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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HEALTH SCIENCE FUNDING, LLC, Plaintiff, v. THE UNITED STATES FOOD & DRUG ADMINISTRATION and STEPHEN OSTROFF, in his official capacity as Acting Commissioner of the FDA, Defendants.	HON. CLAIRE C. CECCHI 2:15-cv-05635-CCC-MF **BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION** Motion Date: November 2, 2016

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INTRODUCTION

The United States Food and Drug Administration ("FDA") and Stephen Ostroff, in his official capacity as Acting Commissioner of FDA ("Defendants"), submit this brief in support of their motion to dismiss plaintiff's complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) and in opposition to plaintiff's motion for a preliminary injunction.

Plaintiff seeks unique judicial treatment for its product, Prastera, which no other sponsor enjoys: the ability to market that product without the possibility of FDA enforcement action, even before FDA has evaluated it to determine whether it may be lawfully marketed. Prastera contains dehydroepiandrosterone ("DHEA"), a hormone that is made by the human body and is commonly sold over the counter as a dietary supplement. Plaintiff believes that Prastera is a "medical food" useful in treating patients with lupus. Compl. ¶ 11. Plaintiff previously sought the same relief that it does now: a declaration from this Court that its product is a medical food and a preliminary injunction to prevent FDA from taking any enforcement action until the Court issues the declaratory judgment that it seeks.

In this new lawsuit, plaintiff asserts that this Court should pave the way for this unprecedented marketing opportunity because, according to plaintiff, it had an "agreement" with FDA that FDA would not take an enforcement action, and FDA has "reneged" on that agreement by threatening enforcement action. But there is no such agreement or threat of enforcement, nor does plaintiff point to anything that would qualify as such. Plaintiff's desire for special judicial treatment to enforce an imaginary agreement has no merit.

Plaintiff's claims suffer from fatal jurisdictional defects and the premature judicial review it seeks ignores settled principles of judicial review under the Administrative Procedure Act ("APA"). None of the actions that FDA has taken amount to either enforcement action or final agency action with respect to plaintiff—FDA has not even taken the basic, preliminary step of

sending plaintiff a warning letter, which in itself would not be final agency action. FDA has not made any final decision about the regulatory status of plaintiff's product. Plaintiff's request that this Court usurp FDA's authority to make a product classification determination in the absence of any cognizable cause of action is unfounded. Plaintiff's claims are not ripe for adjudication. In addition, under settled law, plaintiff may not bring this preenforcement challenge to an action that FDA could conceivably bring in the future.

Plaintiff has also failed to demonstrate that it meets the requirements for obtaining preliminary relief. Plaintiff is not likely to succeed on the merits. Nor does it harm plaintiff to be put in the same regulatory position as other firms who do not enjoy the special treatment it seeks. Further, the balance of harms weighs strongly in favor of respecting the existing regulatory process so that FDA retains flexibility to evaluate products and take any actions it deems may be appropriate in a timeframe that accounts for its many public health priorities.

BACKGROUND

I. Statutory and Regulatory Background

Due to the relatively uncommon manner in which plaintiff seeks to offer its product for sale as a medical food, we briefly summarize the pathways by which medical foods and other, similar products may be legally offered for sale.

A. Medical Foods

Congress defined a "medical food" as part of the Orphan Drug Act Amendments of 1988:

> [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).

Common examples of medical foods that meet the statutory definition include nutritional

formulas to manage metabolic disorders, such as foods that are free of phenylalanine, a commonly occurring substance in food that is toxic to people with phenylketonuria.

FDA has further clarified the statutory definition of "medical food" by regulation, exempting products from certain nutrition labeling requirements if:

> (i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
>
> (ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
>
> (iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
>
> (iv) It is intended to be used under medical supervision; and
>
> (v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

21 C.F.R. § 101.9(j)(8).

After FDA promulgated this regulation through notice and comment rulemaking, it issued an advanced notice of proposed rulemaking ("ANPRM") in 1996, further explaining its thinking for medical foods, and emphasizing the following principles when evaluating these products:

> 1. A product marketed for use as a medical food in the dietary management of a disease or condition should have characteristics that are based on scientifically validated distinctive nutritional requirements of the disease or condition.
>
> 2. There should be a scientific basis for the formulation of the product and the claims made for the product.
>
> 3. There should be sound, scientifically defensible evidence that the product does what it claims to do.

61 Fed. Reg. 60661 (November 29, 1996), at 60666-67. FDA emphasized that efficacy claims would need to be supported by a "strong standard of substantiation," stating that its "preliminary view is that the scientific standard contained in the statutory medical food definition may require

some of the same types of data for medical foods as are needed to support drug claims (e.g., data from clinical investigations)." *Id.* at 60671. FDA did not view the physician as independently determining whether a product is a medical food, but rather as relying upon the labeling when evaluating the product for patient care:

> A physician relies on the claims made for medical foods on their labels and in their labeling as a significant factor in deciding whether to use a particular medical food in the clinical management of a patient. Thus, it is essential that the claims made for such a product present an accurate interpretation of the scientific evidence concerning the usefulness of that product or specific formulation. It is critical for the safe and appropriate use of the medical food that the claims made for it are accurate and unbiased, and that they are based on a critical evaluation of the science available to the manufacturer. The need for physicians and patients to have confidence that any claim that a product is a medical food formulated for the specific dietary management of a disease or condition requires that a strong standard of substantiation be in place. A strong standard of substantiation would be one that requires that all pertinent data be considered in the formulation of the product and in the development of any claims about its use.

Id. at 60669-70. More recently, FDA has issued revised draft guidance expressing a narrow construction of the definition of "medical foods":

> FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food. Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition, and all foods fed to sick patients are not medical foods.[1]

Unlike drugs, medical foods do not undergo FDA premarket review. Medical foods are subject to certain other requirements pertaining to foods. Any component of a medical food

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[1] *See* Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition (Rev. Aug. 2013) ("Draft Medical Food Guidance"), at 4, *available at* http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/UCM362995.pdf (*citing* Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrition Content Revision proposed rule (56 Fed. Reg. 60366 at 60377, Nov. 27, 1991)).

must be (1) a food additive used in accordance with the agency's food additive regulations (21 C.F.R. § 172); (2) a color additive used in accordance with the agency's color additive regulations (21 C.F.R. §§ 73, 74); (3) a substance that is generally recognized, by qualified experts, to be safe under the conditions of its intended use (21 U.S.C. § 321 (s), 21 C.F.R. § 170.30); or (4) a substance that is authorized by a prior sanction issued by FDA (21 C.F.R. § 170.3(e)(l)). Medical foods that contain unapproved food additives are deemed unsafe, 21 U.S.C. § 348(a), and adulterated under 21 U.S.C. § 342(a)(2)(C). DHEA has never been approved as a food additive for any use in food, nor is FDA aware of any basis for the general recognition of safety based either on scientific procedures or common use in food prior to January 1, 1958. In addition, among other requirements, medical foods must be prepared, packed, and held in compliance with current good manufacturing practice requirements applicable to foods. 21 C.F.R. pt. 110.[2]

B. Drugs

As relevant here, a drug is defined as: (1) an article "recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States or official National Formulary, or any supplement to any of them;" (2) an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease"; or (3) an article "(other than food) intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1). If a sponsor wishes to market a drug, it must submit an application for approval unless the product meets specific exceptions (described further below). 21 U.S.C. § 355(a). A sponsor must show substantial evidence that the drug is effective, defined, in part, as "consisting of adequate and well-controlled investigations, including clinical investigations." 21 U.S.C. § 355(d)(7).

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[2] *See* Draft Medical Food Guidance at 6.

Certain exceptions to this requirement for premarketing approval may apply.[3] For instance, a very narrow class of drugs marketed before 1938 (or, as relates to efficacy, before 1962) and which contain in their labeling the same representations concerning the conditions of use before 1938 may be "grandfathered." *Id.* FDA describes this exception in its Compliance Policy Manual Guide for Marketed New Drugs Without Approved NDAs and ANDAs:

> FDA believes that there are very few drugs on the market that are actually entitled to grandfather status because the drugs currently on the market likely differ from the previous versions in some respect, such as formulation, dosage or strength, dosage form, route of administration, indications, or intended patient population. If a firm claims that its product is grandfathered, it is that firm's burden to prove that assertion. *See* 21 CFR 314.200(e)(5).

Id.

C. Dietary Supplements

DHEA is widely available in dietary supplement products.[4] The Dietary Supplement Health and Education Act of 1994 defines a dietary supplement product as:

> a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an amino acid, an herb or other botanical; or a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, a metabolite, a constituent, an extract, or a combination of any ingredient described above; and intended for ingestion in the form of a capsule, powder, softgel, or gelcap, and not represented as a conventional food or as a sole item of a meal or the diet

21 U.S.C. § 321(ff).

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[3] *See generally* Compliance Policy Guide, Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs (Sept. 2011), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074382.htm.

[4] *See, e.g.*, NIH Dietary Supplement Label Database, *available at* http://dsld.nlm.nih.gov/dsld/index.jsp. Of note, DHEA is reportedly banned by the Olympics, the World Anti-Doping Agency, and several other athletic associations. *See* Anne E. Kornblut and Duff Wilson, How One Pill Escaped the List of Controlled Steroids, NY Times (Apr. 17, 2005), *available at* http://www.nytimes.com/2005/04/17/national/17steroid.html?pagewanted=1&_r=0. DHEA may be available in different forms. Plaintiff, for example, has obtained a patent claiming, *inter alia*, a micronized version of DHEA. *See* Patent. No. 8,900,631, *available at* http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=8900631.PN.&OS=PN/8900631&RS=PN/8900631.

As relevant here, the labeling of dietary supplements (and conventional foods) may bear certain "health claims," which describe a relationship between a food, food component, or dietary supplement ingredient, and *reducing the risk* of getting a disease or health-related condition. *See* Claims That Can Be Made for Conventional Foods and Dietary Supplements (Sept. 2003), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm. By contrast, after a patient actually develops a disease or health-related condition, any claims that a product is intended to *treat* that condition would make that product a drug; it would no longer be considered a dietary supplement.

Dietary supplements may also be labeled for certain claims that they are intended to affect the structure or function of the human body, with appropriate disclaimers that FDA has not evaluated the claim, and that "this product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 343(r)(6). And dietary supplement labeling may also claim a benefit related to a classical nutrient deficiency disease, if they also disclose the prevalence of the disease in the United States, among other requirements. *Id.* Dietary supplement manufacturers are subject to current good manufacturing practice requirements at 21 C.F.R. part 111.

D. FDA Inspections, Warning Letters and FDA Enforcement Actions

FDA conducts routine and for-cause inspections of FDA-regulated entities. *See* 21 U.S.C. § 374(a). If, upon inspection, FDA observes violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), the agency may issue a "Warning Letter" to, among other things, give the company an opportunity to take voluntary corrective action before any enforcement is undertaken. FDA describes Warning Letters as "the agency's principal means of achieving prompt voluntary compliance with the [FDCA]." *Regulatory Procedures Manual*, ch. 4, § 4-1-1 (July 2012). *Available at* http://www.fda.gov/downloads/ICECI/ComplianceManuals/

RegulatoryProceduresManual/UCM074330.pdf. Warning Letters are "informal and advisory." *Id.* As such, a Warning Letter "communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued." *Id.; see also, e.g., Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944-945 (D.C. Cir. 2012).

By contrast, FDA may take enforcement actions. For example, FDA may: (1) initiate a seizure under 21 U.S.C. § 334 against adulterated or misbranded products; or (2) seek to enjoin sales of adulterated or misbranded articles under 21 U.S.C. § 332. *Regulatory Procedures Manual*, at §§ 6-1, 6-2. In the context of such an enforcement action, when the factual and legal bases have been developed, the subject of the action can take issue with FDA's position and may be able to obtain judicial review of the relevant issues.

Warning Letters ask for a response within 15 business days, giving the sponsor an opportunity to ask for more time if necessary. *See, e.g.*, Pl.'s Decl. Ex. 24. They generally state that failure to take prompt action to correct the problems "may result in enforcement action without further notice," but provide no timeframe in which such possible enforcement action may occur. *Id.*

II. Factual Background

A. Prastera and Early FDA Communications

A sponsor other than plaintiff submitted an NDA seeking approval of a product containing DHEA to treat lupus, but that application has not been approved.[5] Plaintiff would like to offer Prastera for sale as a medical food. The labeling of plaintiff's product describes it as "200mg oral softgel capsules supplied in a convenience package with ibuprofen oral tablets

[5] *See* Pl.'s Decl. Exs. 12, 13 (referring to NDA 21-239 for Systemic Lupus Erythematosus).

400mg." Pl.'s Decl. Ex. 17 at 1 (rev. 8/2013).[6] According to the labeling, Prastera is indicated "in female patients with mild to moderate, active [] systemic lupus erythematosus (SLE) to restore serum 5-dehydroandrosterone sulfate to levels typical of women without SLE. In Phase III clinical trials in female patients with mild to moderate active SLE, prasterone 200 mg was associated with reduced risk of auto-immune flare, reduced risk of breast cancer and reduced risk of death from any cause." *Id.*[7]

Plaintiff requested that FDA assess whether its product is a medical food, but FDA does not have an established process or available resources to make such assessments upon request (in contrast to the process for drug approvals). FDA responded to plaintiff as a courtesy, noting that it does not conduct such reviews and that "we do not see how this product meets the burden of the statutory definition for medical foods." *See* Letter from Benson Silverman to Mark Pohl (Oct. 17, 2012) (Pl.'s Decl. Ex 19). FDA also noted that "we have some serious questions and concerns related to the proposed marketing of Prastera as a medical food." *Id.* Later, plaintiff's counsel sought clarification and met with FDA officials on February 25, 2013. Pl.'s Decl. Ex. 23. Plaintiff alleges that FDA officials "threatened enforcement action" at this meeting. Compl. ¶ 22. There are no official FDA minutes of this meeting.

B. 2013 Litigation

Plaintiff sued the agency on June 13, 2013, seeking a declaration that its product is a medical food and an order enjoining FDA from taking any enforcement action against Prastera.

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[6] The (rev. 5/2013) labeling litigation described Prastera as packaged "with ibuprofen oral tablets ***300*** mg." *See Health Science Funding, LLC v. FDA*, No. 13-3663, Dkt. No. 7, Pl.'s Dec. Ex. 17 at 1 (emphasis added). Plaintiff also promotes Prastera Clear, described as "a convenience pack combining Prastera with an anti-acne topical." *See* www.prastera.com /#!/?page_id=663.

[7] In the previous litigation, the "indications and usage" statement in the (rev. 5/2013) version of the labeling did not claim reduced risk of breast cancer or reduced risk of death from any cause. *See Health Science Funding, LLC v. FDA*, No. 13-3663, Dkt. No. 7, Pl.'s Dec. Ex. 17 at 1.

See Health Science Funding, LLC v. FDA, No. 13-3663, Dkt. No. 1. This Court required the parties to attend a mandatory settlement conference, at which no transcript was made. Dkt. No. 17. After the settlement conference, on November 4, 2013, the Court, "with the consent of the parties and in an exercise of this Court's discretion to manage its docket" stayed the case and "administratively terminated" it "without prejudice." Dkt. No. 19. The Court stated that "Plaintiff may request to reopen this case within a calendar year from the date of this Order" and denied all pending motions without prejudice. *Id.* FDA consented to stay the case according to the terms set forth in the order, but did not make any separate agreement with plaintiff, nor has plaintiff provided any evidence of any such agreement.

C. Plaintiff's Communications and Litigation With States

In 2015, FDA became aware that Mr. Pohl was telling a North Dakota state official that this "court case concluded that [Prastera is] a Medical Food." Def.'s Ex. 1, at 1. Mr. Pohl also told the North Dakota official that "FDA recognizes" that Prastera is a "grandfathered drug," in an attempt to get North Dakota Medicaid to reimburse for Prastera. *Id.* Similarly, in an attempt to get New York to add Prastera to its Medicaid formulary for reimbursement, Mr. Pohl told a New York state official that Prastera is an "unapproved grandfathered prescription drug," and that FDA "lists it as such." Def.'s Ex. 2, at 1.

Plaintiff sued the New Jersey Division of Health and Human Services ("NJDHHS") on April 22, 2015, seeking an order requiring NJDHHS to reimburse for Prastera. *See Health Science Funding, LLC v. NJDHHS*, No. 15-2933, Dkt. No. 1. In that lawsuit, plaintiff asserted, in the first sentence of the introduction in its brief opposing dismissal, that "[t]he United States Food & Drug Administration (FDA) evaluated Plaintiff's product and (correctly) lists it as a grandfathered Drug." *See id.*, Defs. Ex. 6 at 1.

None of these characterizations about the previous litigation or about FDA's evaluation and recognition of Prastera as a grandfathered drug are correct.

D. 2015 Inspection and Current Litigation

FDA inspected Health Science Funding's facility on June 19, 2015. *See* Def.'s Ex. 3, at 1. Plaintiff's lawyer, Mr. Pohl, spoke with the investigators as the most responsible person at the firm. *Id.* They asked him questions about the ownership, business relationships, operations, and products manufactured, distributed, sold, or marketed by Health Science Funding LLC. *Id.* The investigators provided Mr. Pohl with the Marketed Unapproved Drugs Compliance Policy Guide 400.100 and Federal Register Docket No. FDA-2011-D-0633, which provide notice that unapproved drugs may be subject to enforcement action.[8] There, Mr. Pohl signed a document certifying that Health Science Funding "has not to date sold any Prastera." Def.'s Ex. 4, at 1.

Mr. Pohl also sought the investigators' confirmation of his characterization of a discussion in which he asserted that the 2013 litigation between Health Science Funding and FDA "resolv[ed] the regulatory status of Prastera, [and] that in settling that case FDA conceded that prasterone is a Medical Food and its current labeling is not improper." *Id.* at 2. Mr. Pohl asserted that "an unnamed person at FDA headquarters now threatens the product with immediate seizure as being an allegedly illegal Drug." *Id.* Mr. Pohl asked the investigators to send him a letter if they disagreed with his characterization of their discussion. *Id.* The Acting District Director of FDA's New Jersey District Office, Craig Swanson, responded to Mr. Pohl in a letter he received on July 15, 2015.[9] Pl.'s Decl. Ex. 28. He disagreed with the substance of

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[8] *See* Compliance Policy Guide, Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs (Sept. 2011), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074382.htm.

[9] The letter is incorrectly dated July 2, 2015; it was signed and sent to Mr. Pohl on July 14, 2015. *See* Def.'s Ex. 5, at 1.

Mr. Pohl's assertions about the litigation. *Id.* Mr. Swanson also responded to Mr. Pohl's assertion that someone at FDA had threatened enforcement action, stating that "we are not aware of anyone at FDA headquarters who has threatened the product with immediate seizure as being an "allegedly illegal Drug." *Id.*

After the inspection, this Court held two telephone conferences as part of *Health Science Funding, LLC v. FDA*, No. 13-3663, concerning plaintiff's assertions made in letters written to Magistrate Judge Falk about, *inter alia*, the inspection. *See* Dkt. No. 20 (teleconference of June 23, 2015); Dkt. No. 21 (teleconference of July 15, 2015). This Court did not take action to reopen the previous case. Plaintiff filed the instant case on July 20, 2015, again seeking a declaration that its product is a medical food, and an injunction to prevent FDA from taking enforcement action against plaintiff's product.

ARGUMENT

I. Plaintiff's Complaint Should Be Dismissed

Federal judicial power is limited by Article III of the Constitution to the resolution of "cases" and "controversies." *See, e.g.*, *Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 471 (1982). To invoke federal court jurisdiction, a party must establish the existence of a "justiciable controversy" with the adverse party—one that is "definite and concrete, touching the legal relations of parties having adverse legal interests." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937). The party invoking the jurisdiction of a federal court bears the burden of establishing that the court has jurisdiction. *S.R.P. v. United States*, 676 F.3d 329, 343 (3d Cir. 2012).

To state a claim upon which relief may be granted, the plaintiff must allege "any set of facts consistent with the allegations," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 (2007), that "possess enough heft to 'sho[w] that the pleader is entitled to relief,'" *id.* at 557 (citations

omitted). Upon review of a motion to dismiss for failure to state a claim under Rule 12(b)(6), the court must treat the complaint's factual allegations as true and draw all reasonable inferences in plaintiff's favor. *Warren Gen. Hosp. v. Amgen Inc.*, 643 F.3d 77, 84 (3d Cir. 2011). The court need not accept as true legal conclusions cast as factual allegations or inferences unsupported by facts set out in the complaint. *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007).

A. Plaintiff's Claims Are Not Ripe

Plaintiff is not entitled to judicial review because its claims are not ripe for adjudication. As the Supreme Court explained in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148 (1967), "injunctive 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." The purpose 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.

To determine whether an agency decision is ripe for review, courts examine "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 149. The fitness prong, in turn, depends upon (a) whether the claims raise purely legal questions, and (b) whether the challenge involves final agency action. *Id.* In evaluating the fitness of an issue for judicial review, courts consider whether the issue is "purely legal" and the agency action is final, or, on the other hand, 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). A court must stay its hand when "judicial intervention would inappropriately interfere with further administrative action." *Id.* at 733.

Plaintiff's complaint fails to satisfy the ripeness criteria because FDA has not taken any final agency action relating to plaintiff's product. Plaintiff states that FDA investigators "advise that Defendant now disavows its prior agreement and intends to seize Plaintiff's product." Compl. ¶ 2. But plaintiff cannot point to any imminent threat to seize its product, much less any prior agreement "to leave Plaintiff alone," Compl. ¶ 1, because there is no such agreement. While plaintiff may wish to market its product free of FDA oversight and regulation, any commitment by FDA that it would not take enforcement action before evaluating Prastera could potentially compromise the public health, and FDA has not made any such commitment. Neither has FDA threatened to seize plaintiff's product, as plaintiff repeatedly suggests.

Plaintiff cites an FDA letter that it says "accuses (without explaining why) Plaintiff's product of being illegitimate" and alleges that it "tacitly confirms that FDA headquarters authorized FDA's Acting District Director in FDA's Parsippany NJ office to [make a seizure threat]." Compl. ¶ 30. The letter, however, does no such thing. *See* Pl.'s Decl. Ex. 29. FDA disagreed with plaintiff's unfounded assertions that this Court had "resolved the regulatory status of Prastera" and that "FDA conceded that prasterone is a Medical Food." *Id.* But FDA did not otherwise characterize the regulatory status of prasterone, or describe it as "illegitimate." *Id.* Regarding the alleged seizure "threat," FDA's letter responded to plaintiff's specific allegation that someone at FDA headquarters had threatened seizure, and stated that "we are not aware of anyone at FDA headquarters who has threatened the product with immediate seizure." *Id.*; *see also* Def.'s Ex. 4 at 1 (plaintiff's June 19, 2015 letter to FDA investigators). This is not a "threat," but a *disavowal* of a threat from the very source that plaintiff originally identified.

Plaintiff now asserts that FDA's letter "tacitly confirms" that FDA headquarters authorized the district office to make a seizure threat, but the district's own documentation of the

inspection does not bear that out. Rather than threaten plaintiff with a seizure, the investigators provided plaintiff with a copy of FDA's Compliance Policy Manual to plaintiff. *See* Def.'s Ex. 3, at 2. This manual describes FDA's enforcement policies and states that all unapproved drugs are subject to seizure.[10] Reminding a regulated entity of FDA's enforcement authority during an inspection is standard agency practice and hardly remarkable.[11]

Plaintiff further points to the same alleged seizure threats that it cited in the previous 2013 litigation. *See* Compl. ¶ 22. But no enforcement action resulted from those alleged "threats," and FDA's skepticism about plaintiff's product during the 2013 meeting did not constitute an actionable "threat" of seizure then, any more than it does today.

Plaintiff also asserts injury based on Warning Letters that FDA has sent to *other* manufacturers, noting that they are "specifically designed to produce an *in terrorem* effect." Compl. ¶¶ 23, 24. But, as FDA has made clear, Warning Letters are "informal and advisory," and are intended to give recipients the opportunity to take voluntary corrective action.[12] Such letters "communicate[] the agency's position on a matter," but do not "commit FDA to taking enforcement action." *Id.* For this reason, courts have repeatedly and consistently held that such letters are not subject to judicial review. *See, e.g.*, *Holistic Candlers*, 664 F.3d at 944-945; *Mobil Expl. & Prod. U.S., Inc. v. Dep't of Interior*, 180 F.3d 1192, 1198-99 (10th Cir. 1999) (agency

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[10] *See* Compliance Policy Guide, Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs (Sept. 2011), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074382.htm.

[11] Nor do informal statements by FDA employees constitute a final agency action subject to judicial review. *See* 21 C.F.R. § 10.85(k) ("A statement or advice given by an FDA employee orally, or given in writing . . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.").

[12] *See* FDA *Regulatory Procedures Manual*, ch. 4, § 4-1-1 (2011) *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176860.htm.

letter not final where it served to "initiate further proceedings" and "was not the consummation of the agency's decisionmaking process"); *Dietary Suppl. Coal., Inc. v. Sullivan*, 978 F.2d 560, 563 (9th Cir. 1992) (holding that FDA regulatory letters do not constitute final agency action); *Am. Fed'n of Gov't Emps. v. O'Connor*, 747 F.2d 748, 752-53 (D.C. Cir. 1984) (dismissing claims challenging agency letter because it "binds neither the public nor any agency or officer of government. No precedent known to us sanctions court review of such nonbinding advisory expositions."); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (no jurisdiction to review action challenging FDA Warning Letters because "such letters do not commit the FDA to enforcement action"). Because warning letters themselves are not final agency action, plaintiff would not be able to maintain a suit against FDA based on such a letter even if one had been sent to *plaintiff* (which it has not). Plaintiff's attempt to bootstrap jurisdiction from warning letters sent to *other* manufacturers is unavailing. Compl. ¶ 23.[13]

Plaintiff asks this Court to step into the shoes of FDA, interpret the relevant statutory and regulatory provisions, and apply them to plaintiff's product. This would displace the agency's primary jurisdiction to determine in the first instance whether plaintiff's product may be legally offered for sale as a medical food. FDA, not this Court, is in the best position to interpret the relevant statute in view of other related provisions within the FDCA and apply its scientific expertise to determine whether a product meets the definition of a medical food, and whether an enforcement action may be appropriate if it does not. *See Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 983 (2005) ("[A]mbiguities in statutes within an agency's

[13] Plaintiff also misleadingly argues that FDA warning letters "uniformly threaten product seizure within 15 days." Compl. ¶ 25. Warning letters ask for a *written response* within 15 working days. The letters generally state elsewhere that, *e.g.*, "Failure to promptly correct violations *may* result in regulatory action being initiated by FDA without further notice, such as seizure and/or injunction." *See* Pl.'s Decl. Ex. 24A (emphasis added).

jurisdiction to administer are delegations of authority to the agency to fill the statutory gap in reasonable fashion. Filling these gaps . . . involves difficult policy choices that agencies are better equipped to make than courts."); *Sw. Pa. Growth Alliance v. Browner*, 121 F.3d 106, 117 (3d Cir. 1997) (noting that courts owe deference to "factual determinations within an agency's area of special expertise"). Plaintiff's claims are also unripe because, in addition to the unresolved question whether plaintiff's product is a "medical food," FDA has not considered whether the ingredients in plaintiff's product (including DHEA) are even lawful. *See* 21 U.S.C. § 342(a). Further, plaintiff's product is co-packaged with ibuprofen tablets. *See* Pl.'s Decl. Ex. 17, at 1. FDA has issued at least one warning letter stating that a product offered for sale as a medical food and co-packaged with a drug was a drug.[14] Thus, it is possible that plaintiff's product would not qualify as a medical food on this basis as well. Because FDA's position on these various issues has not "crystallized," as it would be in the context of an actual enforcement action (or a decision after reviewing an NDA), plaintiff's claims are manifestly premature.

Nor has plaintiff demonstrated that withholding judicial review now will cause it hardship. "[I]n order for the parties' hardship to be sufficient to overcome prudential interests in deferral, that hardship must be both immediate and significant." *Felmeister v. Office of Attorney Ethics, Div. of New Jersey Administrative Office of Courts*, 856 F.2d 529, 537 (3d Cir. 1988). Here, plaintiff claims only that it may have "potential loss of future sales," but, despite plaintiff's allegations of verbal threats since 2013, plaintiff's fear of such future losses has not yet crystallized. *Cf. Estee Lauder*, 727 F. Supp. at 5 (regulatory letter warning that FDA was "prepared" to take regulatory action imposed hardship "no greater than any company confronted

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[14] *See* FDA Warning Letter to Physician Therapeutics, L.L.C. (Apr. 8, 2010), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm208680.htm (stating that a therafeldamine (piroxicam 20 mg and theramine) copackaged product was considered to be a drug).

by an interpretation of a law it dislikes"). Plaintiff will not suffer any hardship if judicial review is postponed until such time as FDA may take concrete action against it or its product.

Even though plaintiff has chosen not to avail itself of formal processes that would result in final agency action, *see* Section I.D.2., *infra*, plaintiff will not suffer hardship because plaintiff would obtain meaningful review in the event that FDA actually brings an enforcement action in the future. Then, and only then, will FDA have gathered the necessary evidence, analyzed the relevant facts, and made the requisite administrative determinations to permit meaningful judicial review. But because formal procedures for rendering a premarket decision about plaintiff's product do not exist, and FDA may never bring an enforcement action, plaintiff's claim of any hardship "is not ripe for adjudication" because "it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *See Texas v. United States*, 523 U.S. 296, 300 (1998) (internal quotation marks omitted).

B. FDA Enforcement Action May Not Be Enjoined

Not only does this Court lack jurisdiction to review this suit, but the relief plaintiff seeks runs afoul of well-established Supreme Court and appellate precedent. Plaintiff seeks to preemptively enjoin FDA from taking future enforcement action against its product. Compl. at 20 (prayer for relief). Such preenforcement challenges are foreclosed by the Supreme Court's holding in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), wherein the plaintiff sought judicial review of FDA's determination that there was probable cause to believe that the its products violated the FDCA, a necessary prerequisite to the government initiating a seizure of the products. The Supreme Court ruled that the district court lacked jurisdiction to review FDA's pre-seizure probable cause determination because "[j]udicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the [FDCA]" envisioned by Congress in enacting the statute. *Id.* at 600-01 (observing that the

plaintiff would have ample opportunity to litigate any constitutional, statutory, or factual claims in the enforcement action).

The Supreme Court reaffirmed the *Ewing* principle in *Abbott Laboratories v. Gardner*, calling it "clearly correct." *Abbott*, 387 U.S. at 147. As the Court observed, the "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 [FDCA]." *Id.* at 148. The rule articulated in *Ewing* has been "consistently and strictly observed" by the lower courts, which have held that the decision "precludes judicial interference with the FDA's decision to institute enforcement actions, whatever the precise context." *United States v. Alcon Labs.*, 636 F.2d 876, 881-82 (1st Cir. 1981).[15]

If and when FDA decides that future enforcement action is warranted because of FDCA violations, it has the discretion to initiate, e.g., a seizure or injunction. *See* 21 U.S.C. §§ 332, 334. Should FDA initiate an enforcement action in the future, plaintiff would have a full opportunity to raise and litigate the claims that it advances here. Then, and only then, may such claims properly be heard.

Similarly, plaintiff is not entitled to advance notice of any such enforcement action. *See* Pl.'s Mem. at 11. FDA's refusal to give any advance notice is not, as plaintiff contends, "belligerent," *id.*, but reasonably necessary to ensure that firms do not attempt to evade any

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[15] *See also Se. Minerals, Inc. v. Harris*, 622 F.2d 758, 764 n.10 (5th Cir. 1980) (explaining that *Ewing* "expresses a total and complete proscription of the district court's power both to undertake a pre-enforcement review . . . and to enjoin federal officials from . . . seizing products or initiating enforcement proceedings under the [FDCA]"); *Pharmadyne Labs., Inc. v. Kennedy*, 596 F.2d 568 (3d Cir. 1979) (affirming dismissal of injunction on *Ewing* grounds); *Parke, Davis & Co. v. Califano*, 564 F.2d 1200, 1205-06 (6th Cir. 1977) (reversing, on *Ewing* grounds, a district court's injunction against FDA).

action by diverting product or flooding the market and thereby further endanger the public health, and to assure that any judicial review proceeds upon a final record.

C. Plaintiff Has Failed To State a Valid Claim Under the APA

Plaintiff has failed to plead a valid cause of action. *See United States v. Nordic Village, Inc.*, 503 U.S. 30, 34 (1992)) ("Where the United States is the defendant . . . federal subject matter jurisdiction is not enough; there must also be a statutory cause of action through which Congress has waived sovereign immunity.").[16] The only statute capable of providing the requisite waiver of sovereign immunity for plaintiff's claims is the APA, 5 U.S.C. §§ 701-706. Section 702 of Title 5 waives sovereign immunity for certain suits seeking to obtain judicial review of agency action (or, in some cases, inaction), but, like all waivers of sovereign immunity, it must "be strictly construed, in terms of its scope, in favor of the sovereign." *Dep't of Army v. Blue Fox, Inc.*, 525 U.S. 255, 261 (1999). As shown below, even if this Court had jurisdiction to review plaintiff's claims and generously construed those claims as falling within the ambit of the APA, plaintiff has still failed to sustain a valid action.

1. Plaintiff Has No Claim Because FDA Has Not Taken Final Agency Action

Plaintiff has failed to state a valid claim under the APA because even plaintiff recognizes that FDA has not undertaken the final agency action of determining whether plaintiff's product is a medical food. *See Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (holding that, to be final agency action, it must (1) "mark the consummation of the agency's decisionmaking process – it must not be of a merely tentative or interlocutory nature"; and (2) "must be one by which rights

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[16] The general federal question statute, 28 U.S.C. § 1331, does not waive the government's sovereign immunity. *Swan v. Clinton*, 100 F.3d 973, 981 (D.C. Cir. 1996). 28 U.S.C. § 1346 narrowly waives sovereign immunity only for certain tax refund cases and claims for money damages. Likewise, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, is not an independent basis for subject matter jurisdiction or a waiver of sovereign immunity. *C&E Serv., Inc. v. D.C. Water & Sewer Auth.*, 310 F.3d 197, 201 (D.C. Cir. 2002) (citing cases).

or obligations have been determined, or from which legal consequences will flow"). FDA has neither determined the status of plaintiff's product nor affected any of plaintiff's "rights or obligations." Plaintiff can only point to Warning Letters received by *other* manufacturers for products that are distinct in many ways from plaintiff's product—letters that cannot provide the requisite final agency action needed for review under the APA. Compl. ¶ 23. In *Holistic Candlers*, the D.C. Circuit dismissed plaintiff's claim on that basis alone because an FDA warning letter is not final agency action. 664 F.3d at 946 (noting that the "APA . . . only provides a right to judicial review of 'final agency action for which there is no other adequate remedy in a court.'").

2. Plaintiff Would Have No Valid Claim For Unreasonable Delay

Nor could plaintiff plausibly allege that FDA has unreasonably delayed or unlawfully withheld action on its request for a determination that its product is a medical food. *See* Compl. ¶ 43 (stating that "FDA flatly refuses to explain in writing its alleged concerns"). Any such claim would be without merit because there can be no unreasonable delay where there is no statutory process for premarket review of products to assess whether they meet the definition of a "medical food," and no legal requirement that FDA provide such a determination at all, let alone within a particular timeframe.

Although the APA gives a reviewing court authority to compel agency action unreasonably delayed, *see* 5 U.S.C. 706, such action "can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required* to take." *See Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63 (2004) (emphasis in original). "The limitation to required agency action rules out judicial direction of even discrete agency action that is not demanded by law." *Id.*; *see also Massie v. HUD*, 620 F.3d 340, 347 (3d Cir. 2010).

Further, should FDA elect to take enforcement action against plaintiff, the timing of such enforcement decisions is "committed to agency discretion by law."[17] *See, e.g.*, *Heckler v. Chaney*, 470 U.S. 821, 829 (1985); *see also Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 543 (1978) ("administrative 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") (citations and quotations omitted); *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.") (citations omitted).

D. Plaintiff Has Failed To State a Claim Upon Which Relief Can Be Granted

Even if this Court had jurisdiction to hear plaintiff's claim—whether under the APA or otherwise—plaintiff has still failed to state a claim upon which relief can be granted. This is because even though plaintiff's factual allegations are taken as true for purposes of this motion, plaintiff's claim that this Court should declare its product to be a "medical food" fails as matter of law. Products such as plaintiff's may be legally offered for sale as a medical food only if they meet the statutory and regulatory definition of a "medical food." This is a question for FDA to decide in the first instance. To protect consumers against unsubstantiated labeling claims and to avoid a proliferation of unapproved drug products disguised as medical foods, FDA has narrowly

[17] By contrast, plaintiff could have filed an NDA and would have benefitted from the more specific performance goal timeframes and processes applicable to that type of application. Moreover, plaintiff could have sought a formal determination of the agency's views by filing a citizen petition under 21 C.F.R. § 10.30. Plaintiff argues that "FDA has "refus[ed] to memorialize its alleged concerns," Pl.'s Mem. at 14, but plaintiff has failed to initiate any process that would require such a response.

interpreted the definition of medical food.[18] Plaintiff argues that its product meets each of the statute's elements and qualifies as a medical food "[a]s a matter of law." Compl. ¶ 36. Plaintiff also asserts that the issue of whether a disease has "distinctive nutritional requirements" is for a physician, and not FDA, to decide. Compl. ¶ 38. Plaintiff is wrong on both counts.

1. FDA Has Delegated Authority To Determine Medical Foods

FDA interprets the definition of "medical food" in the governing statute to require a strong showing that the disease or condition at issue needs "specific dietary management" and has "distinctive nutritional requirements, based on recognized scientific principles[ ] established by medical evaluation." 21 U.S.C. § 360ee(b)(3). Absent these and other limitations, the statute would create a gaping regulatory loophole by allowing manufacturers to offer their products for sale as medical foods for the dietary management of specific diseases or conditions without ever having to demonstrate generally that the disease or condition had a distinctive nutritional requirement in the first instance. Physicians, rather than being able to rely on labeling statements, would have to constantly second-guess them to provide appropriate patient care.

Plaintiff's preferred scheme would supplant FDA's jurisdiction to determine whether a product is a "medical food," and instead make the entire regulatory system turn on whether individual physicians agree with the manufacturer's labeling claims. If each individual physician made such a determination, there would be no regulatory system at all. The statute does not contemplate such a free-for-all. *See Mohamad v. Palestinian Auth.*, __ U.S. __, 132 S. Ct. 1702, 1707 (2012) (reading statute in view of context and to avoid an absurd result "Congress could not plausibly have intended"). This interpretation also ignores how labeling works: physicians

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[18] *See, e.g.*, FDA Warning Letter to Nestle Healthcare Nutrition (Dec. 3, 2009) (rejecting medical food claim because "[t]here is no evidence that patients with the medical condition of 'failure to thrive' have distinctive nutritional requirements or unique nutrient needs"), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm194121.htm.

rely on labeling claims when making treatment decisions: "The need for physicians and patients to have confidence that any claim that a product is a medical food formulated for the specific dietary management of a disease or condition requires that a strong standard of substantiation be in place." 61 Fed. Reg. 60666-67. The statute contemplates that the physician has a patient-specific confirmatory role, but does not turn the physician into a regulator.

FDA is unaware of any other instance in which a provision of the FDCA has been interpreted to allow for such potentially arbitrary regulation, in which doctors who unwittingly believe labeling claims (or go the extra mile to attempt to independently verify them) would provide the requisite imprimatur so that a manufacturer could legally offer its product for sale as a medical food, but such a product would not qualify if an individual doctor were more skeptical. Plaintiff even concedes that patients' medical records are not publicly available, and thus that there would be no basis to verify whether a physician has made the requisite judgment to qualify a product as a medical food. Compl. ¶ 21. Thus, it is not even clear that plaintiff's own product would qualify as a medical food, even if plaintiff's interpretation of the statute were correct. Moreover, and more fundamentally, because medical foods are not prohibited by federal law from being dispensed without a prescription, consumers could conceivably buy plaintiff's product without any physician oversight, and without any independent assurance (from FDA or a physician) that the labeling claims were correct.[19]

FDA has been delegated authority to interpret its organic statute, and to decide whether a product is a medical food and whether a disease or condition needs specific dietary management and has distinctive nutritional requirements. *See* 21 U.S.C. § 371(a) (granting FDA general authority to issue binding, substantive regulations). FDA's interpretation of the statute must be

[19] The requirement for a prescription in 21 U.S.C. § 353(b) and 21 C.F.R. § 201.100 only applies to dispensing drug products, not medical foods.

upheld if reasonable. *See Nat'l Cable & Telecomms.*, 545 U.S. at 983; *Sw. Pa. Growth Alliance*, 121 F.3d at 117. Plaintiff's contrary interpretation, which only serves to benefit itself, would upend the complex, interrelated regime governing drug approvals, dietary supplements, and medical foods. Its interpretation is not grounded in reality and should be soundly rejected.

2. Plaintiff Does Not Establish That Its Product Is a Medical Food

Although FDA has not formally considered Prastera's regulatory status, it has serious reservations about plaintiff's claims. Even if plaintiff were correct that lupus patients may benefit from DHEA (a hormone), plaintiff has not shown that lupus results in a "distinctive nutritional requirement" for DHEA, as required by 21 U.S.C. § 360ee(b)(3).[20] Whether the symptoms of a disease or condition are mitigated through the use of a certain substance is not relevant to whether that disease or condition has a "distinctive nutritional requirement" that can be managed with a medical food. Plaintiff ignores that a medical food must be intended for the *dietary management* of a disease or condition. 21 C.F.R. § 101.9(j)(8)(ii). By contrast, a product intended to cure, mitigate, or treat a disease is a drug. 21 U.S.C. § 321(g)(1)(B).

In addition, DHEA is not an approved food additive or otherwise subject to a statutory exemption from the food additive requirements of the FDCA. *See* 21 U.S.C. §§ 321(s), 348(a).[21]

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[20] The studies plaintiff cites do not qualify its product as a medical food as a matter of law. Plaintiff cites a 1987 study showing decreased levels of different androgens in women with lupus, including DHEA, but such low levels do not necessarily mean the low levels (of DHEA) would qualify as a "distinctive nutritional requirement," or that lupus is subject to dietary management with DHEA. Pl.'s Dec. Ex. 4 at 244. Plaintiff also cites clinical studies purporting to show that DHEA may reduce the frequency and severity of lupus autoimmune flares. Pl.'s Dec. Ex. 9-11. Each of these studies appears to have evaluated the potential for DHEA to *treat* lupus, and did not consider whether it is a distinctive nutritional requirement. *See, e.g.*, Ex. 10 at 2924 ("The present study was designed to evaluate the safety and efficacy of DHEA in treatment of female patients with mild-to-moderate [lupus] disease activity."); Ex. 11 at 2858 ("*Objective*. To determine whether prasterone administration results in improvement or stabilization of systemic lupus [] disease activity and its symptoms.").

[21] *See* Draft Medical Food Guidance at 9.

Nor is FDA aware of any basis for the general recognition of safety based either on scientific procedures or common use in food prior to January 1, 1958. *See id.* Unapproved food additives are "presumed unsafe" and a food containing an unapproved food additive is adulterated. 21 U.S.C. § 348(a); 21 U.S.C. § 342(a)(2)(C).[22]

A host of other questions surround plaintiff's product—and are alone sufficient to preclude a finding that the product is a medical food as a matter of law. For instance, plaintiff's labeling indicates the product is packaged in combination with ibuprofen, which may render it a drug. Pl.'s Decl. Ex. 17. Plaintiff's labeling has also changed to include additional indications (reducing the risk of breast cancer and death), as well as changing the amount of ibuprofen from 300mg to 400mg. *See* Pl.'s Decl. Ex. 17, at 1. And differences between plaintiff's "pharmaceutically-pure" DHEA product and other DHEA products may raise other concerns that could impact the regulatory status of Plaintiff's product. *See* Compl. ¶ 15. FDA has not finally considered any of these matters for plaintiff's product, each of which independently precludes it from being declared a "medical food" as a matter of law.

II. Plaintiff's Motion for a Preliminary Injunction Should Be Denied

Preliminary injunctive relief is an "extraordinary" remedy that "may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. NRDC, Inc.*, 555 U.S.

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[22] Plaintiff asserts that its product is "safe," citing its exhibits 13 and 25. Compl. ¶ 51. Exhibit 13 is a postmarketing safety review for DHEA in the context of FDA's review of NDA 21239, which is not approved. Of the adverse events FDA reviewed, "[a]pproximately 40% of the cases were concerning." Although FDA "identified no clear safety signals," FDA noted that "the overall numbers of cases in each of these body systems were small and many cases confounded by concomitant or co-suspect medication." Pl.'s Decl. Ex. 13, at 1-2. Similarly, FDA's review in Exhibit 25 concludes: "*No meaningful conclusion about the association of exogenously administered DHEA and cancer risk can be made* based on these epidemiologic studies of endogenous levels of DHEA." *Id.* at 6 (emphasis added). Neither of these exhibits establishes that FDA has concluded that DHEA is safe, or that it is generally recognized as safe. *See* 21 C.F.R. § 170.30.

7, 22 (2008); *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008). To qualify for preliminary injunctive relief, a party must demonstrate "(1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief." *Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004). While all four elements are essential, the Third Circuit has held that a court may not grant injunctive relief, "regardless of what the equities seem to require," unless the movant carries its burden of establishing both a likelihood of success and irreparable harm. *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484 (3d Cir. 2000).

A. Plaintiff Is Not Likely To Succeed On the Merits

Plaintiff has no likelihood of success on the merits because, as demonstrated above, its Complaint is subject to dismissal in its entirety due to lack of jurisdiction and for failing to state a claim upon which relief can be granted. Plaintiff seeks an injunction "during the pendency of this action and until further Order of this Court" to "enjoin FDA from "[c]ommencing or prosecuting any enforcement action against Plaintiff, its agents, its Prastera product, the physicians who prescribe it, and/or patients who use it, for alleged violations of the Federal Food Drug & Cosmetic Act." Pl.'s Proposed Order, Dkt. # 8-2.[23] But for all of the reasons described above, plaintiff's claim that this Court should usurp FDA's role to interpret and apply the medical food statute has no merit, and should be dismissed outright. Because plaintiff cannot establish any likelihood of eventual success on the merits of its claims, this Court should deny plaintiff's request for extraordinary, emergency relief. *See Munaf*, 553 U.S. at 689-90.

[23] In addition to lacking any likelihood of success on the merits for the Prastera-related claims, the text of plaintiff's proposed order is overbroad, and would, for example, enjoin FDA from taking enforcement action against any patient taking Prastera for any FDCA-related claim, even if such a claim were unrelated to Prastera use.

B. Plaintiff Has Not Established It Will Suffer Irreparable Harm

Plaintiff has also failed to demonstrate that it will suffer irreparable harm absent injunctive relief or that the balance of hardships tips in its favor. Courts insist that only irreparable harm that is likely justifies the issuance of a preliminary injunction. *Winter*, 555 U.S. at 22. Nor is a mere "possibility" of irreparable harm sufficient to justify such relief; plaintiffs seeking preliminary relief must show that irreparable injury is likely. *Winter*, 555 U.S. at 22-23.

Moreover, a preliminary injunction is not appropriate where the harm is speculative and contingent upon future events. *See, e.g., O'Shea v. Littleton*, 414 U.S. 488, 493-495 (1974). "It must be alleged that the plaintiff 'has sustained or is immediately in danger of sustaining some direct injury' as the result of the challenged statute or official conduct." *Id*. at 494 (quoting *Massachusetts v. Mellon*, 262 U.S. 447, 488 (1923)); *Hohe v. Casey*, 868 F.2d 69, 72 (3d Cir. 1989) (plaintiff has the burden of proving a "clear showing of immediate irreparable injury").

Plaintiff does not come close to satisfying this standard. Plaintiff contends that FDA's alleged "threat of seizure chills Plaintiff's willingness to market its product, and chills physicians' willingness to prescribe it." Compl. ¶ 44; Pl. Mem. at 14. Plaintiff does not quantify any harm, but rather speculates that its harm is a "potential loss of future sales and market share," which it characterizes as "irreparable harm" as a matter of law. *Id*. Plaintiff cites *Novartis Consumer Health*, but in that case the court affirmed a finding of irreparable harm because of a showing of a *present* injury to market share. 290 F.3d at 595-96. This Circuit has cited with approval "well-settled law that injunctions will not be issued merely to allay the fears and apprehensions or to soothe the anxieties of the parties." *Cont'l Group, Inc. v. Amoco Chems. Corp.*, 614 F.2d 351, 359 (3d Cir. 1980) (internal citations omitted).

Plaintiff concedes that FDA "has pointedly refrained from taking any" enforcement action (Compl. ¶ 46), and plaintiff has not even received a warning letter for its product. Given

that FDA has not taken enforcement action against any of the medical food manufacturers who have actually received warning letters, any claim that FDA will imminently take action against plaintiff is far-fetched. For all of these reasons, plaintiff cannot meet its burden of establishing that it will suffer irreparable injury in the absence of preliminary injunctive relief.

Moreover, plaintiff could minimize any harm of regulatory uncertainty to itself by filing a new drug application under 21 U.S.C. § 355(b), or by providing documentation to attempt to establish that its product is a "grandfathered" drug, as plaintiff asserts in other litigation. *See Health Science Funding, LLC v. NJDHHS*, No. 15-2933, Defs.' Ex. 6, at 1. Indeed, it is curious that plaintiff even brings this action seeking a declaration that its product is a medical food, given that at least three states do not provide reimbursement for medical foods, and such reimbursement is clearly important to Plaintiff.[24] *Id.* Plaintiff attempts to have it both ways, but FDA does not regulate medical foods as drugs, and different requirements apply to each. *See, e.g.*, Draft Medical Foods Guidance at 5 ("Medical foods are not drugs.").

In these circumstances, where Congress has not provided a premarket approval pathway for medical foods, plaintiff's choice to attempt to market its product as a medical food (at least to FDA, if not to states) has inherent regulatory uncertainty. Such uncertainty is not "irreparable harm," but the necessary result of the choice that plaintiff has made.

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[24] Plaintiff even claims that FDA "evaluated Plaintiff's product and (correctly) lists it as a grandfathered Drug." *Id.* Plaintiff has refused to provide its affidavit in that litigation to defendants, which was filed under seal and is not available to the public. Further, it appears that plaintiff was relying on a printout from an FDA label search at http://labels.fda.gov, which does not represent a finding by FDA of a product's regulatory status, as the website expressly disclaims. *See Health Science Funding, LLC v. NJDHHS*, No. 15-2933, Dkt. No. 15, at 7 (NJDHHS's reply memorandum discussing misplaced reliance on FDA's website).

C. The Balance of Harms and the Public Interest Weigh Against Relief

The balance of harms also weighs against an injunction because plaintiff's desire for a more certain regulatory landscape in which to market its product does not outweigh FDA's interest in its exercise of enforcement discretion and the timing of its regulatory decisionmaking without judicial interference. *See, e.g.*, *Mobil Oil*, 498 U.S. at 230 ("An agency enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures and priorities."). Moreover, it is certainly not in the public interest to waste judicial resources adjudicating unripe disputes. *See Abbott Labs.*, 387 U.S. at 148. Plaintiff touts its product to treat lupus, asserting that a court order would save four women's lives every day. Compl. ¶ 53; Pl.'s Mem. at 17. While it is certainly in the public interest to save lives, plaintiff has not demonstrated that its product is capable of doing so, nor has it demonstrated that it should be given a judicial green light to offer its product for sale to patients who might be misled by unsubstantiated labeling claims.[25]

CONCLUSION

For the foregoing reasons, plaintiff's complaint should be dismissed with prejudice and its motion for a preliminary injunction should be denied.

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[25] Plaintiff's apparent misrepresentations to the states and the court should preclude equitable relief in its favor. In seeking to have Prastera be recognized both as a grandfathered drug and a medical food, plaintiff asserted to North Dakota that, *inter alia*, this Court has "concluded that it's a Medical Food." Def.'s Ex. 1. Nor has FDA "evaluated" the product and listed it as a grandfathered drug, as plaintiff baldly asserts in the NJDHHS litigation. *See Health Science Funding, LLC v. NJDHHS*, No. 15-2933, Dkt. No. 13, at 1.

Date: October 19, 2015

Respectfully submitted,

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