UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

HI-TECH PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	Civil Case
	)	No. 13-cv-3675-WBH
v.	)	
	)	
MARGARET A. HAMBURG, M.D., et al.,	)	
	)	
Defendants.	)	

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Hi-Tech Pharmaceuticals, Inc.'s ("Hi-Tech") allegations that Defendants (hereinafter referred to collectively as "FDA") have taken final agency action with respect to 1, 3-dimethylamylamine ("DMAA") and such action effectively banned the substance without a purported statutorily-mandated rulemaking are belied by the facts and controlling precedent. Hi-Tech's entire case rests on the incorrect contention that FDA cannot take any action against dietary supplements containing DMAA unless FDA first bans the substance through formal rulemaking.

The parties agree on the facts: FDA sent warning letters regarding dietary supplements containing DMAA to some manufacturers, but not Hi-Tech; FDA put a statement about such dietary supplements in a "Questions and Answers" section on its webpage; some manufacturers voluntarily ceased manufacturing and

marketing dietary supplements containing DMAA after they received FDA warning letters; FDA did not engage in rulemaking regarding DMAA; and the government filed a seizure action (that this Court has yet to adjudicate) against Hi-Tech's products. None of these actions constitutes final agency action, which is required for this Court to have jurisdiction over Hi-Tech's Administrative Procedure Act ("APA") complaint regarding those actions. Moreover, Hi-Tech concedes that it did not avail itself of the available administrative remedies that would have led to final agency action and disclaims any obligation to do so. Hi-Tech's failure to exhaust administrative remedies is also fatal to its APA complaint.

Controlling precedent establishes that FDA has the discretion to proceed against adulterated products through individual enforcement actions and/or rulemaking; Hi-Tech has identified no authority to the contrary. Controlling precedent further establishes that the seizure action itself provides Hi-Tech all the procedural protections which it is due. This Court should dismiss Hi-Tech's Complaint for lack of subject matter jurisdiction and failure to state a claim.

I. THIS COURT LACKS SUBJECT MATTER JURISDICTION OVER HI-TECH'S COMPLAINT

A. Hi-Tech's Characterization Notwithstanding, The Injunction Hi-Tech Seeks Would Contravene *Ewing* And Its Progeny

Hi-Tech does not dispute that *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), and its progeny foreclose pre-enforcement challenges to FDA seizure actions, but nonetheless argues that *Ewing* does not apply to its APA suit. *See* ECF No. 45 ("Pl.'s Opp'n"), at 12. Hi-Tech is wrong. The injunction it seeks would require this Court – in an action brought under the APA rather than in the seizure action itself – to determine whether FDA has the right to detain and seize products containing DMAA absent formal rulemaking banning the substance. That very type of pre-enforcement review is foreclosed by *Ewing* and its progeny.

The Supreme Court in *Ewing* held that district courts lack jurisdiction to enjoin Federal Food, Drug, and Cosmetic Act ("FFDCA") seizure actions, because to do so would amount to impermissible pre-enforcement review of FDA's enforcement decisions. *Ewing*, 339 U.S. at 601. Courts have relied on *Ewing* repeatedly to bar claims for injunctive relief by litigants challenging a proposed or, as here, filed FFDCA enforcement action. *See* ECF No. 43-1 ("Defs.' Mem."), at 11-12. By seeking "preliminary and permanent injunctive relief prohibiting

Defendants from detaining or seizing DMAA containing products," *see* ECF No. 41-1 ("Compl."), at 11, 12, 14, 17, 19, 21, Hi-Tech's requested injunctive relief falls squarely within *Ewing*'s prohibition. Indeed, Hi-Tech's requested injunction is materially indistinguishable from the one rejected by the old Fifth Circuit in *Southeastern Minerals, Inc. v. Harris*, 622 F.2d 758 (5th Cir. 1980). *See id.* at 764 (applying *Ewing* and vacating injunction preventing FDA from interfering with the manufacturing and marketing of a company's products).

Hi-Tech's reliance on *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), and *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167 (1967), is misplaced. They involved challenges to FDA regulations promulgated after rulemaking proceedings. *See Abbott Labs.*, 387 U.S. at 138, 147-48 (declining to apply *Ewing* because, although the *Ewing* decision "was quite clearly correct," the plaintiff "challeng[ed] a promulgated regulation," not a seizure action); *Toilet Goods*, 387 U.S. at 168-70. As Hi-Tech admits (indeed, as it complains), there is "no formal regulation" at issue here. Pl.'s Opp'n 14.

Hi-Tech's attempt to distinguish *Southeastern Minerals* on the ground that it did not involve APA claims is equally unavailing. As that decision makes clear, it is not the nature of the claims but, rather, a request for injunctive relief that would

prohibit FDA from seizing product and initiating FFDCA enforcement proceedings, that runs afoul of *Ewing*. *See Se. Minerals*, 622 F.2d at 763. This controlling Supreme Court and Circuit precedent requires dismissal of Hi-Tech's claims for injunctive relief for lack of jurisdiction.

B. Hi-Tech Has Failed To Establish That Its APA Claims Are Ripe

1. None of FDA's conduct related to DMAA, taken individually or viewed collectively, constitutes final agency action

Hi-Tech concedes that "courts have concluded that, taken separately, warning letters, informal statements, and enforcement actions may not constitute final agency action for purposes of the APA." Pl.'s Opp'n 18. Yet Hi-Tech insists that FDA's statement in a "Questions & Answers" section of its webpage about "DMAA in Dietary Supplements" pronounced a ban on products containing DMAA and constituted final agency action. *See id.* 16. Such informal statement, however, neither "mark[s] the consummation of the agency's decisionmaking process" nor is "one by which rights or obligations have been determined, or from which legal consequences will flow," *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal quotations omitted), and is not final agency action.

Indeed, the statement on FDA's website cited by Hi-Tech is materially indistinguishable from other informal FDA statements that courts, including the old Fifth Circuit, have held do *not* constitute final agency action. *See Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 945 (D.C. Cir. 2012) (discussion of enforcement actions against ear candles on FDA webpage titled "Don't Get Burned: Stay Away From Ear Candles" not final agency action); *Se. Minerals*, 622 F.2d at 764 & n.11, 766 (FDA's "formal position" about a product set forth in a Compliance Policy Guide not final agency action); *Clinical Reference Lab., Inc. v. Sullivan*, 791 F. Supp. 1499, 1502 n.4, 1504 (D. Kan. 1992) (statements in an FDA newsletter about the legal status of a product not final agency action), *rev'd in part on other grounds*, *United States v. Undetermined Number of Unlabeled Cases*, 21 F.3d 1026 (10th Cir. 1994).

Hi-Tech is also wrong that FDA's website statement, in conjunction with the fact that the government commenced a seizure action against Hi-Tech's dietary supplements, distinguishes this case from the ones upon which FDA relies, *see* Pl.'s Opp'n 18. In *Southeastern Minerals*, the Court found "[n]o final agency action" in a situation where FDA had taken a "formal position" about the product in a Compliance Policy Guide and multiple seizure actions had been filed against

the product. *Se. Minerals*, 622 F.2d at 764, 766. Under similar facts, the D.C. Circuit found it "plain" that "various statements by FDA officials, coupled with the FDA's position" in two seizure actions, "do not constitute 'final agency action.'" *Schering Corp. v. Heckler*, 779 F.2d 683, 686 n.18 (D.C. Cir. 1985). Similarly, in *Clinical Reference Laboratory*, the court found "wholly without merit" the argument that a regulatory letter demanding a company cease its activities combined with statements by FDA officials in an internal newsletter constituted final agency action. *Clinical Reference Lab.*, 791 F. Supp. at 1503, 1504 n.6.

FDA has not taken final agency action regarding DMAA-containing dietary supplements, and Hi-Tech's claims must be dismissed for lack of jurisdiction.

2. Hi-Tech's failure to exhaust available administrative remedies should not be excused

Hi-Tech argues that its failure to exhaust available administrative remedies should be excused because any effort to do so would have been futile. "[E]xhaustion is the rule in the vast majority of cases." *Bowen v. City of New York*, 476 U.S. 467, 486 (1986). Futility is an exception to this general rule, and applies only when "requiring a plaintiff to exhaust an administrative scheme would be an empty exercise in legal formalism." *Perrino v. S. Bell Tel. & Tel. Co.*, 209

F.3d 1309, 1318 (11th Cir. 2000); *see Ass'n of Flight Attendants-CWA v. Chao*, 493 F.3d 155, 159 (D.C. Cir. 2007) (excusing exhaustion "only when resort to administrative remedies is clearly useless").

Hi-Tech summarily contends that exhaustion would have been futile here because FDA would not have changed its position in light of the warning letters sent to other companies (not to Hi-Tech), the administrative detention, and the seizure. Such "bare allegations" are insufficient to establish futility. *Springer v. Wal-Mart Assocs.' Grp. Health Plan*, 908 F.2d 897, 901 (11th Cir. 1990) (quotations omitted); *see Bickley v. Caremark RX, Inc.*, 461 F.3d 1325, 1330 (11th Cir. 2006) (rejecting as "speculative" conclusory allegations of futility). As FDA already has shown, Hi-Tech has no standing to raise claims based on warning letters it never received. *See* Defs.' Mem. 16 & n.7. And, as discussed above in section I.B.1, FDA did not culminate an administrative process by sending warning letters, detaining products administratively, and recommending that a seizure action be instituted by the Department of Justice.[1]

[1] The absence of final agency action here distinguishes this case from *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 65-66, 68 n.7 (D.D.C. 2010), in which at least one plaintiff was already subject to a final agency action. Similarly,

Hi-Tech does not dispute that it could have filed a citizen petition and squarely presented its issues regarding DMAA to FDA for an administrative determination. Courts have dismissed APA cases against FDA for lack of jurisdiction when litigants who are facing pending seizure actions have "failed to avail themselves of several different avenues through which they can obtain judicial review of their claims," including using the citizen petition process. *Genendo Pharm. N.V. v. Thompson*, 308 F. Supp. 2d 881, 886 (N.D. Ill. 2003)*; see also Clinical Reference Lab.*, 791 F. Supp. at 1504.

Hi-Tech argues nonetheless that it should be relieved of the obligation to have done so because filing a citizen petition "would essentially flip the burden [of proof] upon Hi-Tech" by "forcing" it to seek FDA approval to use DMAA when DMAA, under DSHEA, is "entitled to a presumption of safety." Pl.'s Opp'n 22. Hi-Tech is wrong for two reasons. First, the citizen petition process that Hi-Tech failed to exhaust was not one to seek FDA approval to use DMAA but, rather, to

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Halbig v. Sebelius, Civil Action No. 13-623 (PLF), 2014 WL 129023, at *8 (D.D.C. Jan. 15, 2014), involved a challenge to an IRS regulation that constituted final agency action. Moreover, the appellate opinion in *Halbig* has been vacated pending rehearing en banc, *see Halbig v. Burwell*, No. 14-5018, 2014 WL 4627181 (D.C. Cir. Sept. 4, 2014) (per curiam), so the value of *Halbig*'s district court opinion is highly limited.

present to FDA the arguments it seeks to raise in its APA action, *i.e.*, that DMAA is a dietary ingredient and FDA can only proceed against dietary supplements containing DMAA under DSHEA's provisions and only after rulemaking. Hi-Tech nowhere explains why these issues could not and should not have been brought up for final agency decision in a citizen petition. Second, Hi-Tech is confusing the legal burden of proof that FDA bears when it brings an enforcement action under certain DSHEA provisions, *see NVE, Inc. v. Dep't of Health & Human Servs.*, 436 F.3d 182, 192 (3d Cir. 2006), with the task of preparing and submitting the citizen petition document to FDA. Whatever "burden" the latter may entail does not obviate the need for Hi-Tech to pursue available administrative remedies before it sues FDA in federal court, and does not impermissibly shift any legal burden of proof to Hi-Tech.

Hi-Tech makes the unsubstantiated and incorrect assertion that FDA somehow manipulated the process to deprive it of its opportunity to administratively appeal the detention order and, therefore, FDA similarly would have thwarted any effort by Hi-Tech to pursue a citizen petition. On November 1, 2013, pursuant to its statutory and regulatory authority, FDA administratively detained all products labeled or identified by Hi-Tech as containing DMAA. ECF

No. 41-7 (Ex. 1); *see* 21 U.S.C. § 334(h)(1)(A); 21 C.F.R. §§1.377-1.406 (2013). The FFDCA authorizes FDA to administratively detain food that an "officer or qualified employee has reason to believe" is adulterated or misbranded, for no more than 30 days, to enable FDA to institute a seizure or injunction action. 21 U.S.C. §§ 334(h)(1)(A), (h)(2). Under the FFDCA, any person who "would be entitled to be a claimant for such article if the article were seized under [21 U.S.C. § 334(a)]" may administratively appeal the detention order, *id.* § 334(h)(4)(A), but the process for appealing a detention order terminates if FDA institutes a seizure action regarding the article of food involved in the detention, *id.* § 334(h)(4).

The United States filed the seizure action against the articles of food involved in the detention on November 7, 2013 (ECF No. 1), six days after FDA administratively detained those products, and at that time, the administrative process provided in the FFDCA terminated. Hi-Tech did not file an administrative appeal of the detention order until November 12, 2013, ECF No. 41-9 (Ex. 6).[2]

[2] Pursuant to 21 C.F.R. § 1.402(a)(2), Hi-Tech was required to file its administrative appeal within 10 calendar days after receiving the detention order. Although Hi-Tech received the detention order on November 1, 2013, ECF No. 41-7 (Ex. 1), it did not file its administrative appeal until November 12, 2013, ECF No. 41-9 (Ex. 6), eleven days after receiving the detention order.

Even if Hi-Tech had filed its appeal on November 11, 2013—within the ten day timeframe set forth in FDA's regulations—its administrative appeal rights had already terminated under the FFDCA's provisions with the institution of the seizure action, and not as the result of any untoward FDA action.

Hi-Tech has not and cannot show that its failure to exhaust the administrative remedies available to it in this matter would have been futile. Its failure to exhaust its administrative remedies requires dismissal of its APA complaint.

II. HI-TECH HAS FAILED TO STATE AN APA OR DUE PROCESS CLAIM UPON WHICH RELIEF CAN BE GRANTED

A. Hi-Tech Cites No Authority That Requires FDA To Proceed Against DMAA-Containing Dietary Supplements By Rulemaking

In its opening brief, FDA established that Hi-Tech's Complaint is premised on the clearly erroneous legal assertion that FDA first must ban DMAA through rulemaking before it may take enforcement action against products containing DMAA. *See* Defs.' Mem. 22-24. FDA noted Hi-Tech's inability to cite any authority in the FFDCA, as amended by the Dietary Supplement Health and Education Act ("DSHEA"), that requires rulemaking as a prerequisite to enforcement. Indeed, under the FFDCA, FDA possesses the statutory discretion to

proceed against violative products by seizure actions and/or rulemakings. *See* Defs.' Mem. 22-24.

In its response, Hi-Tech acknowledges that its Complaint is premised upon FDA's failure to exercise "rulemaking authority," Pl.'s Opp'n 23, and continues to cite no authority supporting its position that FDA is required to proceed through rulemaking. Instead, Hi-Tech simply recites as a truism that FDA must ban DMAA by rulemaking. *See*, *e.g.*, *id.* 2, 12, 14, 16. Such "unsupported conclusions of law" are insufficient to prevent dismissal of the Complaint. *McGinley v. Houston*, 361 F.3d 1328, 1330 (11th Cir. 2004). Accordingly, the Court should dismiss Hi-Tech's APA claims for failure to state a claim.

B. Hi-Tech Has Received And Will Receive All The Process It Is Due

Hi-Tech now refines its due process cause of action to comprise two arguments: filing the seizure action violated DSHEA; and FDA effectively issued a rule banning DMAA without allowing Hi-Tech to participate in the rulemaking process. Neither argument has merit.

Hi-Tech's first due process argument has been fully briefed in the seizure action as part of the United States's motion to strike. *See* ECF No. 42 (Hi-Tech and Wheat's Opp'n to Mot. to Strike), at 13-15; ECF No. 44 (U.S. Reply in

Support of Mot. to Strike), at 2-9. The seizure action is precisely where *Ewing* requires such arguments (and the others advanced by Hi-Tech) be raised and decided, not in this separate action seeking to frustrate the enforcement action. To avoid repetition, FDA now incorporates the arguments against that alleged due process violation made in the United States's brief filed at Docket Entry 44.

Hi-Tech's second due process claim, that FDA effectively issued a rule banning DMAA without allowing Hi-Tech to participate in the rulemaking process, rests upon the faulty premise that FDA has undertaken a final agency action related to DMAA without proceeding by formal rulemaking. As discussed, no final agency action has occurred, and FDA is not required to proceed by rulemaking. *See supra*; Defs.' Mem. 6, 14-18, 22-24.

More fundamentally, Hi-Tech has not been and will not be deprived of any property without receiving the constitutionally-required notice and opportunity to be heard. As the Supreme Court has held, the seizure action itself "satisfies the requirements of due process." *Ewing*, 339 U.S. 594 at 598.

Hi-Tech's reliance on *Springs Mills, Inc. v. Consumer Product Safety Commission*, 434 F. Supp. 416 (D.S.C. 1977), is completely misplaced. First, *Springs Mills* involved a challenge to the Consumer Product Safety Commission's

("CPSC") regulation banning a flame-retardant used in children's sleepwear under the Federal Hazardous Substances Act ("FHSA"), which was adopted without providing a full rule-making hearing. Here, there is no final rule or regulation being challenged by Hi-Tech. Second, one year after the District Court for the District of South Carolina decided *Spring Mills*, the Fourth Circuit, in *United States v. Articles of Hazardous Substance*, 588 F.2d 39, 42 (4th Cir. 1978), rejected the argument "that an appropriate administrative regulation is a prerequisite to any enforcement action," which is the same argument that Hi-Tech makes here. Instead, the Fourth Circuit recognized the CPSC's right to "proceed against a substance by regulation pursuant to its rulemaking authority, or [to] go directly to court upon its allegation that the goods or substance" are subject to seizure and condemnation. *Id.* It further held that the FHSA's seizure provisions, modeled on those in the FFDCA, satisfied due process. *Id.* at 42-43; *see also X-tra Art, Inc. v. CPSC*, No. C-91-1336-MHP, 1991 WL 405183, at *7 n.8 (N.D. Cal. June 12, 1991) (finding *Spring Mills* "of little value as guidance" because it "runs contrary to the holding in *Articles of Hazardous Substance*, a case decided subsequently by its own Circuit Court").

Hi-Tech's due process claim should be dismissed for failure to state a claim.

CONCLUSION

For the foregoing reasons and those cited in Defendants' Memorandum, this Court should grant Defendants' Motion to Dismiss Hi-Tech's Complaint.

Dated: December 11, 2014

Respectfully submitted,

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CERTIFICATION OF TYPEFACE COMPLIANCE

I hereby certify, pursuant to Local Rules 5.1 and 7.1(D), that the foregoing motion and accompanying memorandum has been prepared using Times New Roman, 14 point font.

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CERTIFICATE OF SERVICE

I hereby certify that the above motion and attached memorandum were electronically filed using the CM/ECF system and served upon counsel of record via electronic mail on this the 11th day of December, 2014.

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