UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACEUTICALS, INC., et al.,	)	
Plaintiffs,	)	Civil Action No. 19-1268 (RBW)
v.	)	
STEPHEN HAHN, M.D., in his official capacity as Commissioner of the United States Food and Drug Administration, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

The plaintiffs, Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") and Jared Wheat, President and Chief Operating Officer of Hi-Tech, bring this civil action against the defendants, the United States Food and Drug Administration ("FDA"), Stephen Hahn, in his official capacity as the Commissioner of the FDA, the United States Department of Health and Human Services (the "Department"), and Alex Azar, in his official capacity as the Secretary of the Department, for declaratory and injunctive relief pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706 (2018), the Declaratory Judgment Act, 28 U.S.C. § 2201 (2018), and the Fifth Amendment of the United States Constitution, U.S. Const. amend. V. See Complaint for Declaratory Judgment and Injunctive Relief ("Compl.") ¶ 4. Currently pending before the Court is the Defendants' Motion to Dismiss and Memorandum of Points and Authorities in Support Thereof ("Defs.' Mot."). Upon careful consideration of the parties' submissions,[1] the Court concludes for the following reasons that it must grant the defendants' motion.

[1] In addition to the filings already identified, the Court considered the following submissions in rendering its decision: (1) the Memorandum of Law by Plaintiffs Hi-Tech Pharmaceuticals, Inc., and Jared Wheat in Opposition (continued . . .)

I. BACKGROUND

Hi-Tech is a manufacturer and distributor of dietary supplements. See Compl. ¶ 6. Several of the Hi-Tech's supplements contain 2-Aminoisopheptane HCl ("DMHA"), a dietary supplement ingredient. See id. ¶ 1.[2]

On April 10, 2019, the FDA issued a warning letter to Hi-Tech ("FDA Warning Letter") regarding Hi-Tech's products that contain DMHA. See Compl., Exhibit ("Ex.") 2 (Warning Letter (Apr. 10, 2019) ("FDA Warning Letter")) at 1. The FDA Warning Letter stated that

> [u]nder the [Federal Food, Drug, and Cosmetic Act (the "Act")], a dietary supplement that contains a new dietary ingredient shall be deemed adulterated . . . unless it meets one of two requirements: (1) [t]he 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) [t]here 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 [the] 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 [the "notification requirement")].

Id., Ex. 1 (FDA Warning Letter) at 1–2. The FDA Warning Letter further stated that "[g]iven that Hi-Tech ha[s] declared DMHA as a dietary ingredient in the labeling of [its] product, [the FDA] assumes [that] [Hi-Tech] ha[s] a basis to conclude that DMHA is a 'dietary ingredient' under . . . the Act[,] and that "[i]f [Hi-Tech] ha[s] 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

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(. . . continued)
to Defendants' Motion to Dismiss the Complaint Pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) ("Pls.' Opp'n"); and (2) the Reply Memorandum in Support of Defendants' Motion to Dismiss ("Defs.' Reply").

[2] DMHA is also known as 1,5 DMHA, 2-amino-6-methylheptane, 2-amino-5-methylheptane, 1,5-Dimethylhexylamine, 2-Isooctyl amine, and Octodrine. See Compl. ¶ 1.

the United States before October 15, 1994) under . . . the Act[.]" Id., Ex. 1 (FDA Warning Letter) at 1. The FDA informed Hi-Tech that

> [t]o the best of [the] 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 . . . . [And,] [e]ven if a new dietary ingredient notification had been submitted . . . , [i]n 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 . . . 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 . . . . To the best of [the] 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.

Id., Ex. 1 (FDA Warning Letter) at 2. The FDA also noted that

> [it] ha[s] questions about whether DMHA is, in fact, a dietary ingredient. If DMHA were not a dietary ingredient . . . , it would be an unsafe food additive. . . . 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 . . . . Adulterated foods cannot be legally imported or marketed in the United States.

Id., Ex. 1 (FDA Warning Letter) at 2. The FDA stated that Hi-Tech "should take prompt action to correct the violations addressed in [its] letter," and that "[f]ailure to immediately cease distribution of [its] products . . . could result in enforcement action by [the] FDA without further notice." Id., Ex. 1 (FDA Warning Letter) at 3. According to the FDA, the Act "provide[s] for seizure of violative products and injunction against the manufacturers and distributors of violative products." Id., Ex. 1 (FDA Warning Letter) at 3. The FDA requested that Hi-Tech, "[w]ithin fifteen working days of receipt of this letter, [ ] notify [the FDA's Office of Compliance] in writing of the specific steps that [Hi-Tech] ha[s] taken to correct these

violations," and that "[i]f [Hi-Tech] believe[s] that [its] products are not in violation of the Act, [to] include [in its response] [its] reasoning and any supporting information for [the FDA's] consideration." Id., Ex. 1 (FDA Warning Letter) at 3.

On May 1, 2019, the plaintiffs filed their Complaint in this case. See Compl. at 1. Thereafter, the defendants filed their motion to dismiss, which is the subject of this Memorandum Opinion.

II. STANDARDS OF REVIEW

A. Rule 12(b)(1) Motion to Dismiss

Federal district courts are courts of limited jurisdiction, Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994), and therefore, "[a] motion for dismissal under [Federal Rule of Civil Procedure] 12(b)(1) 'presents a threshold challenge to the [C]ourt's jurisdiction[.]'" Morrow v. United States, 723 F. Supp. 2d 71, 75 (D.D.C. 2010) (Walton, J.) (quoting Haase v. Sessions, 835 F.2d 902, 906 (D.C. Cir. 1987)). Thus, the Court is obligated to dismiss a claim if it "lack[s] [ ] subject matter jurisdiction[.]" Fed. R. Civ. P. 12(b)(1). And, because "it is to be presumed that a cause lies outside [ ] [the Court's] limited jurisdiction," Kokkonen, 511 U.S. at 377, the plaintiff bears the burden of establishing by a preponderance of the evidence that a district court has subject matter jurisdiction, see Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992).

In deciding a motion to dismiss based upon lack of subject matter jurisdiction, the Court "need not limit itself to the allegations of the complaint." Grand Lodge of the Fraternal Order of Police v. Ashcroft, 185 F. Supp. 2d 9, 14 (D.D.C. 2001). Rather, the "[C]ourt may consider such materials outside the pleadings as it deems appropriate to resolve the question [of] whether it has jurisdiction to hear the case." Scolaro v. D.C. Bd. of Elections & Ethics, 104 F. Supp. 2d 18, 22

(D.D.C. 2000); see also Jerome Stevens Pharms., Inc. v. Food & Drug Admin., 402 F.3d 1249, 1253 (D.C. Cir. 2005). Additionally, the Court must "assume the truth of all material factual allegations in the complaint and 'construe the complaint liberally, granting [the] plaintiff the benefit of all inferences that can be derived from the facts alleged[.]'" Am. Nat'l Ins. Co. v. Fed. Deposit Ins. Corp., 642 F.3d 1137, 1139 (D.C. Cir. 2011) (quoting Thomas v. Principi, 394 F.3d 970, 972 (D.C. Cir. 2005)). However, "the [p]laintiff's factual allegations in the complaint . . . will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim." Grand Lodge, 185 F. Supp. 2d at 13–14 (alterations in original) (citation and internal quotation marks omitted).

B. Rule 12(b)(6) Motion to Dismiss

A Rule 12(b)(6) motion tests whether a complaint "state[s] a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss [under Rule 12(b)(6)], 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)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw [a] reasonable inference that the defendant is liable for the misconduct alleged." Id. (citing Twombly, 550 U.S. at 556).

In evaluating a motion to dismiss under Rule 12(b)(6), "the Court must construe the complaint in favor of the plaintiff, who must be granted the benefit of all inferences that can be derived from the facts alleged." Hettinga v. United States, 677 F.3d 471, 476 (D.C. Cir. 2012) (internal quotation marks omitted). While the Court must "assume [the] veracity" of any "well-pleaded factual allegations" in a complaint, conclusory allegations "are not entitled to the assumption of truth." Iqbal, 556 U.S. at 679. Thus, "[t]hreadbare recitals of the elements of a

cause of action, supported by mere conclusory statements, do not suffice." Id. at 678 (citing Twombly, 550 U.S. at 555). Also, the Court need not accept "legal conclusions cast as factual allegations," or "inferences drawn by [the] plaintiff if those inferences are not supported by the facts set out in the complaint." Hettinga, 677 F.3d at 476. The Court "may consider only the facts alleged in the complaint, any documents either attached to or incorporated in the complaint[,] and matters of which [the Court] may take judicial notice." Equal Empl't Opportunity Comm'n v. St. Francis Xavier Parochial Sch., 117 F.3d 621, 624 (D.C. Cir. 1997).

III. ANALYSIS

The defendants argue that the Complaint should be dismissed for lack of subject matter jurisdiction because the "[p]laintiffs' claims are unripe," Defs.' Mot. at 18 (capitalization removed); see also id. at 16, and for failure to state a claim because there is no final agency action, see id. at 8–16.[3] In response, the plaintiffs claim that "the circumstances surrounding [the] plaintiffs' bail conditions render [the] defendants' actions ripe for review." Pls.' Opp'n at 10.

The ripeness doctrine, which "generally deals with when a federal court can or should decide a case," Am. Petroleum Inst. v. Envtl. Prot. Agency, 683 F.3d 382, 386 (D.C. Cir. 2012), is "designed '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,'" Chlorine Inst., Inc. v. Fed. R.R.

[3] The defendants also argue that the Complaint should be dismissed because (1) the plaintiffs are "attempt[ing] to enjoin an FDA enforcement action," Defs.' Mot. at 16, (2) the plaintiffs have "fail[ed] to exhaust [their] administrative remedies," id. at 20 (capitalization removed), and (3) it "is based on misunderstandings of the [Act.]" Defs.' Mot. at 22. However, the Court need not address these arguments because the issue of whether the plaintiffs' claims are ripe for review due to a lack of final agency action is dispositive.

Admin., 718 F.3d 922, 927 (D.C. Cir. 2013) (quoting Nat'l Park Hosp. Ass'n v. U.S. Dep't of Interior, 538 U.S. 803, 807–08 (2003)). "Determining whether administrative action is ripe for judicial review requires [courts] to evaluate (1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration." Nat'l Park Hosp. Ass'n, 527 U.S. at 808. "To do so . . . , [the Court] must consider: (1) whether delayed review would cause hardship to the plaintiffs; (2) whether judicial intervention would inappropriately interfere with further administrative action; and (3) whether the courts would benefit from further factual development of the issues presented." Ohio Forestry Ass'n v. Sierra Club, 523 U.S. 726, 733 (1998). "Although both the fitness and hardship prongs encompass a number of considerations, a dispute is not ripe if it is not fit, and (at least in an APA case) it is not fit if it does not involve final agency action." Holistic Candlers & Consumers Ass'n v. Food & Drug Admin., 664 F.3d 940, 946 n.4 (D.C. Cir. 2012).

It is well established that "a court may not review a non-final agency action." Conservation Force v. Salazar, 919 F. Supp. 2d 85, 89 (D.D.C. 2013); see also Holistic Candlers, 664 F.3d at 943 ("The APA . . . only provides a right to judicial review of 'final agency action for which there is no other adequate remedy in a court.'" (quoting 5 U.S.C. § 704)). "An agency action is final if it '1) marks the consummation of the agency's decision[-]making process' and 2) affects the 'rights or obligations . . . [or the] legal consequences' of the party seeking review." Conservation Force, 919 F. Supp. 2d at 89 (third alteration in original) (quoting Bennett v. Spear, 520 U.S. 154, 177–78 (1997)). "[T]he finality requirement is concerned with whether the initial decisionmaker has arrived at a definitive position on the issue that inflicts an actual, concrete injury[.]" Darby v. Cisneros, 509 U.S. 137, 144 (1993) (first alteration in original) (quoting Williamson Cty. Reg'l Planning Comm'n v. Hamilton Bank of Johnson City, 473 U.S. 172, 193

(1985)). "Agency action is considered final to the extent that it imposes an obligation, denies a right, or fixes some legal relationship." Reliable Automatic Sprinkler Co., Inc. v. Consumer Prod. Safety Comm'n, 324 F.3d 726, 731 (D.C. Cir. 2003) (citing Role Models Am., Inc. v. White, 317 F.3d 327, 331–32 (D.C. Cir. 2003)).

Here, the Court agrees with the defendants and concludes that the "FDA [W]arning [L]etter[] do[es] not represent final agency action subject to judicial review." Holistic Candlers, 664 F.3d at 944–45; see also Orton Motor, Inc. v. U.S. Dep't of Health & Human Servs., 884 F.3d 1205, 1215 (D.C. Cir. 2018) ("FDA warning letters, while potentially significant as bases for later enforcement, are not subject to review where 'no legal consequences flow from the agency's conduct to [that point].'" (quoting Holistic Candlers, 664 F.3d at 944–45)).[4] As to the first element of the final agency action analysis, that the action "marks the consummation of the agency's decision[-]making process," Conservation Force, 919 F. Supp. 2d at 89, "[t]he [FDA Warning] [L]etter[] plainly do[es] not mark the consummation of FDA's decisionmaking," Holistic Candlers, 664 F.3d at 944. As this Circuit previously recognized:

> The FDA Regulatory Procedures Manual [(the "Manual')] describes FDA warning letters as giving "firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action." The Manual states that the violations for which warning letters are issued "may lead to enforcement action if not promptly and adequately corrected," not that they inevitably will.

Id. (citations omitted). Consistent with this description, the FDA Warning Letter at issue here states that "[f]ailure to immediately cease distribution of your products . . . could result in enforcement action by [the] FDA," and that such action includes "seizure of violative products and injunction against the manufacturers and distributors of violative products." Compl., Ex. 2 (FDA Warning Letter) at 3 (emphasis added). "No such actions have been taken against the

[4] The Court's "conclusion that the warning letters do not constitute final agency action makes it unnecessary for [the Court] to consider the remainder of the ripeness inquiry." Holistic Candlers, 664 F.3d at 946 n.4.

[plaintiffs] to date." Holistic Candlers, 664 F.3d at 944. Moreover, contrary to the plaintiffs' claims that the defendants have "tak[en] the unilateral position that DMHA is not a lawful dietary ingredient and that any product containing it is adulterated and therefore violates [the] [Act]," Pls.' Opp'n at 10; see also id. at 9 (claiming that the FDA Warning Letter "is unambiguous in that it considers the continued marketing of DMHA containing dietary supplements 'violations' of various provisions of [the Act] and that the products containing DMHA are adulterated"), the FDA requested a response from the plaintiffs "[w]ithin fifteen working days of receipt of th[e] [FDA Warning] [L]etter" and informed the plaintiffs that if they did not "believe that [their] products [were] in violation of the [Act], [to] [submit] [their] reasoning and any supporting information for [the FDA's] consideration." Compl., Ex. 2 (FDA Warning Letter) at 3 (emphasis added). "This indicates that [the plaintiffs] ha[d] alternatives." Estee Lauder, Inc. v. U.S. Food & Drug Admin., 727 F. Supp. 1, 5 (D.D.C. 1989) (concluding that language in the agency's letter—requesting that the plaintiff "advise [the FDA]" if it was "unwilling to make the changes identified in [its] letter"—"was by its very nature informal and advisory"). Moreover, "[t]his language is equivocal—there is no definite plan of attack on the part of the [FDA]." Id.

The Court also finds that the FDA Warning Letter fails to satisfy the second requirement for final agency action—that the action "affects the 'rights or obligations . . . [or the] legal consequences' of the party seeking review." Conservation Force, 919 F. Supp. 2d at 89; see also Holistic Candlers, 664 F.3d at 944 ("Nor do the [FDA warning] letters represent a decision determining rights or obligations, or one from which legal consequences flow."). In Holistic Candlers, the Circuit noted that

> [t]he [ ] Manual explains that "[a] [w]arning [l]etter is the [FDA's] principal means of achieving prompt voluntary compliance with the Federal Food, Drug

> and Cosmetic Act." Although a warning letter "communicates the [FDA's] position on a matter," it is only "informal and advisory" and "does not commit [the] FDA to taking enforcement action." Indeed, the Manual states that, "[d]espite the significance of the violations [for which a warning letter may be issued], there are some circumstances that may preclude the [FDA] from taking any further enforcement action following the issuance of a [w]arning [l]etter." In short, an FDA warning letter compels action by neither the recipient nor the [FDA].

664 F.3d at 944 (second, eighth, and ninth alterations in original). And, the Court reiterates, "[o]nce again, [that] the [FDA Warning] [L]etter[] at issue here are consistent with the Manual's description." Id. It merely advises the plaintiffs that they "should take prompt action to correct the violations addressed in th[e] letter," and states that "[f]ailure to immediately cease distribution of your products . . . could result in enforcement action by [the] FDA." Compl., Ex. 2 (FDA Warning Letter) at 3 (emphasis added). "It is plain, therefore, that [n]o legal consequences flow from the [FDA's] conduct to date, for there has been no order compelling [the plaintiffs] to do anything." Holistic Candlers, 664 F.3d at 944 (internal quotation marks omitted).

Nonetheless, in support of their claim of finality, the plaintiffs rely on "a bond condition in an unrelated criminal matter," which, according to the plaintiffs, would "produce serious legal consequences for [Jared Wheat]." Pls.' Opp'n at 10.[5] Specifically, the plaintiffs claim that the FDA Warning Letter has "effectively determined various rights or obligations . . . from which legal consequences will flow" because the defendants have "affirmatively [sought] [a] bail order currently in place in the Northern District of Georgia." Id. (internal quotation marks omitted).

[5] In an unrelated criminal matter pending in the Northern District of Georgia, Wheat was released on bond and is subject to certain conditions of release, including being "prohibited from, directly or indirectly through third parties, manufacturing, distributing or selling adulterated foods or misbranded drugs, including but not limited to products containing DMAA or its chemical equivalent." Order Setting Conditions of Release, Ex. A (E-mail from Steven Grimberg to Lisa Enix (Oct. 4, 2017)), United States v. Wheat, Crim. Action No. 17-229 (AT) (CMS) (N.D. Ga. Oct. 4, 2017), ECF No. 22-1. He is also prohibited from "purchasing or receiving DMAA ingredients; and manufacturing, processing, packaging, marketing, or distributing food or dietary supplement products containing DMAA or its chemical equivalent." Id.

However, the bond condition does not "suppl[y] the finality that the [FDA] [W]arning [L]etter[] lack[s]." Holistic Candlers, 664 F.3d at 946. Contrary to the plaintiffs' claim that Wheat "remain[s] in danger of violating their bail condition," Pls.' Opp'n at 11, as the defendants point out, prior to the revocation of Wheat's bond, the following must occur:

> (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 [ ] 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."

Defs.' Mot. at 15 (quoting 18 U.S.C. § 3148(b)). Therefore, in addition to the speculative nature of Wheat's potential detention, his possible revocation would not be a consequence of the FDA Warning Letter but rather a consequence of an independent determination made by the judicial officer in Wheat's pending criminal matter.[6]

IV. CONCLUSION

For all of the foregoing reasons, the Court concludes because the FDA Warning Letter is not a final agency action subject to judicial review, the Court lacks subject matter jurisdiction over the plaintiffs' claims. Therefore, the Court must grant the defendants' motion to dismiss.

[6] For the same reasons, the Court agrees with the defendants that the "plaintiffs' claim[] under the Fifth Amendment . . . must be dismissed." Defs.' Mot. at 24. "[D]ue process is required only where government action threatens a deprivation of life, liberty, or property," and because a due process violation has not been adequately pleaded, the plaintiffs have "failed to show that the mere issuance of a warning letter, absent further enforcement action, effects any such deprivation." Orton Motor, 884 F.3d at 1215. The plaintiffs have therefore neither demonstrated that the FDA Warning Letter creates legally binding consequences nor established that it is even judicially reviewable, and thus the plaintiffs have not shown that it effects a cognizable due process violation. Accordingly, the Court concludes that dismissal of the plaintiffs' Fifth Amendment claim is also appropriate.

SO ORDERED this 29th day of June, 2020.[7]

REGGIE B. WALTON
United States District Judge

[7] The Court will contemporaneously issue an Order consistent with this Memorandum Opinion.