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

REPLY MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

Plaintiffs' Opposition brief brings them no closer to stating claims for relief within the Court's jurisdiction. Dkt. No. 7 ("Opp."). Plaintiffs do not dispute several critical points argued in Defendants' Motion to Dismiss, Dkt. No. 5 ("Mot."): (1) that to date, the sole public statement FDA issued with respect to DMHA, and thus the sole issue in this suit, is the Warning Letter issued to Plaintiffs and others, *see* Mot. at 5-6, 14, Opp. at 7-9; (2) that under the *Regulatory Procedures Manual*, FDA's Warning Letters are "informal and advisory," and "communicate[] the agency's position on a matter," but "do[] not commit FDA to taking enforcement action," *see* Mot. at 9-14 (citing RPM § 4-1-1); (3) that the D.C. Circuit's opinion in *Holistic Candlers,* 644 F.3d 940 (D.C. Cir. 2012), recognized this and provides the binding analysis with respect to final agency action in this case;[1] (4) that Plaintiffs themselves also recognized as much just earlier this

[1] *See* Mot. at 9-14; Opp. at 10-11 (acknowledging but attempting to distinguish *Holistic Candlers* on other grounds).

year in another case, arguing Warning Letters serve to "start a dialogue" between the Agency and the affected entity,[2] a fact of which the Court may take judicial notice, *see* Mot. at 10 n.5; (5) that by law, Mr. Wheat's bond condition in Georgia could not be revoked based on a Warning Letter's own force, but only after the government moved and a judicial officer found "clear and convincing evidence" that Mr. Wheat distributed adulterated food;[3] and (6) that there does not exist any "proceeding under" DSHEA, the statute on which Plaintiffs base their entire suit, in which the government violated any burden of proof. *See* Mot. at 22.

To the extent Plaintiffs confront the government's arguments at all, their responses are unavailing, as further explained below.

I. There Has Been No Final Agency Action Under the APA

Relying on binding D.C. Circuit precedent, Defendants' motion established that there has been no final agency action on which Plaintiffs can sue, *see* Mot. at 8-16 (citing *Holistic Candlers* and *Bennett v. Spear*, 520 U.S. 154 (1997)). Plaintiffs offer little in response, giving lip service to *Holistic Candlers* and the *Bennett* test, Opp. at 10, but not much more.

As to the first *Bennett* prong, Plaintiffs contend that the Warning Letter issued to them *does* reflect the "consummation of the agency's decision making process" because FDA has not yet conveyed to Plaintiffs its view regarding a report that Plaintiffs appended to this lawsuit in May. *See* Opp. at 11. Not only does this rationale fly in the face of *Holistic Candlers*, 664 F.3d at 943-46, it is also implausible on its face. Indeed, Plaintiffs elected to respond to FDA's Warning Letter not by merely submitting their scientific views on DMHA or otherwise initiating

[2] *See* Mot. at 2, 10, 12 (citing 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) ("*United States v. Wheat* Reply Br.")).

[3] *See* Mot at 14-16 (citing 18 U.S.C. § 3148(b)); Opp. at 8-11 (reiterating the Complaint's argument that the Warning Letter alone puts his liberty at risk).

a dialogue with the agency, but by filing a lawsuit seeking an injunction. But the lack of regulatory communications with the Agency during the pendency of litigation is neither remarkable nor indicative of the state of the Agency's decision making process. And plainly, the Agency is free to further consider its position on DMHA without keeping Plaintiffs in the loop at each step along the way. *See* RPM § 4-1-8, *available at* https://www.fda.gov/media/71878/ download) (FDA "should acknowledge . . . receipt of" and "will evaluate" responses to Warning Letters, after which FDA may consider and take a number of actions, including enforcement).

Plaintiffs also complain that the Warning Letter uses the word "violations" and evidences the Agency's "unilateral position," Opp. at 9-10, yet that language does not distinguish the Warning Letter issued to Plaintiffs from any other. *See Holistic Candlers*, 664 F.3d at 944 ("[d]espite the significance of the *violations* [for which a Warning Letter may be issued], there are some circumstances that may preclude the agency from taking any further enforcement action following the issuance of a Warning Letter.") (quoting RPM § 4-1-1) (emphasis added). Likewise, the Warning Letter's use of what Plaintiffs call "weasel-words to give the impression that the Government has not reached a conclusion," Opp. at 11, is consistent with *Holistic Candlers'* reliance on the very same type of language, as well as reliance on the RPM. *See* 664 F.3d at 944 (observing Warning Letters' use of "*appear*," "*may*," "*should*," and "*request*") (emphases in original); *see also* Mot. at 9-13.

Plaintiffs fare no better on the second *Bennett* prong, which asks whether the Warning Letter represents a decision determining rights or obligations, or one from which legal consequences flow. Plaintiffs' brief alleges that federal prosecutors "specifically sought" a bond

condition (to which Mr. Wheat agreed)[4] in an unrelated case almost two years before FDA sent him the Warning Letter he contests here, in an apparent attempt to further link the two events. Opp. at 8-9. But that bond condition does nothing to transform FDA's Warning Letter into final agency action or provide the court with jurisdiction. Plaintiffs fail to explain how an informal and advisory regulatory Warning Letter could plausibly invoke a fear of incarceration, and they simply ignore the fact that a Warning Letter alone could not form the basis for a bond revocation under criminal law. *Compare* Mot. at 15-16 (discussing 18 U.S.C. § 3148) *with* Opp. at 11-12. To whatever extent Plaintiff Wheat assertedly fears incarceration, that is not a "legal consequence" of the Warning Letter itself. *See* Mot. at 13-16; *Holistic Candlers*, 644 F.3d at 944 ("'[n]o legal consequences flow from the agency's conduct to date, for there has been no order compelling [the appellants] to do anything.'") (quoting *Reliable Automatic Sprinkler Co. Inc.*, 324 F.3d 726, 732 (D.C. Cir. 2003)) (marks in original). Put differently, though Mr. Wheat may fear legal consequences that might flow from his own DMHA-related activities, they do not flow *from the Warning Letter*.

Needing to meet both *Bennett* prongs, Plaintiffs thus fail under either. *See* Mot. at 9, 13 (citing *Soundboard Ass'n v. Fed. Trade Comm'n*, 888 F.3d 1261, 1267, 1271 (D.C. Cir. 2018)). At bottom, Plaintiffs cannot avoid *Holistic Candlers* and its progeny, which squarely hold that FDA Warning Letters like the one at issue here do not satisfy the *Bennett* test and are not final agency action on which FDA may be sued. *See* Mot. at 8 (collecting cases). Accordingly, Plaintiffs' Complaint must be dismissed.

[4] *See United States v. Wheat*, No. 17-cr-229, Hr' g Tr. at 11-12, Dkt. No. 34 ("Mr. Wheat is agreeable to the terms that we have discussed with the government . . . . not to manufacture and distribute adulterated and misbranded foods and drugs.") (N.D. Ga. Oct. 4, 2017); *id*. Dkt. Nos. 45, 71 (seeking amendment of only different, DMAA-specific bond conditions).

II. *Ewing* Bars Plaintiffs' Pre-Enforcement Suit

Plaintiffs also have no answer for *Ewing*'s prohibition on suits seeking pre-enforcement review of anticipated FDA action. *See* Mot. at 16-18 (discussing *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950)). Plaintiffs offer two cases to support their argument that *Ewing*'s bar should not apply, Opp. at 12-13, but neither aids their cause. In *Abbott Labs. v. Gardner*, 387 U.S. 136, 147-48 (1967), the Supreme Court *reaffirmed Ewing* as "quite clearly correct," but distinguished it from the case before it, which was a "declaratory judgment action challenging a promulgated regulation." *Id*. (suit challenging FDA regulation applying to all labels and advertisements relating to prescription drugs). The Court contrasted FDA's administrative finding of probable cause in *Ewing*, merely a "'prerequisite to the bringing of a lawsuit'" and an "administrative determination as to specific facts," that had "'no effect in and of itself,'" with the "promulgation of a self-operative industry-wide regulation" that was at issue in the case before it and which "would immunize nearly all agency rulemaking activities from the coverage of the [APA]." *Id*. (quoting *Ewing*, 339 U.S. at 598). Only the agency rulemaking, as the quote in Plaintiffs' brief itself recognizes, is a form of "*final* agency action." Opp. at 12 (quoting 387 U.S. at 148) (emphasis added).

Gardner v. Toilet Goods Ass'n, 387 U.S. 167 (1967), a companion case decided on the same day as *Abbot Laboratories*, does not help Plaintiffs for the same reason. In that case, the Supreme Court reaffirmed the rule in *Abbott Laboratories*, namely, that *Ewing*'s pre-enforcement jurisdictional bar does not apply to challenges to self-operative agency *regulations*. *See id*. at 171-72 (suit challenging three FDA regulations expanding the "color additives" subject to FDA's premarket approval). But that decision (and the passages selectively quoted in

Plaintiffs' brief) focused not on the applicability of the *Ewing* rule, but rather on the "hardship" prong of the ripeness inquiry.[5] *See id*. at 170-73; *but see* Opp. at 12-13.

Unlike in *Abbott Laboratories* and *Toilet Goods*, there is no agency rulemaking at issue here — as Plaintiffs concede, Opp. at 13 — or anything close to it. Rather, FDA's Warning Letter to Hi-Tech is far more akin to the non-final administrative determination in *Ewing*. As Defendants previously explained, multiple courts have applied *Ewing*'s bar against pre-enforcement suits in several other contexts outside of agency rulemaking — and in cases specifically involving FDA Warning Letters — cases Plaintiffs ignore. *See* Mot. at 17-18 (collecting cases). The cases Plaintiffs cite in response bring them no closer to avoiding *Ewing's* application here.

Curiously, Plaintiffs also attempt to evade *Ewing* by claiming that they do not actually seek "pre-enforcement review." Opp. at 1, 11. But that claim is directly contrary to the relief their Complaint seeks: an injunction "prohibiting Defendants from detaining or seizing [their] products," and "forbidding [them] from claiming in any court that DMHA containing products are adulterated or misbranded." Compl. ¶¶ 38, 45, 58, 62, 70. That is precisely the context that *Ewing* and its progeny address.

[5] Plaintiffs never directly address Defendants' argument that Plaintiffs' claims are not ripe for adjudication. Mot. at 18-20 (addressing both fitness and hardship). The closest they come is their invocation of a "Hobson's choice" argument in reliance on *Toilet Goods*, Opp. at 13, which cites that case's discussion of hardship. But to that end, the distinction of *Toilet Goods* is the same: it involved "regulations [that] are self-executing, and have an immediate and substantial impact upon the respondents." 387 U.S. at 171. A Warning Letter, by contrast, is neither "self-executing" nor binding on anyone. As this Court explained in finding another challenge to an FDA Warning Letter unripe, where "the FDA has not issued a formal ruling . . . nor has it established a standard. . . a different calculus of [hardship] interests arises. Because [Plaintiff] is seeking a pre-enforcement review of a projected agency position, the claimed hardship is no greater than any company confronted by an interpretation of a law it dislikes." *Estee Lauder, Inc. v. FDA,* 727 F. Supp. 1, 5 (D.D.C. 1989); Mot. at 19.

To the extent Plaintiffs attempt to shift their focus beyond FDA's Warning Letter issued to *Hi-Tech*, and instead to a supposed "industry-wide ban on DMHA" for which rulemaking is allegedly required (apparently based on FDA's Warning Letters sent to other manufacturers of DMHA-containing dietary supplements), Opp. at 5, 12, the distinction is of no legal moment. This Court found *Ewing* to bar a challenge to FDA Warning Letters issued to the five named plaintiffs in *Holistic Candlers I*, even though FDA had sent Warning Letters to ten other ear candle manufacturers or distributors. *See Holistic Candlers & Consumer Ass'n v. FDA*, 770 F. Supp. 2d 156, 158, 162–63 (D.D.C. 2011) (Leon, J.) ("*Holistic Candlers I*"), *aff'd*, 664 F.3d 940 (D.C. Cir. 2012); *see also* Mot. at 17-18 (discussing *id*.).[6] As in *Holistic Candlers I*, Plaintiffs cannot sue FDA in an attempt to stave off enforcement before the Agency has initiated enforcement against them. *Id*. at 163.

Lastly, to the extent Plaintiffs attempt to retreat to a more amorphous claim that they "merely seek[] to compel FDA to comply with its statutory obligations," Opp. at 11-12, untethered to an actual Agency action that has harmed or will harm them, they do not plead a case or controversy at all. Therefore, Plaintiffs have failed to demonstrate that their case falls outside *Ewing*'s bar, and they cannot establish subject-matter jurisdiction.

III. Plaintiffs Have Not Exhausted Their Remedies

Numerous times, this Court has found that a failure to exhaust administrative remedies precludes a challenge to an FDA Warning Letter. *See* Mot. at 21-22 (citing *Holistic Candlers I*, 770 F. Supp. 2d at 163; *Estee Lauder*, 727 F. Supp. at 7). Simply ignoring this precedent, Plaintiffs instead cite two inapposite cases finding, in different contexts, that the exhaustion

[6] Moreover, to the extent Plaintiffs attempt to expand their case to include third parties, they lack standing to assert claims on such third parties' behalf. *See Kowalski v. Tesmer,* 543 U.S. 125, 129 (2004).

requirement was inapplicable because it would have been futile under the circumstances of those cases. Opp. at 14-15. Once more, Plaintiffs' cases are readily distinguishable: *Halbig v. Sebelius* involved a "pre-enforcement challenge to a *final agency rule*," 27 F. Supp. 3d 1, 12 (D.D.C. 2014) (emphasis added); and *Smoking Everywhere, Inc. v. FDA* challenged FDA's decision to detain multiple imports of e-cigarette products, 680 F. Supp. 2d 62, 64-65, 69 n.7 (D.D.C. 2010). Both of these cases arose in postures vastly different from a Warning Letter.

As Plaintiffs acknowledge, to escape the exhaustion requirement, they must demonstrate that the Agency "'has evidenced a strong position on the issue together with an unwillingness to reconsider.'" *See* Opp. at 14 (quotation omitted). But Plaintiffs do not persuasively argue that those conditions are met. If a Warning Letter alone satisfied those conditions, the exception to exhaustion would swallow up the rule, contrary to both *Holistic Candlers I* and *Estee Lauder*.

Moreover, Plaintiffs' claim that FDA has "refus[ed] to date to even examine or review the scientific information submitted by Plaintiffs," Opp. at 11, 15, is flawed in multiple respects. First, it is a novel factual allegation not pled in the Complaint and brought in opposition to a motion to dismiss. *See Koker v. Aurora Loan Servicing, LLC*, 915 F. Supp. 2d 51, 59 (D.D.C. 2013) (Walton, J.) (new allegations in a brief "nowhere to be found in the complaint" should not be considered). Second, it is facially unfounded, because Plaintiffs have no way of knowing what FDA is "examining" or "reviewing" — they point merely to the Agency's silence to date to support their claim, and as explained above, the Agency is under no obligation to keep them apprised. Third, it overlooks that the more likely explanation for FDA's silence may well be this lawsuit.

Here, FDA issued Plaintiffs a Warning Letter setting forth the Agency's views on DMHA and inviting them to respond if they disagreed. Compl. Ex. 2 at 3 ("WL"). Plaintiffs responded,

but with a lawsuit seeking an injunction from this Court, to which they appended a report they contend forms the basis of the disagreement. That FDA has not yet responded to Plaintiffs' report is unremarkable considering that the report addresses the very issue Plaintiffs simultaneously have sought to raise in pending litigation against the Agency. As Plaintiffs themselves have recently acknowledged, FDA Warning Letters can be an important and beneficial way to "start a dialogue" with an affected entity about the legality of its product.[7] To the extent Plaintiffs have stymied that dialogue by electing to file this lawsuit instead, that is a circumstance entirely of their own making.

IV. Plaintiffs Continue to Misstate the FDCA and DSHEA

Turning to the merits, Plaintiffs assert that they are entitled to prevail on their "well-pleaded factual allegations that must be assumed true." Opp. at 15. But their Complaint must fail because of its legal, not factual, infirmities. Once more, Plaintiffs' brief fails to explain away law that simply does not support their arguments, instead merely reiterating the same legal inaccuracies set forth in the Complaint.

Plaintiffs continue to insist, without citing any authority, that rulemaking is the only method by which FDA may regulate DMHA, but they are wrong. *Compare* Opp. at 5, 12 *with* Mot. at 5, 22. Indeed, the Eleventh Circuit recently rejected this same argument following FDA's seizure of Hi-Tech's dietary supplements containing a substance called DMAA: "FDA was not required to engage in rulemaking but could elect instead to proceed through a forfeiture action against Hi-Tech's DMAA products. . . . As part of the forfeiture proceeding, Hi-Tech was afforded the full range of procedural due process available in a federal court." *United States v.*

[7] *United States v. Wheat* Reply Br. at 6; *see also* 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).

Undetermined Quantities of All Articles of Finished & In-Process Foods, No. 17-13376, -- F.3d --, 2019 WL 4123964, at *1 (11th Cir. Aug. 30, 2019); *but see* Opp. at 6 n.2. There is simply no legal support for Plaintiffs' argument that FDA may only regulate products containing DMHA solely through rulemaking. Plaintiffs also continue to ignore that no "proceeding under" DSHEA, 21 U.S.C. § 342(f)(1), *exists* in which the government could have violated any burden of proof with respect to DMHA, the linchpin of Plaintiffs' DSHEA arguments. *See* Opp. at 5, 16; *but see* Mot. at 22.

Finally, Plaintiffs wrongly assume that 21 U.S.C. § 342(f) is the only provision by which a "dietary supplement" may be adulterated, Opp. at 5, 16; rather, 21 U.S.C. § 342(a)(2)(C)(i) provides that a "food" (which includes a dietary supplement, *see* § 321(ff)) is adulterated if it contains an "unsafe food additive." *See also* Mot. at 3-4, 23-24. Plaintiffs appear to argue that the FDCA's "food additive" provisions are wholly inapplicable here because "dietary ingredients" under 21 U.S.C. § 342(ff) that are intended for use in dietary supplements are excluded from the definition of "food additives." *See* Opp. at 16 (citing 21 U.S.C. § 321(s)(6)). But they ignore the fact that if DMHA is *not* a "dietary ingredient" as set forth in 21 U.S.C. § 321(ff), then it *may* be a "food additive" under 21 U.S.C. § 321(s)(6).[8] As the Warning Letter plainly states, that is precisely one of FDA's theories of adulteration: that DMHA may not be a dietary ingredient under 21 U.S.C. § 321(ff), and "if DMHA were not a dietary ingredient under [§ 321(ff)], it would be an unsafe food additive" instead. WL at 2. Accordingly, the food additive provisions may apply to DMHA. *See* Mot. at 3-4, 23-24.

[8] *See also, e.g.*, FDA Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements (Jan. 2014), *available at* https://www.fda.gov/media/87680/download.

To be sure, Plaintiffs are free to disagree with the factual bases for FDA's legal conclusions that DMHA is in fact either a "new dietary ingredient" or an "unsafe food additive." *Compare* WL at 2-3, Mot. at 3-5, 12 *with* Opp. at 16. But assuming the truth of Plaintiffs' factual allegations does not require accepting their misconceptions of the statutory framework that applies to their products. Even at the motion to dismiss stage, Plaintiffs are not entitled to incorrect legal conclusions.

CONCLUSION

For the foregoing reasons, and for the reasons explained in the Motion, this Court should grant Defendants' Motion to Dismiss Plaintiffs' Complaint.

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Respectfully submitted,

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