundboard Ass'n v. Fed. Trade Comm'n*, 888 F.3d 1261, 1267, 1269 (D.C. Cir. 2018), *cert. denied*, No. 18-722, 2019 WL 1590248 (U.S. Apr. 15, 2019); *Orton Motor, Inc. v. United States Dep't of Health & Human Servs.*, 884 F.3d 1205, 1215 (D.C. Cir. 2018); *Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023, 1028 (D.C. Cir. 2016). This binding precedent is fatal to Plaintiffs' case, and alone should result in dismissal of the Complaint. Nevertheless, we explain below why *Holistic Candlers'* holding applies here.

To be final, and thus to sustain a valid cause of action, a challenged agency action must meet two requirements: "First, the action must mark the consummation of the agency's decisionmaking 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." *U.S. Army Corps of Eng'rs v. Hawkes, Co. Inc.*, 136 S. Ct. 1807 (2016) (quoting *Bennett v. Spear*, 520 U.S. 154, 1813 (1997)); *see also Sabino Canyon Tours, Inc. v. USDA Forest Serv.*, 298 F. Supp. 3d 60, 67 (D.D.C. 2018). "Because each prong of *Bennett* must be satisfied independently for agency action to be final, deficiency in either is sufficient to deprive [Plaintiffs] of a cause of action under the APA." *Soundboard Ass'n*, 888 F.3d at 1267.

As explained below, the Warning Letter Plaintiffs challenge does not meet either *Bennett* prong.

A. The Warning Letter Does Not Mark the Consummation of the Agency's Decisionmaking Process

The D.C. Circuit has held that Warning Letters "plainly do not mark the consummation of FDA's decisionmaking." *Holistic Candlers*, 744 F.3d at 944. Citing FDA's *Regulatory Procedures Manual* ("RPM"), which describes FDA Warning Letters as "giving 'firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action,'" the Court held that Warning Letters are "'informal and advisory,'" "'communicat[ing] the agency's position on a matter.'" *Id*. (quoting RPM § 4-1-1, *available at* https://www.fda.gov/media/71878/download).

The D.C. Circuit has further explained that while FDA Warning Letters "'*may* lead to enforcement action'" if the cited violations are not corrected, they "'do[] not commit FDA to taking enforcement action.'" *Id*. Indeed, as the RPM explains, "[d]espite the significance of the

violations, there are some circumstances that may preclude the [A]gency from taking any further enforcement action following the issuance of a Warning Letter." RPM § 4-1-1. The RPM describes Warning Letters as "'the [A]gency's principal means of achieving prompt voluntary compliance with the [FDCA].'" *Holistic Candlers*, 744 F.3d at 944 (quoting RPM § 4-1-1). For these reasons, "FDA does not consider Warning Letters to be final agency action on which it can be sued." RPM § 4-1-1.

Although Plaintiffs are challenging here the Warning Letter issued to them regarding their DMHA-containing products, they fully understand the purpose of Warning Letters. Earlier this year, in a different action involving other dietary supplements Plaintiffs manufacture, they complained that FDA *did not* send them a Warning Letter before criminal FDCA charges were brought against them. Plaintiffs quoted the RPM and acknowledged that FDA's Warning Letters are "'informal and advisory' . . . [and] can serve to *start a dialogue* with the manufacturer or retailer about the legality of the subject product."[5] In that case, Plaintiffs claimed that because they were not sent a Warning Letter, they were "deprived . . . of an opportunity for dialogue" with FDA.

In line with this view, the RPM explains that if FDA receives a response to a Warning Letter, the response "will [be] evaluated." RPM § 4-1-8. Even if that response is deemed

[5] *United States v. Wheat* Reply Br., *supra* note 1, at 6 (quoting RPM § 4-1-1) (emphasis added). The Court may take judicial notice of this publicly-available court filing without converting Defendants' motion to one for summary judgment. *See Latson v. Holder*, 82 F. Supp. 3d 377, 382 (D.D.C. 2015) (Walton, J.); *Banks v. Inspired Teaching Sch.*, 243 F. Supp. 3d 1, 4 (D.D.C. 2017) (Walton, J.), *aff'd,* No. 17-7048, 2017 WL 4220006 (D.C. Cir. Aug. 1, 2017); *Mdewakanton Sioux Indians of Minnesota v. Zinke,* 264 F. Supp. 3d 116, 123 n.12 (D.D.C. 2017). We note that both counsel representing Plaintiffs in this case signed the Reply Brief filed in that criminal case.

inadequate, enforcement action is far from guaranteed.[6] In that event, FDA merely "*should* consider further administrative and/or regulatory actions," and before deciding to bring such an action, FDA can decide to issue a second Warning Letter or convene a regulatory meeting with the firm's management. RPM § 4-1-8.3 (emphasis added). As the RPM makes clear, initiating an enforcement action involves a significant amount of additional Agency deliberations and procedures. *See generally* RPM ch. 5 (Administrative Actions), *available at* https://www.fda.gov/media/77026/download & ch. 6 (Judicial Actions), *available at* https://www.fda.gov/media/71837/download. In concluding that FDA Warning Letters do not satisfy *Bennett*'s first prong, the D.C. Circuit has given great weight to the RPM's description of FDA's Warning Letters and their effect in the RPM. *See Holistic Candlers*, 644 F.3d at 944-45; *see also Soundboard Ass'n*, 866 F.3d at 1267, 1269) (citing *id*.) (discussing the RPM).

As in *Holistic Candlers*, the language of the Warning Letter issued to Hi-Tech is "consistent with the [RPM]'s description." It tells Plaintiffs they "*should* take prompt action to correct" the identified deviations, WL at 3, 644 F.3d at 944 (emphasis in original); states that failure to comply "*could* result in enforcement action," WL at 3 (emphasis added), *see* 644 F.3d at 944 ("*may* result"); and invites Plaintiffs to submit to FDA further information, including any reasons it believes its "products are not in violation of the Act," WL at 3, *see* 644 F.3d at 944 ("FDA will evaluate the information you submit"). Rather than responding to the Warning Letter with a scientific basis for why they believe FDA's initial determination was incorrect and permitting the Agency to review the materials, Plaintiffs appended the scientific report to this lawsuit. *See* Compl. Ex. 3.

[6] The converse is also true — the Warning Letter is "not a prerequisite" step the Agency must take before bringing an enforcement action. RPM § 4-1-1.

Also supporting a finding that the Warning Letter is not final agency action is the fact that its entire discussion proceeds in a tentative manner. The Warning Letter notes, "*we have questions* about whether DMHA" is a dietary ingredient, but "assume[s Plaintiffs] have a basis to conclude" it is: "*[i]f* [Plaintiffs] have a basis to conclude that DMHA is a 'dietary ingredient,' it *would* also be a 'new dietary ingredient' because "*[t]o the best of FDA's knowledge*, there is no information demonstrating" that it would meet certain statutory exemptions, and would be adulterated because "*[t]o the best of FDA's knowledge*, there is no history of use or other evidence of safety." *Id.* at 1-2 (emphases added). The Warning Letter reasons that *if* that analysis is incorrect, and "*[i]f* DMHA is not a dietary ingredient . . . dietary supplements containing DMHA *would be* adulterated . . . because they *would* contain an unsafe food additive." *Id.* at 3 (emphasis added). Such conditional language is the hallmark of "'the type of workaday advice letter that agencies prepare countless times per year in dealing with the regulated community.'" *Rhea Lana*, 824 F.3d at 1028.

As the Warning Letter makes clear on its face, it was not based on a complete administrative record. At this stage, FDA's Warning Letter statements regarding Plaintiffs' DMHA-containing productions are not "final and binding" on the Agency or Plaintiffs, but rather remain "tentative and interlocutory in nature," *Bennett*, 520 U.S. at 178. Plaintiffs acknowledged as much in *United States v. Wheat*, characterizing FDA's Warning Letters as "'informal and advisory'" communications that "start a dialogue" between the manufacturer and FDA "about the legality of the subject product."[7] Clearly, Plaintiffs cannot prevail here. Because the Warning Letter they received did not mark the consummation of FDA's decisionmaking, *Bennett*'s first necessary requirement for final agency action is not met. This alone is sufficient

[7] *United States v. Wheat* Reply Br., *supra* note 1, at 6 (quoting RPM § 4-1-1).

grounds for dismissal. *See Soundboard Ass'n*, 888 F.3d at 1271 (dismissal warranted based on failure to meet first *Bennett* prong).

B. The Warning Letter Sets No Rights, Obligations, or Legal Consequences

The Warning Letter also fails to meet *Bennett*'s second requirement, as it does not "represent a decision determining rights or obligations, or one from which legal consequences flow." *Holistic Candlers*, 644 F.3d at 944. Instead, it "communicates the agency's position on a matter," but "does not commit FDA to taking enforcement action." *Id*. (quoting RPM § 4-1-1). Nor does it impose any "legal consequences" on Plaintiffs. *See id*. ("In short, an FDA warning letter compels action by neither the recipient nor the agency."). Critically, FDA Warning Letters do not expose anyone to increased civil or criminal penalties, and they are neither necessary nor sufficient for an enforcement action (as Plaintiffs recognized in their *United States v. Wheat* brief). *See* RPM § 4-1-1. Without this, they cannot be final. *See Holistic Candlers*, 644 F.3d at 944; *cf. Sackett*, 132 S. Ct. at 1372 (agency "order" created exposure to double penalties in enforcement proceeding); *Hawkes*, 136 S. Ct. at 1814 ("negative" agency determinations "limit[ed] the potential liability a landowner faces" while "affirmative" determinations "deni[ed] . . . [a] safe harbor from administrative enforcement proceedings."); *Rhea Lana*, 824 F.3d at 1030 (agency letter created "exposure to willful-violation penalties" in civil proceeding).

Indeed, it is telling that the Complaint seeks broad injunctive relief relating to seizure actions and court proceedings, yet nowhere seeks the retraction, withdrawal, or invalidation of the Warning Letter. *See generally* Compl. That omission further underscores the fact that the Warning Letter carries no legal consequences for anyone, as retraction of the letter would put the parties in no different legal position than they currently hold. Accordingly, and as the D.C.

Circuit held in *Holistic Candlers*, FDA's Warning Letter to Plaintiffs does not satisfy either prong of the *Bennett* test and does not constitute final agency action.

C. Additional Circumstances Alleged in the Complaint Do Not Create Finality

Notwithstanding the straightforward application of law and fact foreclosing Plaintiffs' claim, the Complaint cites two other factual circumstances in an apparent attempt to manufacture finality. Neither suffices.

First, the Complaint takes issue with dietary supplement-related statements on certain FDA web pages as evidence of a further "tactic of removing dietary ingredients/supplements" like DMHA from the marketplace. Compl. ¶ 27. But the website about which the Complaint chiefly complains contains a Dietary Supplement Ingredient List that *does not include DMHA*, and accordingly, is immaterial to this case. *See id*. ¶¶ 27-28; *id* Ex. 3.[8] And the one web page that does reference the *DMHA* Warning Letters, *see id*. ¶ 29, *id*. Ex. 1, does just what the Warning Letter did; it warns the affected entities about FDA's view regarding DMHA. As in *Holistic Candlers*, the FDA web page statements here are "insufficient to transform advisory letters into final agency action." 644 F.3d at 945.[9]

Second, Plaintiff Wheat's fears of "the specter of incarceration" based on a criminal bond in another case in another jurisdiction cannot bootstrap FDA's Warning Letter into finality.

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[8] Similarly immaterial is the Complaint's discussion of FDA's regulation of another ingredient that is not the subject of this action, DMAA, *see* Compl. ¶¶ 24-26, though it was a case involving DMAA-containing products in which Plaintiffs once more complained they *did not* receive "the benefit of a warning letter" before action was initiated. Pls.' Mem. in Supp. of Mot. for S.J., *United States v. Undetermined quantities finished and in-process foods*, No. 1:13-cv-03675-WBH-JCF, at 42 n.12 (N.D. Ga. Dec. 30, 2016).

[9] And indeed, unlike in *Holistic Candlers*, here there is no further Agency representation in a regulatory meeting following a Warning Letter. *Cf. id.*

Compl. ¶ 32. As Mr. Wheat states, he is currently under a bond condition "that he not manufacture, distribute, or sell adulterated foods." Compl. ¶ 3.[10] He asserts that he "faces the very real threat that the [government] could move to revoke his bond based on nothing more than the FDA's [Warning Letter] assertion, without proof, that Hi-Tech's DMHA containing products are deemed adulterated." *Id*.

The first fault with this argument is that for Mr. Wheat's bond to be revoked: (1) the United States Attorney's Office for the Northern District of Georgia would need to file a motion for revocation; (2) there would be a hearing before a judicial officer; and (3) the judicial officer would need to find that there is "*clear and convincing evidence*" that Mr. Wheat violated the condition of release that he not distribute adulterated food, and that he either is likely to flee or pose a danger to others or "is unlikely to abide by any condition or combination of conditions of release." 18 U.S.C. § 3148(b) (emphasis added). Notwithstanding Mr. Wheat's fear, the government could not and would not seek revocation of his bond, nor could or would a court grant it, based on an FDA Warning Letter. This is because, as explained *supra*, Warning Letters are "informal and advisory" and determine no legal consequences. In other words, even if the government sought to revoke Mr. Wheat's bond, the government would still need to prove, using

[10] As the Complaint references, and we have noted previously, Plaintiff Wheat is a defendant in a criminal case relating to his/Hi-Tech's distribution of other dietary supplements (*i.e.,* products not mentioned in FDA's Warning Letter at issue here). He has been charged with eighteen counts including wire fraud, money laundering, conspiracy to introduce and introduction of misbranded drugs in interstate commerce, and violations of the Controlled Substances Act. *United States v. Wheat*, No. 17-cr-229 (N.D. Ga.). Wheat was arrested and the court set bond in October 2017, which included the FDCA-related conditions mentioned above, and a more general standard provision that Mr. Wheat "must not violate federal, state, or local law while on release." *See id*. Dkt. No. 22 (Oct. 4, 2017). Mr. Wheat signed and agreed to those provisions. That case remains ongoing.

admissible evidence, that the dietary supplements Mr. Wheat shipped were adulterated. The Warning Letter at issue would certainly not suffice to accomplish that task.[11]

Defendants also note that Mr. Wheat's pending criminal case and bond conditions in the Northern District of Georgia are problems of Mr. Wheat's own making that do not and cannot alter this Court's lack of subject-matter jurisdiction over the instant, unrelated issue.

Although a court must accept a plaintiff's alleged facts as true on a motion to dismiss, it need not accept his implausible inferences, unsupported conclusory allegations, or legal conclusions. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). In short, Plaintiff Wheat's fears surrounding the Warning Letter he received cannot be enough to imbue it with "legal consequences" out of whole cloth. The existence of the separate criminal proceeding changes nothing, and in no way transforms FDA's Warning Letter into final agency action**.**

III. Plaintiffs' Complaint Should Be Dismissed for Lack of Jurisdiction

A. The Complaint Is an Impermissible Attempt to Enjoin an FDA Enforcement Action

Hi-Tech asks this Court to broadly enjoin FDA from taking enforcement action against DMHA, including from "detaining or seizing DMHA containing products" and "claiming in any court that DMHA containing products are adulterated or misbranded." Compl. ¶¶ 38, 45, 58, 62, 70. Granting the requested relief would prevent the government from enforcing the FDCA against Hi-Tech or its products in an administrative detention or civil seizure action pursuant to 21 U.S.C. § 334, or in any other civil or criminal enforcement action under the FDCA. *See* 21 U.S.C. §§ 332-33. Hi-Tech thereby attempts to short-circuit the litigation process and seek *pre-*

[11] *See Caudill Seed & Warehouse Co., Inc. v. Jarrow Formulas, Inc.*, No. 3:13CV-82-CRS, 2017 WL 4364204, at *11-12 (W.D. Ky. Sept. 29, 2017) (Warning Letter was "informal and advisory" and "not a final statement of an agency as to legality," and accordingly could not have "preclusive force" establishing a violation on summary judgment.).

enforcement review as to whether FDA may proceed against Hi-Tech or its dietary supplements containing DMHA.

The law is well-settled that district courts lack jurisdiction to enjoin enforcement proceedings brought pursuant to the FDCA. *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950). *Ewing* held that district courts do not have jurisdiction to review FDA's pre-filing determination that there is probable cause to believe that a product violates the FDCA. *Id*. at 600-01. This is because Congress, in enacting the FDCA, did not intend to permit pre-enforcement judicial review. *See id.* Rather, parties subject to an enforcement action must raise any defenses—constitutional, statutory, or factual—in the seizure action itself. *Id.* at 598–99.

Ewing's proscription against pre-enforcement challenges to FDA seizure actions has been reaffirmed by the Supreme Court and consistently applied by the lower courts to prevent such challenges to FDCA enforcement actions generally. *See, e.g.*, *Abbott Labs. v. Gardner*, 387 U.S. 136, 147–48 (1967) (*Ewing* was "quite clearly correct" because to have ruled otherwise, "would have prevented the regular operation of the seizure procedures established by the [FDCA]"), *abrogated on other grounds*, *Califano v. Sanders*, 430 U.S. 99, 105 (1977); *United States v. Alcon Labs.*, 636 F.2d 876, 881–82 (1st Cir. 1981) ("*Ewing* precludes judicial interference with the FDA's decision to institute enforcement actions, *whatever the precise context*.") (emphasis added); *Southeastern Minerals, Inc. v. Harris*, 622 F.2d 758, 764 n.10 (5th Cir. 1980); *Premo Pharm. Labs., Inc. v. United States*, 629 F.2d 795, 801 (2d Cir. 1980); *Genendo Pharm. v. Thompson*, 308 F. Supp. 2d 881, 882–83 (N.D. Ill. 2003); *see also Rapsomanikis v. U.S. Dep't of Health & Human Servs.*, 990 F.2d 1259 (Table), 1993 WL 61371, at *2 (9th Cir. 1993) (FDA's administrative detention determination not reviewable under *Ewing*). And under nearly identical facts to those here, this Court dismissed the *Holistic Candlers* complaint under *Ewing*'s

jurisdictional bar, which was affirmed by the D.C. Circuit on the APA grounds discussed above. *See Holistic Candlers & Consumer Ass'n v. FDA*, 770 F. Supp. 2d 156, 162–63 (D.D.C. 2011) (Leon, J.), *aff'd on other grounds*, 664 F.3d 940 (D.C. Cir.). As Judge Leon ruled, the court lacked jurisdiction to "review requests for injunctive or declaratory relief preventing the FDA from bringing enforcement actions against plaintiffs." *Id.* at 163.

Under *Ewing* and its progeny, this Court lacks jurisdiction to enjoin FDA from initiating seizures, administrative detentions, or other enforcement actions under the FDCA against Plaintiffs or their products containing DMHA. Rather, as these cases make clear, Plaintiffs must raise any challenges within an enforcement action itself, if any. Therefore, the Complaint should be dismissed for want of jurisdiction.

B. Plaintiffs' Claims Are Unripe

A claim "is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation marks and citation omitted). "[I]njunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these arise in the context of a controversy 'ripe' for judicial resolution." *Abbott Labs.*, 387 U.S. at 148. The doctrine serves "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Id.* at 148-49. To determine whether a dispute is ripe, a reviewing court must "evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.*

As the *Holistic Candlers* court held, an issue "is not fit [for judicial decision] if it does not involve final agency action." 644 F.3d at 943 n.4. Nor will withholding judicial review now cause Plaintiffs the requisite hardship. "In order to outweigh institutional interests in the deferral of review, the hardship to those affected by the agency's action must be immediate and significant." *Devia v. NRC*, 492 F.3d 421, 427-28 (D.C. Cir. 2007) (citation omitted). Here, however, FDA has merely warned Plaintiffs that failure to take corrective action "may" result in regulatory action. *Cf. Estee Lauder, Inc. v. FDA*, 727 F. Supp. 1, 5 (D.D.C. 1989) (regulatory letter warning that FDA was "prepared" to take regulatory action imposed hardship "no greater than any company confronted by an interpretation of a law it dislikes"). Plaintiffs have not been harmed by the Warning Letter, which requested voluntary compliance, and they will suffer no hardship if judicial review is postponed until FDA takes concrete action against their products, if it does at all. So too with Mr. Wheat's concern about his criminal case; as explained above, the Warning Letter alone cannot subject him to incarceration.

To be sure, entities who receive Warning Letters court the risk of enforcement if they fail to heed FDA's warnings, but Plaintiffs cannot *now* challenge any enforcement action that FDA *may* take in the future. It takes little imagination to foresee the effect on court dockets if every person who feared an enforcement action could gain access to the courts to preempt it:

> The FDA . . . has a strong institutional interest in having this Court withhold its review. The Administration issues approximately 450 regulatory letters[12] and numerous opinion letters each year. If FDA were subject to suit each time it warned a company that its product violated the Act, the Administration would be inhibited from performing a valuable public service – the issuing of informal advisory opinions.

[12] The number of Warning Letters issued yearly by FDA has increased significantly since the *Estee Lauder* case in 1989. For example, FDA reported issuing 17,232 Warning Letters in 2015. *See Orton Motor Co. d/b/a Orton's Bagley*, 2016 WL 4076361 at *21, n.16 (H.H.S. Jun. 30, 2016).

Id. at 5.

Only if or when FDA brings a specific enforcement action will review be appropriate, because only in the context of a specific action will FDA have gathered the necessary evidence, analyzed the relevant facts, made the requisite administrative determinations, and created the administrative record, to permit meaningful judicial review. In the absence of an actual enforcement action, Plaintiffs' claims of any hardship "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas*, 523 U.S. at 300. For these reasons, Plaintiffs' claims are not ripe for review.

IV. Plaintiffs' Complaint Should Be Dismissed for Failure to Exhaust Administrative Remedies

It is well-established that a plaintiff generally must exhaust administrative remedies before proceeding to federal court. *See Bowen v. New York*, 476 U.S. 467, 484 (1986); *Ass'n of Flight Attendants-CWA v. Chao*, 493 F.3d 155, 160 (D.C. Cir. 2007). Here, Plaintiffs have made no attempt to avail themselves of, much less exhaust, the administrative remedies available to them. Plaintiffs failed to present to FDA outside of litigation the evidence they attach to their Complaint, which they believe supports their views on DMHA's history and safety. Instead, Plaintiffs seek to circumvent FDA's processes by asking this Court to rule definitively on DMHA's regulatory status based on that evidence.

In addition, an agency action is "final for the purposes of [the APA]" only after a plaintiff "has exhausted all administrative remedies expressly prescribed by statute or agency rule." *Darby v. Cisneros*, 509 U.S. 137, 146 (1993) (quotation marks omitted). Plaintiffs could have, but did not, file a citizen petition with FDA pursuant to 21 C.F.R. §§ 10.25 and 10.30. FDA regulations require that "before any legal action is filed in a court," a party must first use the citizen petition process to "request that the Commissioner take or refrain from taking any form of

administrative action." *Id.* § 10.45(b). Through this process, Plaintiffs could have properly raised before the Agency the issues that they now seek to raise to this Court: whether DMHA is a dietary ingredient, whether it is a new dietary ingredient, and whether there are reasonable assurances of DMHA's safety. FDA's response to a citizen petition would constitute final agency action. *Id.* § 10.45(d).

Allowing Plaintiffs to bypass the available administrative process also would frustrate meaningful and efficient judicial review. Requiring Plaintiffs to present their views on DMHA and raise potentially complex regulatory issues with the Agency before seeking judicial recourse would allow FDA to consider and address Plaintiffs' concerns and could potentially resolve the issues. At the very least, the administrative process might crystalize the issues in contention. *See Parisi v. Davidson*, 405 U.S. 34, 37 (1972) ("The basic purpose of the exhaustion doctrine is to allow an administrative agency to perform functions within its special competence — to make a factual record, to apply its expertise, and to correct its own errors so as to moot judicial controversies."); *Lannett Co.*, 300 F. Supp. 3d at 45 ("[e]xhaustion gives an agency 'an opportunity to correct its own mistakes with respect to the programs it administers before it is haled into federal court,' and it discourages 'disregard of [the agency's] procedures.'") (quoting *Woodford v. Ngo*, 548 U.S. 81, 88-89 (2006)) (marks in original)..

Because Plaintiffs have failed to avail themselves of the administrative process, dismissal of their action is appropriate for this reason as well. "By failing to challenge the Warning Letters through a citizen petition, *see* 21 C.F.R. § 10.25, plaintiffs preclude, as a matter of law, judicial review of their claims." *Holistic Candlers*, 770 F. Supp. 2d at 163; *see also Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 22 (D.D.C. 2008) (dismissing APA and constitutional claims under Rule 12(b)(6) where the plaintiffs neglected to file a citizen petition

as "mandated" by §§ 10.25 and 10.45), *aff'd*, 358 Fed. App'x 179, 181 (appellants failed to exhaust their administrative remedies where they "filed no such citizen petition with FDA"); *Estee Lauder*, 727 F. Supp. at 7 (holding Plaintiff failed to exhaust remedies before challenging FDA regulatory letter, finding an improper attempt "to circumvent the administrative process").

V. The Complaint Otherwise Fails to State a Claim

A. The Complaint Is Based on Misunderstandings of the FDCA and DSHEA

The Complaint also must be dismissed under Rule 12(b)(6) because it rests on a fundamental misunderstanding of DSHEA's statutory framework and FDA's enforcement authorities under the FDCA.

Plaintiffs claim, without citing any authority, that DSHEA requires FDA to undertake rulemaking to ban DMHA before the Agency may initiate enforcement action against Hi-Tech or its products. *See, e.g.*, Compl. ¶¶ 4, 38. In fact, no such requirement exists in the FDCA or DSHEA. *See generally, e.g.*, §§ 331, 332, 334, 342(f), 350b; *see also SEC v. Chenery*, 332 U.S. 194, 201-02 (1947). In addition, Plaintiffs claim that FDA has not met its DSHEA "burden of proof" in asserting in the Warning Letter that Plaintiffs' DMHA-containing dietary supplements are adulterated. *See, e.g.*, Compl. ¶¶ 15, 46-54, 64-68. There are at least three different reasons this claim is legally baseless.

First, DSHEA's provisions describing the government's burden apply *in a proceeding* under 21 U.S.C § 342(f)(1). *See id.* § 342(f)(1) ("[i]n any *proceeding under this subparagraph*, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated.") (emphasis added); Compl. ¶ 15. Because no such "proceeding" exists at this time, it is impossible for FDA to have acted contrary to such burden. Indeed, as explained above, FDA's Warning Letter reflects that it has not made a final decision regarding Plaintiffs' DMHA-containing dietary supplements.

Second, Plaintiffs argue more specifically that FDA has not met its "burden" of establishing adulteration under a particular DSHEA provision, § 342(f)(1)(A), that FDA has never asserted — not in the Warning Letter or anywhere. The Complaint charges that FDA has not shown that DMHA-containing products present a "significant or unreasonable risk of illness or injury" under § 342(f)(1)(A). *See, e.g.*, Compl. ¶¶ 13, 47, 53, 64-67. But FDA has never said that Plaintiffs' DMHA-containing dietary supplements are adulterated under this provision. Instead, the Warning Letter asserts that if DMHA is a dietary ingredient, Plaintiffs' dietary supplements would be adulterated under § 350b(a) and § 342(f), because DMHA appears to be a "new dietary ingredient" for which Hi-Tech has not submitted a new dietary ingredient notification as required, and even if it had submitted such notification, for which there is not adequate evidence of safety. *See* WL at 1-2. A dietary supplement that contains a new dietary ingredient for which a notification is required under 21 U.S.C. § 350b(a)(2) but has not been submitted "shall be deemed adulterated" under 21 U.S.C. § 342(f)(1)(B). And a dietary supplement that contains "a new dietary ingredient for which there is *inadequate information to provide reasonable assurance* that such ingredient does not present a significant or unreasonable risk of illness or injury" is also deemed to be adulterated under 21 U.S.C. § 342(f)(1)(B) (emphasis added). Plaintiffs' focus on § 342(f)(1)(A) is completely misplaced.

Third, DSHEA's provision relating to the government's burden, § 342(f), applies to dietary ingredients but not to food additives, for which a manufacturer bears the burden of demonstrating safety to FDA. *See supra* p. 3–4. Unlike a dietary ingredient, a food additive generally "shall . . . be deemed to be unsafe" unless FDA has approved its use by regulation and its use conforms to such regulation. *See* 21 U.S.C. § 348(a). As described above, FDA's Warning Letter states that DMHA might be a food additive and not a dietary ingredient and, if

so, the dietary supplements containing DMHA at issue are adulterated under 21 U.S.C. § 342(a)(2)(C)(i). *See* WL at 3-4. To the extent that DMHA is a food additive, the DSHEA provision on which Plaintiffs base their entire Complaint, § 342(f) and its subparagraphs, are entirely inapplicable.

In sum, Plaintiffs' theories about DSHEA's requirements are unrelated to the statements made in the Warning Letter about dietary supplements containing DMHA, are at odds with the language of the statute itself, and cannot provide a viable claim for relief under Rule 12(b)(6).

B. Plaintiffs' Claims Under the Fifth Amendment and for Declaratory Relief Must Be Dismissed

To the extent Plaintiffs assert a standalone Fifth Amendment claim, in addition to the reasons above, it must be dismissed under Rule 12(b)(6) because Plaintiffs cannot "show that the mere issuance of a warning letter, absent further enforcement action, effects any such deprivation" of life, liberty, or property. *Orton Motor*, 884 F.3d at 1215-16. And were any enforcement action instituted in the future, plaintiffs would be afforded a meaningful opportunity to be heard at that time. *See id.*; *supra* p. 4.

Plaintiffs' invocation of the Declaratory Judgment Act, Compl. ¶¶ 5, 37-38, is likewise unavailing. Because, as explained above, Plaintiffs have no valid cause of action under the APA, they cannot state a claim under the Declaratory Judgment Act, 28 U.S.C. § 2201, over which this Court has jurisdiction. The Declaratory Judgment Act "does not provide a cause of action" and "'is not an independent source of federal jurisdiction.' Rather, 'the availability of [declaratory] relief presupposes the existence of a judicially remediable right.'" *Ali v. Rumsfeld*, 649 F.3d 762, 778 (D.C. Cir. 2011) (internal quotations omitted). Where a plaintiff has otherwise failed to state a claim (including under the APA), he is left without "any cause of action through which the Court may exercise subject matter jurisdiction" and accordingly cannot bring a standalone action

under the Declaratory Judgment Act. *Perrigo Research & Dev. Co. v. FDA*, 290 F. Supp. 3d 51, 63–64 (D.D.C. 2017) (citing *Rumsfeld*, 649 F.3d at 778).

The Complaint should be dismissed in its entirety,[13] including its claims under the Declaratory Judgment Act.

CONCLUSION

For all of the foregoing reasons, this Court should grant Defendants' Motion to Dismiss Plaintiffs' Complaint.

Dated: July 29, 2019

Respectfully submitted,

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[13] To the extent Plaintiffs seek an order enjoining the Defendants here — FDA, Acting Commissioner of Food and Drugs Sharpless, HHS, and HHS Secretary Azar — from "claiming *in any court* that DMHA containing products are adulterated or misbranded," Compl. ¶¶ 38, 45, 58, 62, 70 (emphasis added), they have also not named a proper defendant. This is because FDA enforcement actions are brought by and in the name of the United States, *see* 21 U.S.C. § 337(a), not in the name of HHS or FDA. In other words, the Department of Justice, and not the Defendants in this case, makes "claim[s] in . . . court." Although FDA can administratively detain foods, those actions are not brought in federal court, such actions are time-limited (no longer than 30 days), and any party that could be a claimant if such articles were judicially seized may appeal the detention and request an administrative hearing. *See* 21 U.S.C. § 334(h); 21 C.F.R. §§ 1.378-1.405.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACEUTICALS, INC., and JARED WHEAT,

Plaintiffs,

v.

NORMAN E. SHARPLESS, M.D., UNITED STATES FOOD AND DRUG ADMINISTRATION, ALEX M. AZAR II, and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants.

Civil Action No. 19-1268

PROPOSED ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Upon due consideration of the defendants' motion to dismiss and the parties' filings related to the motion, this Court has determined that the motion is hereby GRANTED and this action is dismissed with prejudice.

Dated: _____, 2019

_____

United States District Judge

LOCAL RULE 7(k) CERTIFICATION:
Names of Persons to Be Served with Proposed Order

Pursuant to LCvR 7(k), the following attorneys are entitled to be notified of the entry of the foregoing Stipulated Order:

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