DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
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Hon. Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, DC 20436

OCT 0 6 2017

Re: Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form, Docket No. 3247

Dear Secretary Barton:

On behalf of the United States Food and Drug Administration ("FDA"), we write to express FDA's views to the Commission on the above-referenced Complaint.[1] FDA respectfully submits that the Commission should decline to initiate the requested investigation. As pled, Complainants' claims—unfair methods of competition under the Tariff Act based on false advertising under the Lanham Act and violations of the Federal Food, Drug, and Cosmetic Act ("FDCA")—can succeed only if the Commission finds that Respondents' products are unapproved "new drugs" rather than "dietary supplements" under the FDCA. The Complaint here is predicated on open questions of law and policy on which FDA has not reached final conclusions.[2] Any such findings by the Commission on those issues may conflict with later determinations by FDA. Further, through the Complaint, Complainants attempt an unlawful private FDCA enforcement action based on Complainants' allegations, not on FDA's findings. As detailed below, because Congress has authorized only FDA to initiate FDCA enforcement actions, the FDCA precludes claims that would require the adjudicator to interpret, apply, or enforce the FDCA. For Complainants to succeed on any of their claims, the Commission would have to do all three of those things.

A. FDA Has Not Determined Whether The Challenged Products Are Drugs Or Dietary Supplements.

The FDCA and its implementing regulations set forth the legal definitions of "drugs," "new drugs," and "dietary supplements," as well as legal requirements for, among other things, the distribution of such products in interstate commerce. *See, e.g.*, 21 U.S.C. §§ 321(g)(1), (p), 355, 21 C.F.R. Part 314 (drugs and new drugs); 21 U.S.C. §§ 321(ff), 350b, 21 C.F.R. Part 190 (dietary supplements). Congress has delegated to FDA the authority to determine whether products are "drugs," "new drugs," and/or "dietary supplements." *See, e.g.*, 21 U.S.C. §§ 355,

[1] The Office of Unfair Import Investigations ("OUII"), Complainants (Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.), and the Council for Responsible Nutrition, a trade association representing dietary supplement manufacturers, have sought FDA's views on this matter.

[2] As explained below, Complainants' suggestion that their arguments here "do not turn on open questions of law or policy" under the FDCA, *see* Amarin Juris. Br. at 24, is mistaken.

350b; *see generally Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973) ("The heart of the new procedures designed by Congress [for determining whether a product is a 'new drug'] is the grant of primary jurisdiction to FDA."); *Hi-Tech Pharms, Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1331 (N.D. Ga. 2016) (the determination of whether a product marketed as a "dietary supplement" is instead a "new drug" is one that "Congress has delegated exclusively to the FDA").

The FDA statutory scheme is undeniably "complex."[3] For example, to be a dietary supplement, a product must, among other things, contain one or more "dietary ingredients." 21 U.S.C. § 321(ff)(1). "Dietary ingredients" include, among other things, "a dietary substance for use by man to supplement the diet by increasing the total dietary intake," or "a concentrate, metabolite, constituent, extract, or combination of any" other dietary ingredient or ingredients. 21 U.S.C. § 321(ff)(1)(E)&(F).[4] And a manufacturer wishing to market a dietary supplement which contains a "new dietary ingredient" ("NDI")—defined as a dietary ingredient that was not marketed in the United States before October 15, 1994—must submit a pre-market notification to FDA unless the NDI and any other dietary ingredients in the dietary supplement "have been present in the food supply as an article used for food in a form in which the food has not been chemically altered." 21 U.S.C. § 350b; *see also* 21 C.F.R. § 190.6.

Because of this complex statutory scheme, determinations of whether a product is a dietary supplement require case-specific analysis, as very small differences in factors such as an ingredient's chemical structure or history of presence in the food supply can mean the difference between dietary-ingredient status and non-dietary-ingredient status. In other words, the determination requires, among other things, a careful and thorough scientific review of the ingredients of the product at issue as well as review of the history of those ingredients. Any determination by the Commission on those issues in this case may conflict with later determinations by FDA on the same issues.

Moreover, FDA is in the process of developing a guidance document for industry on when a dietary supplement ingredient is an NDI, when the manufacturer of a dietary ingredient or supplement should submit an NDI notification, the evidence needed to document the safety of an NDI, appropriate methods for establishing the identity of an NDI, and related issues. FDA guidance documents "describe the agency's interpretation of or a policy on a regulatory issue," 21 C.F.R. § 10.115(b), and are one of the tools Congress gave to the agency for the administering the FDCA, *see* 21 U.S.C. § 371(h)(1)(A) (the "Secretary shall develop guidance documents with public participation," and those documents "present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration").

FDA initially published a draft guidance document on NDI issues for public comment in 2011. *See* 76 F.R. 39111, *Draft Guidance for Industry; Dietary Supplements: New Dietary*

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[3] *See, e.g.*, *Boehringer Ingelheim Pharma GMBH & Co. v. FDA*, 195 F. Supp. 3d 366, 380 (D.D.C. 2016) (noting FDA's "long experience in administering this complex statute"); *Hi-Tech Pharms, Inc.*, 230 F. Supp. 3d 1323 at 1331; *see also Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 627 (noting that Congress created an "expert agency"—FDA—to administer the FDCA).

[4] *See also* 21 U.S.C. § 321(ff)(1)(A)-(D)&(F) (addressing additional substances that qualify as "dietary ingredients").

Ingredient Notifications and Related Issues; Availability (Jul. 5, 2011). FDA received thousands of comments on the initial draft guidance, and issued a revised draft guidance in 2016. *See* 81 F.R. 53486, *Dietary Supplements; New Dietary Ingredient Notifications and Related Issues: Revised Draft Guidance for Industry; Availability* (Aug. 12, 2016).[5] To date, FDA has received over 300 comments on the revised draft guidance, some of which address issues raised in the Complaint. Accordingly, a Commission finding on issues raised in the Complaint could conflict with later-finalized FDA guidance.

In the revised draft guidance, FDA stated its willingness to compile an authoritative list of pre-October 15, 1994, dietary ingredients based on independent and verifiable data to be supplied by industry. Comments submitted regarding the revised draft guidance generally support the idea that FDA should develop a list of pre-October 15, 1994, dietary ingredients, but reflect varying opinions on the standard of evidence for demonstrating that an ingredient was marketed before October 15, 1994, and on the process by which ingredients should be added to the list. Because FDA believes that public discussion of these issues will be beneficial to the agency in developing the list, FDA held a public meeting on these issues on October 3, 2017. *See* 82 F.R. 42098, *Development of a List of Pre-Dietary Supplement Health and Education Act Dietary Ingredients; Public Meeting; Request for Comments* (Sept. 6, 2017). A Commission finding on issues raised in the Complaint here could conflict with any later FDA-finalized list of pre-October 15, 1994, dietary ingredients.

Furthermore, FDA is concerned that initiation of the investigation requested by Complainants could create an incentive for other parties to file similar complaints about other FDA-regulated products. FDA's regulatory authority is not limited to foods (which include dietary supplements) and drugs. Under complex statutory and regulatory regimes, FDA also regulates a broad range of other types of products, including biologics, blood products, cosmetics, medical devices, medical foods, radiation-emitting devices, tobacco products, vaccines, and animal drugs. Just like in this case, Commission investigations involving those types of products would present the possibility of the Commission reaching findings that conflict with FDA findings.

Accordingly, even if Complainants have pled a viable claim (which, as explained below, they have not), FDA believes that the Commission should decline to initiate an investigation under principles of comity to FDA—the federal agency that has the congressionally-delegated authority to determine the status of the products at issue. Complainants contend that the requested investigation will not intrude on FDA's jurisdiction because the Tariff Act provides that the Commission will "consult with, and seek advice from," relevant federal agencies, including FDA. *See* Amarin Juris. Br. at 18 (quoting 19 U.S.C. § 1337(b)(2)). But the Tariff Act also requires "expeditious adjudication" and conclusion of investigations "at the earliest practical time" after initiation of the investigation. *See* 19 U.S.C. § 1337(b)(1). FDA respectfully submits that consultation with FDA during such an expedited process is not an adequate substitute for FDA's normal regulatory process.

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[5] The 2016 revised draft guidance is available on FDA's website at www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm515733.pdf.

B. Private Parties Have No Private Right of Action Under The FDCA

Because FDA is the expert agency responsible for determining whether products comply with the FDCA, Congress gave FDA a number of enforcement tools to address the distribution of products in violation of the FDCA. For example, FDA may initiate a civil injunction action against a firm distributing such products. *See* 21 U.S.C. §§ 331(a)-(d), 332. In such an action, a district court can enjoin the firm from continuing to distribute the product at issue. *See, e.g.*, *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547 (D.N.J. 2004). Other enforcement mechanisms include seizure of violative products, civil money penalties, and criminal prosecution of individuals and firms. 21 U.S.C. §§ 331, 333, 334; *see also, e.g.*, *Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (discussing enforcement mechanisms available to FDA); *United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692 (D. Md. 2001) (seizure of unapproved new drugs); *United States v. Kaminski*, 2008 WL 1886008 (S.D. Ohio Apr. 28, 2008) (criminal prosecution for distribution of unapproved new drugs).[6]

But while Congress gave *FDA* these and other tools to enforce the FDCA, Congress prohibited *private parties* from bringing actions to enforce the FDCA. *See* 21 U.S.C. § 337(a) ("all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States"); *see also, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the [FDCA.]"); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 936 (6th Cir. 2014) ("because the FDA has exclusive power to enforce the FDCA, there is no private right to enforce the statute").

The reason that the FDCA prohibits private enforcement actions—including unfair trade practice and false advertising actions that seek to enforce the FDCA—is straightforward. FDA cannot administer and enforce the FDCA effectively if core FDA issues—such as whether a product is a "new drug" or a "dietary supplement" under the FDCA—are decided in actions brought by private parties. After all, "Congress's decision to centralize authority to determine the legality of drug sales in the FDA was obviously intended to provide uniformity of administration" of the FDCA, *JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 1005 (C.D. Cal. 2014) (quotation and citation omitted), and allowing private parties to bring enforcement actions—either in courts or in other federal agencies—threatens such uniformity of administration. *See also Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 624 (noting FDA "cannot administer the Act intelligently and rationally unless it has authority to determine what drugs are 'new drugs' under [21 U.S.C. § 321(p)].").

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[6] FDA may take other steps short of enforcement action to address products that appear to be violative. For example, FDA may issue import alerts to detain violative products at the border. *See* 21 U.S.C. § 381(a). FDA may also issue a Warning Letter to the firm identifying violations of the FDCA and asking the firm to take voluntary corrective action. *See FDA Regulatory Procedures Manual*, p. 4-2 (Mar. 2017) (available at www.fda.gov). A Warning Letter is "informal and advisory," and "FDA does not consider Warning Letters to be final agency action." *Id.* at 4-3; *see also Holistic Candlers and Consumers Ass'n v. FDA*, 664 F.3d 940 (D.C. Cir. 2012) (finding that FDA Warning Letter was not final agency action).

Indeed, in keeping with these principles, less than a year ago (and more than two years after the Supreme Court's *POM Wonderful* decision) the Commission's Staff correctly recognized: "the Staff believes that a cause of action is likely not precluded by the FDCA *if* it does *not* require the Commission to directly apply, enforce, or interpret the FDCA." *See* Staff Response to Respondents' Motion for Summary Determination Dismissing Claims Precluded by the FDCA in *In the Matter of Certain Potassium Chloride Powder Prods.*, Inv. No. 337-TA-1013, EDIS Doc. I.D. 593245 at 4 n.2 (Oct. 21, 2016) (emphasis added). *A fortiori*, the FDCA *would* preclude such a claim if—as is the case here—it required the Commission to directly apply, enforce, or interpret the FDCA.

Similarly, even after *POM Wonderful*, courts continue to routinely recognize that because the FDCA prohibits private enforcement actions, the FDCA "preclude[s] Lanham Act claims" where, "in order to determine the falsity or misleading nature of the representation at issue, the court would be required to interpret and apply FDCA statutory [and] regulatory provisions." *Hi-Tech Pharms, Inc.*, 230 F. Supp. 3d at 1330 (quotation and citation omitted). *See also, e.g.*, *Intra-Lock Intern., Inc. v. Choukroun*, 2015 WL 11422285, *7 (S.D. Fla. May 4, 2015) ("because the FDCA forbids private rights of action under the statute, a private action brought under the Lanham Act may not be pursued when the claim would require litigation of the alleged underlying FDCA violation in circumstances where the FDA has not itself concluded there was such a violation") (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010)); *Church & Dwight Co, Inc. v. SPD Swiss Precision Diagnostics*, 104 F. Supp. 3d 348, 361 (S.D.N.Y. 2015) ("*POM Wonderful* did not disturb the longstanding proposition that private parties may not use the Lanham Act as a vehicle to enforce the FDCA. That is, because the FDCA does not contain a private right of action, claims that require a court to interpret, apply, or enforce the FDCA remain precluded.");[7] *Catheter Connections, Inc. v. Ivera Med. Corp.*, 2014 WL 3536573, *4 (D. Utah. Jul. 17, 2014) ("because no private right of action exists under the FDCA, a plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation," and Lanham Act "claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA") (quoting *Cottrell, Ltd. v. Biotrol, Int'l*, 191 F.3d 1248, 1254-55 (10th Cir. 1999)).

The Complaint requires interpretation, application, and enforcement of the FDCA. Specifically, Complainants' claims—whether styled as a Tariff Act claim, a Lanham Act claim, or an FDCA claim—all depend on the allegation that the products at issue are falsely labeled as "dietary supplements" because they do not meet the FDCA definition of "dietary supplements" and instead meet the FDCA definition of "new drugs." *See, e.g.*, Complaint at ¶ 60 (alleging that labeling the products "as 'dietary supplements' is literally false because these products (i) cannot meet the definition of 'dietary supplement" in section 201(ff) of the FDCA, 21 U.S.C. § 321(ff)

[7] Although Complainants' "Jurisdictional Brief" relies heavily on *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), that case is inapposite here. In *POM Wonderful*, the Court ruled that the FDCA did not preclude a private party from bringing a Lanham Act claim alleging that certain fruit juice labeling was misleading even though FDA regulates juice labels. Unlike this case, however, *POM Wonderful* did not require the tribunal to interpret, apply, or enforce the FDCA. And, as the above-cited cases demonstrate, even after *POM Wonderful*, courts have adhered to the principle that the FDCA precludes Lanham Act claims when those claims amount to attempts to interpret, apply, or enforce the FDCA.

and (ii) are being referred to as 'dietary supplements' to hide the fact that they are actually unapproved 'new drugs.'"); ¶ 120 (alleging that Tariff Act and Lanham Act claim is based on false statements that the products can be used in "'dietary supplements' when these products are actually unapproved 'new drugs.'").[8] In short, in order to resolve any of Complainants' claims, the Commission will necessarily have to step into the shoes of the FDA to interpret, apply, and enforce the FDCA. But the FDCA precludes such action.

Finally, we note that FDA has, in the past, addressed questions regarding the regulatory status of certain products through the agency's citizen petition process. *See* 21 C.F.R. §§ 10.25(a), 10.25(b) ("FDA has primary jurisdiction to make initial determinations on issues within in statutory mandate"); 10.30;[9] *see also, e.g.*, 70 F.R. 69976, *Request for Comment on Status of Pyridoxamine* (Nov. 18, 2005); FDA Response to Citizen Petition, Docket No. FDA-2005-P-0259 at p.3 (Jan. 12, 2005) ("FDA has concluded that a product containing pyridoxamine is not a dietary supplement under the Act because pyridoxamine is excluded from the dietary supplement definition under the prior market clause in 21 U.S.C. § 321(ff)(3)(B)(ii).").[10]

For these reasons, FDA respectfully requests that the Commission decline to initiate the requested investigation.

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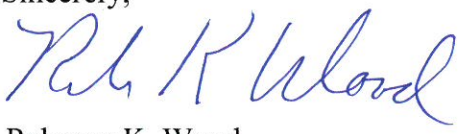
[8] *See also, e.g.*, ¶¶ 58, 61-68, 70-71, 79, 82, 84-88, 92-93, 95-100, 102, 106-107, 109-111, 113, 116-120, 124-127, 131-134, 138-141, 144-146, 151-154, 158-161, 168-169, 171-172, 178-180, 184, 186-187, 191-193, 197-198, 200-202 (all citing the FDCA).

[9] Generally, FDA must respond to a citizen petition within 180 days, although that response may be a tentative response. *See* 21 C.F.R. § 10.30(e)(2)(iv).

[10] Available at https://www.regulations.gov/document?D=FDA-2005-P-0259-0004.

Sincerely,

Anna K. Abram
Deputy Commissioner for
Policy, Planning, Legislation, and Analysis
U.S. Food and Drug Administration



Rebecca K. Wood
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U.S. Food and Drug Administration

CERTIFICATE OF SERVICE

I hereby certify that I have obtained the consent of Anna K. Abram to file the forgoing letter, and that the forgoing letter was served on the following parties on October 6, 2017, as indicated below:

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