NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HEALTH SCIENCE FUNDING LLC, Plaintiffs, v. THE UNITED STATES FOOD AND DRUG ADMINISTRATION and STEPHEN OSTROFF, in his official capacity as Acting Commissioner of the FDA, Defendants.	Civil Action No.: 15-5635 (CCC-MF) **OPINION**

CECCHI, District Judge.

I. INTRODUCTION

Before the Court are two pending motions: (1) Plaintiff Health Science Funding LLC's ("Plaintiff") Motion for a Preliminary Injunction (ECF No. 8); and (2) Defendant United States Food and Drug Administration's ("FDA") Motion to Dismiss (ECF No. 12). In the interests of judicial economy and efficiency, the Court evaluates the motions together. The Court decides the motions without oral argument pursuant to Rule 78.[1] Having considered the parties' submissions and for the reasons set forth below, the Court will grant FDA's motion to dismiss and deny Plaintiff's preliminary injunction motion.

[1] The Court considers any arguments not presented by the parties to be waived. *See Brenner v. Local 514, United Bhd. of Carpenters & Joiners*, 927 F.2d 1283, 1298 (3d Cir. 1991) ("It is well established that failure to raise an issue in the district court constitutes a waiver of the argument.").

II. BACKGROUND

The following facts are alleged in Plaintiff's Verified Complaint, ECF No.1. Plaintiff is the developer of a pharmaceutically pure dehydroepiandrosterone ("DHEA") product called "Prastera" for sale as a medical food.[2] (ECF No. 1 ¶ 15.) DHEA is typically sold as a dietary supplement for women with systemic lupus erythematosus ("lupus"). (*Id.* ¶ 11.)

On September 13, 2012, Plaintiff sent a letter to FDA asking for FDA's review of the labeling of the product. (*Id.* ¶ 18; ECF No. 3, Ex. 18.) One month later, FDA responded as follows:

> We are in receipt of your letter dated September 12, 2012 re: Medical Food Package Insert Review for the proposed product, Prastera. While we do not do premarket reviews or approvals for proposed medical food products (including review of any associated label or labeling), upon cursory review, we do not see how this product meets the burden of the statutory definition for medical foods. In fact, we have some serious questions and concerns related to the proposed marketing of Prastera as a medical food.

(*See* ECF No. 1 ¶ 18; ECF No. 3, Ex. 19.)

Plaintiff sent two additional letters to FDA inquiring as to the nature of FDA's concerns about the product. (ECF No. 1 ¶ 19; ECF No. 3, Exs. 20, 21.) In response, an employee of FDA left a voice message for Plaintiff providing additional detail as to the nature of FDA's concerns

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[2] The term "medical food" is defined in the Federal Food, Drug, and Cosmetic Act ("FDCA"). The statute states:

> The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

21 U.S.C. § 360ee(b)(3).

about the product. (ECF No. 1 ¶ 19.) First, FDA stated that a dietary supplement ingredient is not automatically marketable as a medical food. (ECF No. 1 ¶¶ 19-20; ECF No. 3, Ex. 22.) Second, FDA stated that it was not aware of any distinctive nutritional requirements that have been established for lupus. (ECF No. 1 ¶¶ 19-21; ECF No. 3, Ex. 22.) FDA concluded:

> First and foremost, the product must meet the burden of the statutory definition of medical food. Based on the materials you provided, along with other publicly-accessible studies and resources, this product does not appear to meet that standard.

(ECF No. 1 ¶ 19; ECF No. 3, Ex. 22.) Subsequently, Plaintiff attended an in-person meeting with FDA, during which FDA reiterated its concerns. (ECF No. 1 ¶ 22.) During that meeting FDA allegedly "threatened enforcement action," "noted [] that it can seize mislabeled product," and "threatened to seize Plaintiff's product as allegedly not complying with [the statute]." (*Id.*)

In response to FDA's alleged threats, on June 13, 2013, Plaintiff filed a complaint in this Court seeking a declaration that Plaintiff's Prastera product meets every element of the statutory definition of "medical food." *See generally Health Sci Funding LLC v. Food & Drug Administration*, 13-cv-3663-CCC-MF (D.N.J. 2013), ECF No. 1. Plaintiff also filed a motion for a preliminary injunction barring an FDA enforcement action against Plaintiff's product during the litigation. *Id.*, ECF Nos. 6, 7. FDA responded by filing a motion to dismiss the complaint. *Id.*, ECF No. 11. Magistrate Judge Mark Falk held a conference with the parties on October 31, 2013, during which FDA allegedly "agreed to leave Plaintiff alone" and "Plaintiff reciprocated by staying its request for a Declaratory Judgment." (ECF No. 1 ¶ 26.) On November 4, 2013, the matter was stayed and administratively terminated without prejudice, and the pending motions were denied without prejudice. Case No. 13-3663, ECF No. 19.

From November 2013 until June 19, 2015, the parties appear to have had no communications. On June 19, 2015, FDA inspectors Michael Klapal and Tonia Bernard of FDA's

Parsippany, NJ District Office visited Plaintiff and allegedly advised that FDA intended to seize Plaintiff's product. (ECF No. 1 ¶ 27.) On June 20, 2015, Plaintiff allegedly contacted Judge Falk's chambers and asked that he "review the situation." (*Id.* ¶ 28.) Plaintiff asserts that Judge Falk held a conference during which FDA informed him that "there was no live controversy," "that no one at FDA headquarters had threatened enforcement action," and that FDA would send a letter to that effect. (*Id.* ¶ 29.) Plaintiff further asserts that both Plaintiff and Judge Falk agreed that there was no live controversy. (*Id.*)

On July 2, 2015, FDA sent a letter to Plaintiff in which FDA confirmed that it was "not aware of anyone at FDA headquarters who has threatened the product with immediate seizure." (ECF No. 3, Ex. 28.) FDA also informed Plaintiff that they disagreed with any characterization of the 2013 litigation as having been settled, noting that no settlement agreement exists between the parties. (*Id.*) They further pointed out that all motions in that case were denied, including Plaintiff's preliminary injunction motion seeking to enjoin FDA from taking enforcement action. (*Id.*) And they noted that neither Judge Falk nor this Court made any findings concerning the regulatory status of Plaintiff's product. (*Id.*)

Plaintiff forwarded FDA's letter to Judge Falk. (ECF No. 1 ¶ 31.) Plaintiff alleges that Judge Falk suggested that FDA notify Plaintiff in advance of any enforcement action. (*Id.*) Upon FDA's alleged refusal, Plaintiff claims that Judge Falk "agreed that Plaintiff could file the instant action." (*Id.*)

On July 20, 2015, Plaintiff filed the Verified Complaint in this action seeking a declaration that its product meets the statutory definition of "medical food" provided by the FDCA. (ECF No. 1.) Plaintiff's Verified Complaint also seeks an injunction enjoining FDA from taking enforcement action against Plaintiff's product. (*Id.*) On September 26, 2015, Plaintiff filed a

Motion for a Preliminary Injunction seeking to enjoin FDA from commencing or prosecuting any enforcement action against Plaintiff for alleged violations of the FDCA. (ECF No. 8.) FDA responded to Plaintiff's motion on October 19, 2015, and filed a cross Motion to Dismiss the Verified Complaint for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1) and alternatively for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6).

III. LEGAL STANDARD

A. Subject Matter Jurisdiction

Federal courts have only limited jurisdiction to entertain certain lawsuits and therefore the party seeking to invoke federal court jurisdiction bears the burden of proving subject matter jurisdiction. *See Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994). "Under Rule 12(b)(1), the [C]ourt's jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of a jurisdictional fact)." *Ezeiruaku v. Bull*, No. 14-2567, 2014 U.S. Dist. LEXIS 155306, at *3 (D.N.J. Nov. 3, 2014) (citing *Gould Electronics Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000)). "The substantive distinction between a facial attack and a factual attack is that in a facial attack the defendant contests the sufficiency of the complaint, while a factual attack challenges the existence in fact of federal subject matter jurisdiction." *LaLoup v. United States*, 29 F. Supp. 3d 530, 536 (E.D. Pa. July 10, 2014). In considering a facial challenge to subject matter jurisdiction under Rule 12(b)(1), the Court considers "the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." *Gould*, 220 F.3d at 176; *Taliaferro v. Darby Twp. Zoning Bd.*, 458 F.3d 181, 188 (3d Cir. 2006). Accordingly, the complaint must be dismissed if the allegations on the face of the complaint, accepted as true, fail to "allege facts

sufficient to invoke the jurisdiction of the district court." *Licata v. U.S.P.S.*, 33 F.3d 259, 260 (3d Cir. 1994).

"Article III of the Constitution limits the jurisdiction of federal courts to 'Cases' and 'Controversies.'" *Lance v. Coffman*, 549 U.S. 437, 439 (2007). Accordingly, as a threshold jurisdictional matter, a declaratory judgment action must present an actual case or controversy. *Luis v. Dennis*, 751 F.2d 604, 607 (3d Cir. 1984). In order to present an actual case or controversy,

> [t]he controversy must be definite and concrete, touching the legal relations of parties having adverse legal interests. It must be a real and substantial controversy admitting of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.

Aetna Life Insurance Co. v. Haworth, 300 U.S. 227, 240-41 (1937) (internal citations omitted).

One aspect of the case-or-controversy requirement is embodied in the "ripeness doctrine". Specifically in the context of judicial review of administrative actions, the Supreme Court has been reluctant to apply declaratory judgment and injunctive remedies "unless these arise in the context of a controversy 'ripe' for judicial resolution." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967). The Supreme Court has stated:

> [The] basic rationale [of the ripeness doctrine] is 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. The Supreme Court has provided two factors to consider in determining ripeness: (1) the fitness of the issues for judicial resolution; and (2) the hardship to the parties of withholding court consideration. *Id.*at 149. In evaluating the fitness of issues for judicial resolution, consideration must be given to the Administrative Procedure Act ("APA"). *See Id.*; *see also* 5 U.S.C. § 700 *et seq.* Specifically, the Court must consider whether review is being sought of

"'final agency action' within the meaning of § 10 of the Administrative Procedure Act, 5 U.S.C. § 704, as construed in judicial decisions." *Id.* Furthermore, the fitness of the issues for judicial resolution depends on whether the issue tendered is a purely legal one. *Id.* If the issue depends on facts that must be developed further within the context of an administrative record, it is not fit for judicial resolution.

Another related aspect of the case-or-controversy requirement is standing. *Lance*, 549 U.S. at 439; *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) ("[T]he core component of standing is an essential and unchanging part of the case-or-controversy requirement of Article III."). "The standing inquiry focuses on whether the party invoking jurisdiction had the requisite stake in the outcome when the suit was filed." *Constitution Party v. Aichele*, 757 F.3d 347, 360 (3d Cir. 2014) (citing *Davis v. FEC*, 554 U.S. 724, 734 (2008)). To establish standing, a plaintiff must satisfy a three-part test, showing:

> (1) an 'injury in fact,' *i.e.*, an actual or imminently threatened injury that is 'concrete and particularized' to the plaintiff; (2) causation, *i.e.*, traceability of the injury to the actions of the defendant; and (3) redressability of the injury by a favorable decision by the Court.

Nat'l Collegiate Athletic Ass'n v. Gov. of N.J., 730 F.3d 208, 218 (3d Cir. 2013) (citing *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009)).

IV. DISCUSSION

A. Plaintiff's claims for relief are not ripe.

Plaintiff's Verified Complaint seeks a declaration by this Court that the labeling on Plaintiff's product meets the statutory definition of "medical food" set forth in 21 U.S.C. § 360ee(b)(3). Plaintiff also seeks an injunction enjoining FDA from taking any enforcement action against Plaintiff's product once the product is declared a "medical food." For the reasons that follow, those claims are not ripe under the Declaratory Judgment Act and the APA.

Plaintiff's Verified Complaint asks this Court for an advisory opinion as to whether a product that it intends to sell will fall within a definition provided by the FDCA—a statute that FDA is charged with enforcing. FDA, however, has not enforced, nor made any attempt to enforce that statute against Plaintiff or its products. FDA has taken no agency action—let alone "final agency action" within the meaning of the APA—that would render this case fit for judicial resolution. If and when FDA does attempt to enforce the statute, through the use of administrative procedures that will result in the development of an administrative record and a final agency action, Plaintiff will have a claim ripe for judicial resolution.

The Supreme Court's decision in *Ewing v. Myteinger & Cassleberry, Inc.* is instructive. 339 U.S. 594 (1950). In *Ewing*, the Court determined that a district court "had no jurisdiction to review [an] administrative determination of probable cause" because "[t]he determination of probable cause in and of itself had no binding legal consequence . . . ." *Id.* at 600. Similarly, in this case, FDA has taken no action that has any legal consequence for Plaintiff. Plaintiff contends that there will be no further administrative proceedings because FDA admits that it has no statutory requirement or process for pre-marketing review of medical foods. However, FDA does have pre-enforcement review procedures that it will—and must be allowed to—follow in order to develop an administrative record for a district court to review. *See, e.g.*, 21 U.S.C. §§ 332, 334, 337(a).

Furthermore, the issue presented to this Court is not a purely legal one. To the contrary, it depends almost entirely on scientific facts about the product and the disease it purportedly manages (*e.g.*, whether lupus requires specific dietary management or has distinctive nutritional requirements). Plaintiff summarily states in its Verified Complaint that its product meets each and every one of the elements in the definition of "medical food" set forth in 21 U.S.C. § 360ee(b)(3) and therefore it is a medical food "as a matter of law." (ECF No. 1 ¶ 36.) However, whether the

product actually meets each element in the statute—an issue which FDA challenges—presents questions of scientific fact best decided by FDA prior to this Court's review.

Because FDA has taken no final agency action and there is no developed administrative record for this Court to review, Plaintiff's claims are not ripe. Accordingly, this Court lacks subject matter jurisdiction to consider them.

B. Plaintiff lacks standing to bring its claims for injunctive relief.

Plaintiff's Verified Complaint explicitly requests a preliminary injunction enjoining FDA from taking enforcement action against it during the pendency of this litigation. (ECF No. 1 at ¶¶ 40-52.) It cannot be ignored, however, that Plaintiff's Complaint implicitly seeks a permanent injunction enjoining FDA from taking enforcement action against Plaintiff's product. Ultimately, for similar reasons to those discussed above, Plaintiff has not suffered any actual or imminent injury. Additionally, Plaintiff does not have standing because any alleged injury is not redressable by this Court.

In confirming the correctness of its prior decision in *Ewing*, the Supreme Court in *Abbott Labs.* stated:

> The drug manufacturer in *Ewing* was quite obviously seeking an unheard-of form of relief which, if allowed, would have permitted interference in the early stages of an administrative determination as to specific facts, and would have prevented the regular operation of the seizure procedures established by the act.

Abbott Labs., 387 U.S. at 148. This case presents a similar request for an "unheard-of form of relief" which would prevent FDA from following its own procedures to determine whether to take enforcement action against Plaintiff. Plaintiff has not alleged any statutory or common law authority that allows this Court to grant such relief. Accordingly, even assuming Plaintiff can show that the case is ripe and it has suffered some injury caused by FDA, that injury is not

redressable by this Court. Accordingly, Plaintiff lacks standing to bring its claims for injunctive relief.

C. Other pending motions

Because the Court does not have subject matter jurisdiction over Plaintiff's claims, the Court need not reach the issue raised by FDA's Motion to Dismiss of whether the Verified Complaint states a claim upon which relief can be granted. Furthermore, for substantially the same reasons, Plaintiff's preliminary injunction motion is moot.

However, the Court notes that Plaintiff's claims appear to depend entirely on Plaintiff's argument that the FDCA authorizes individual doctors to determine whether a product qualifies as a "medical food." Plaintiff anchors this argument in an interpretation of the words "established by medical evaluation" in 21 U.S.C. §§ 360ee(b)(3) as requiring an individual doctor's medical evaluation of an individual patient. (*See e.g.*, ECF 1 ¶ 21.) Plaintiff, however, points to no legal authority for this strained reading of the statute. Moreover, FDA succinctly sums up the unworkability of such an interpretation as follows:

> The patient-specific medical evaluation confirms that the product is appropriate for that patient, but such an individualized determination cannot substitute for the agency's regulatory decision about whether the product is a medical food in the first instance.

(ECF No. 14 at 8.) Accordingly, even if this Court had jurisdiction (which it does not), Plaintiff's Verified Complaint appears to fail to state a claim upon which relief can be granted.

As for Plaintiff's preliminary injunction motion, Plaintiff bears the burden of showing that all four preliminary injunction factors weigh in its favor: (1) likelihood of success on the merits; (2) immediate irreparable harm; (3) balance of the hardships; (4) public interest. *See, e.g.*, *Pappan Enters. v. Hardee's Food Sys.*, 143 F.3d 800, 803 (3d Cir. 1998). The Third Circuit has stated that

a failure to establish any one of the factors renders a preliminary injunction inappropriate. *ACE Am. Ins. Co. v. Wachovia Ins. Agency Inc.*, 306 F. App'x 727, 730-31, (3d Cir. 2009).

The Court finds that Plaintiff has not carried its burden on any of the four factors. For the reasons described above, Plaintiff has not shown it is likely to succeed on the merits. Furthermore, Plaintiff has not shown that it has suffered or will suffer any harm, let alone immediate irreparable harm. *See Adams v. Freedom Forge Corp.*, 204 F.3d 475, 488 (3d Cir. Pa. 2000) ("[For a preliminary injunction] the risk of irreparable harm must not be speculative."). Regarding the balance of the hardships, any harm Plaintiff claims to suffer is outweighed by FDA's interest in exercising discretion with respect to enforcement and regulatory decision making. *See Mobil Oil Expl. & Producing Se., Inc. v. United Dist. Cos.*, 498 U.S. 211, 230 (1991) ("An agency enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures and priorities."). For similar reasons, the Court also finds that the public interest lies in allowing FDA to undertake its administrative procedures in cases such as these. *See id.*; *see also Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 543 (1978) ("[A]dministrative agencies should be free to fashion their own rules of procedure and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties.").

V. CONCLUSION

For the reasons set forth above, FDA's Motion to Dismiss (ECF No. 12) is GRANTED. Plaintiff's Motion for a Preliminary Injunction (ECF No. 8) is DENIED. An appropriate order accompanies this Opinion.

Dated: May 31, 2016

CLAIRE C. CECCHI, U.S.D.J.