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October 13, 2017

The Honorable Lisa Barton
Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, DC 20436

Re: ***Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form, Docket No. 3247*** **Complainants' Reply To FDA's October 6, 2017 Submission**

Dear Secretary Barton:

On behalf of complainants, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively, "Amarin"), we respectfully request leave to file the attached submission titled Amarin's Response To FDA's October 6 Submission, which responds to the October 6, 2017 letter brief filed by the U.S. Food and Drug Administration ("FDA") requesting the Commission not to institute the above-referenced investigation.

Good cause exists to accept Amarin's Response To FDA's October 6 Submission. Although the Commission's rules contain no provision authorizing pre-institution submissions from other governmental agencies, the FDA filed extensive submissions on the topic of the Commission's jurisdiction and authority to institute this Section 337 investigation. If the Commission accepts FDA's submission, it also should accept Amarin's submission so that it has a more complete understanding of Amarin's views on the Commission's jurisdiction over Amarin's complaint.

For the foregoing reasons, Amarin respectfully requests leave to file Amarin's Response To FDA's October 6 Submission.

Respectfully submitted,

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Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

UNITED STATES INTERNATIONAL TRADE COMMISSION

In The Matter Of	)	
	)	
Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form	)	**Docket No. 3247**

AMARIN'S RESPONSE TO FDA'S OCTOBER 6, 2017 SUBMISSION

INTRODUCTION AND OVERVIEW

On behalf of complainants, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively, "Complainants" or "Amarin"), we submit this reply to the October 6, 2017 letter filed by the Food and Drug Administration ("FDA") urging the Commission not to institute an investigation into the allegations in Amarin's complaint. The Commission should decline FDA's request for three reasons: (1) FDA's request fails to take into account the statutory scheme under Section 337 of the Tariff Act, which requires the Commission to institute an investigation where, as here, the complaint is properly pled and also builds in processes to ensure interagency comity; (2) Amarin is not attempting an unlawful private enforcement of the federal Food, Drug and Cosmetic Act ("FDCA"), nor is it asking the Commission to break new ground or to act outside of its expertise or authority; and (3) FDA's request intrudes upon the Commission's jurisdiction and attempts to eliminate a remedy that Congress provided to competitors and the domestic industry under the Lanham Act and Section 337.

First, through the repeated use of the statutory term "shall," Congress mandated that the Commission institute investigations based on properly pled cases by repeatedly directing the Commission in unequivocal terms to do so. 19 U.S.C. § 1337(a)(1), (b). Amarin's complaint

alleges the types of claims that have repeatedly been the subject of Commission Section 337 investigations, specifically unfair trade practice actions under the Lanham Act and under the standards established by other federal agencies. Interagency comity is not a reason to decline institution, but rather a reason to institute here — in fact, in enacting Section 337, Congress anticipated the prospect of inter-agency conflict and built in processes to ensure inter-agency comity. Such processes include post-institution notice to FDA, submission of evidence by FDA through the Staff Attorney, the ability of the President to mediate any interagency conflicts during the Presidential Review phase of the investigation, and post-investigation modification proceedings. Congress specifically provided these mechanisms to deal with potential interagency conflict, and FDA has cited no statutory authority that contradicts this scheme. In short, "shall" means shall, and the Commission must institute this investigation.

Second, Amarin is not attempting an unlawful private enforcement of the FDCA, as FDA contends. Rather, it is simply seeking the remedies that Congress authorized under the Lanham Act and Section 337 by asking the Commission to police the marketplace, which is rife with literally false statements based on the understandings of the meanings of the terms "dietary supplement" and "drug" in the FDCA by suppliers and purchasers of the synthetically produced omega-3 products at issue here (e.g., the distributors selling the products to pharmacies and physicians, the pharmacies and physicians themselves, and consumers). That these understandings are based on definitions found in the FDCA, or FDA's precedent, strengthen, not weaken Amarin's allegations.

Contrary to FDA's assertions, the Commission has ample authority and capacity to determine whether the products at issue are falsely labeled or promoted in violation of the Lanham Act and Section 337, and doing so would not require unique expertise like that of FDA.

FDA also suggests that the Commission should not take this case because there may be "open" questions of policy regarding "dietary ingredients" that FDA has not yet found time to address. *See* FDA Letter to the Hon. Lisa R. Barton, Secretary, U.S. International Trade Commission, dated Oct. 6, 2017 ("FDA's October 6 Letter"), at 2-3. But the policy is well-settled and it has not changed. As explained below and in Amarin's Reply Brief on Jurisdiction, the Commission can make the necessary determinations regarding "dietary ingredients" based on the definition of that term in the FDCA and well-settled FDA policy.

Regardless, FDA argues that if the Commission institutes the investigation, there is a risk that FDA might decide to adopt a policy in the future that might in some manner conflict with the Commission's decision. *See id.* at 3. But the question for the Commission is not whether FDA (or some other agency) might at some point seek to change regulatory requirements or expectations in a way that might have some bearing on whether the products at issue in this case are lawfully marketed as "dietary supplements" under the Lanham Act and Section 337. Instead, the question is whether the statements being made today are false or misleading in a manner that is causing competitive harm.

Third, FDA's request is troubling from a comity perspective among other things. If the Commission were to abdicate its jurisdiction in this matter, and in all matters affecting FDA-regulated products, as FDA requests,[1] then it would not only subvert Congress's objectives in enacting Section 337 and the Lanham Act, but also effectively provide a shield for wrong-doing. Amarin's competitive interests, as well as the competitive interests of countless others — and "indirectly the public at large" — would be substantially harmed. *See POM Wonderful LLC v.*

[1] "FDA is concerned that the 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 October 6 Letter, at 3.

Coca-Cola Co., 134 S.Ct. 2228, 2239 (2014) (observing that if Lanham Act claims challenging food and beverage labeling were precluded, commercial interests and "indirectly the public at large" would be less protected than in other industries).

Moreover, FDA's assertions regarding its purported exclusive jurisdiction are overbroad. To the extent that the agency is implying that courts cannot look to the standards established in the FDCA in private actions, there would be a spill-over effect for countless tort cases and other actions proceeding under state law. Significantly, the Federal Circuit recently upheld a decision where a district court reviewed promotional materials associated with a product sold as a cosmetic and found that it was an unapproved "new drug" under the California FDCA analog, and that therefore, the defendant was violating the California Unfair Competition Law. *Allergan, Inc. v. Athena Cosmetics, Inc. et al.*, 738 F.3d 1350 (Fed. Cir. 2013). The U.S. Solicitor General also supported that ruling in an *amicus* brief recommending that the Supreme Court deny *certiorari* when that case was appealed on preemption grounds. *See Athena Cosmetics, Inc. v. Allergan, Inc.*, No. 13-1379, Brief for the United States as Amicus Curiae, at 10-14 (attached to Amarin's Reply Brief on Jurisdiction ("Amarin Reply Br.")).

Further, the position FDA has taken — that it has exclusive jurisdiction over this matter displacing Commission's authority — is precisely the position that was rejected by the U.S. Supreme Court in *POM Wonderful*. *POM Wonderful*, 134 S.Ct. at 2228. Contrary to FDA's contention, the FDCA, the Lanham Act, and Section 337 can work together.

Unfortunately, this is not the first time that FDA has inappropriately claimed special expertise in determining what constitutes false or misleading promotion of FDA-regulated products. In *Washington Legal Foundation v. Friedman*, 13 F. Supp.2d 51, 67 (D.D.C. 1998), *amended in part*, 36 F. Supp. 2d 16 (D.D.C. 1999), *vacated in part, sub nom., Washington Legal*

Foundation v. Henney, 202 F.3d 331 (D.C. Cir. 2000). Judge Lamberth admonished FDA for precisely this behavior:

> In asserting that any and all scientific claims about the safety, effectiveness, contraindications, side effects, and the like regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe. It is certainly the case that by statute, no drug may be introduced or delivered into interstate commerce without FDA approval, and that the claims that a manufacturer may make about a drug through labeling, advertising and other forms of promotion are subject to FDA regulatory authority. However, the conclusions reached by a laboratory scientist or university academic and presented in a peer-reviewed journal or textbook, or the findings presented by a physician at a [Continuing Medical Education] seminar are not 'untruthful' or 'inherently misleading' merely because the FDA has not yet had the opportunity to evaluate the claim.

Id.

The Supreme Court also called the federal government to task in *POM Wonderful* for arguing that Lanham Act claims are precluded when the FDCA or its implementing regulations specifically require or authorize the claims challenged under the Lanham Act. According to the Supreme Court:

> It is necessary to recognize the implications of the United States' argument for preclusion. The Government asks the Court to preclude private parties from availing themselves of a well-established federal remedy because an agency enacted regulations that touch on similar subject matter but do not purport to displace that remedy or even implement the statute that is its source. Even if agency regulations with the force of law that purport to bar other legal remedies may do so [citations omitted], it is a bridge too far to accept an agency's after-the-fact statement to justify that result here. An agency may not reorder federal statutory rights without congressional authorization.

POM Wonderful, 134 S.Ct. at 2241.

ARGUMENT

I. FDA's Request Fails To Take Into Account The Statutory Scheme Under Section 337 Of The Tariff Act

A. The Commission must investigate allegations of unfair trade practices, and that authority is entirely separate from the authority Congress delegated to FDA.

Section 337 directs the Commission to investigate unfair acts and unfair methods of competition. Congress made its mandate unequivocal: unfair acts and unfair methods of competition "are unlawful, and when found by the Commission to exist *shall* be dealt with, in addition to any other law . . . ." 19 U.S.C. § 1337(a)(1)(A) (emphasis supplied). Congress was equally clear that the Commission *must* initiate an investigation when presented with a properly pled complaint: "[t]he Commission *shall* investigate any alleged violation of this section on complaint under oath or its own initiative." *Id.* § 1337(b)(1) (emphasis supplied). Similarly, the Commission "*shall* conclude any such investigation and make its determination under this section at the earliest practicable time after the date of publication of notice of such investigation." *Id.* (emphasis supplied).

These unambiguous statutory provisions — with their repeated used of the mandatory term "shall" — make clear that the Commission lacks discretion to decline to institute an investigation over a properly pled complaint. *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998) ("The mandatory 'shall' ... normally creates an obligation impervious to [agency] discretion."). Consistent with these binding Congressional directives, the Commission has rarely declined to institute an investigation or stay its proceedings pending action by other agencies. By contrast, FDA has no enforcement authority under the Lanham Act or Section 337. *POM Wonderful*, 134 S.Ct. at 2241. There is no reason the Commission should break new ground here.

B. Congress recognized the potential for inter-agency conflict and resolved those issues in favor of Commission investigations under Section 337.

Nothing in the FDCA contradicts Congress's plain directives to the Commission or permits the Commission not to initiate an investigation when presented with a properly plead complaint. Nor does it grant FDA or any other agency authority to override the Commission's investigative responsibilities. Instead, Congress provided a detailed procedure for the Commission to consider the views of other government agencies.

1. The Commission has jurisdiction over Amarin's Section 337 allegations "in addition to any other law."

As noted above, the remedies under Section 337 are "in addition to any other provision of law." 19 U.S.C. § 1337(a)(1). The statute's text echoes the 1974 Senate Report accompanying the enactment of Section 337, which states that "[t]he relief provided for violations of section 337 is in 'addition to' that granted in 'any other provisions of law.' The criteria of section 337 differ from other statutory provisions for relief against unfair trade practices." S. Rep. No. 93-1298, 93d Cong. 2d Sess. 196. Accordingly, Congress considered the possibility that other enforcement mechanisms for violations may exist under other provisions of federal law, but nonetheless ensured that Section 337 investigations would be instituted and concluded notwithstanding any of those other provisions. This makes perfect sense in the context the Tariff's Act's focus on protecting domestic industry from unfair trade practices of foreign competitors where Congress has understandably determined additional remedies are warranted.

FDA's October 6 Letter cites certain FDCA provisions that FDA contends are subject to its exclusive administration and enforcement. *See* FDA's October 6 Letter, at 1-2 (citing 21 U.S.C. §§ 355, 350b, which give FDA authority to approve "new drugs" and receive "new dietary ingredient" notifications for certain "dietary ingredients," respectively, but do nothing to suggest that FDA has exclusive jurisdiction over interpreting the terms "drug" or "dietary supplement"). But this case has nothing to do with *enforcing* these provisions. Amarin is not

asking the Commission to decide whether the relevant products should be approved by FDA as "drugs" or whether FDA should receive notifications of certain "dietary ingredients." Nor does anything in the FDCA eliminate the Commission's jurisdiction or contradict Congress's requirement that the Commission investigate properly pled complaints under Section 337 "in addition to any other law." Indeed, FDA's October 6 Letter cites no statutory authority preventing the Commission from instituting its investigation because there is none.

Significantly, Amarin's complaint alleges violations of Section 43(a) of the Lanham Act. Specifically, Section VI.A. of the complaint is titled "Proposed Respondents' Importation And Sale Of Synthetically Produced Omega-3 Products Violate The Lanham Act." Complaint § VI.A. The Complaint's Section VII details the specific false statements made by each of the manufacturer and distributor respondents. Complaint § VII. Lanham Act cases have long been within the Section 337 jurisdiction of the Commission. *See* CAUSES OF ACTION UNDER SECTION 337, USITC GC-G-243 (Sept. 30, 1983), 1983 WL 206913 at *4 (identifying Section 43(a) of the Lanham Act as a cause of action under Section 337). Indeed, the Commission has instituted numerous Section 337 investigations based on alleged Lanham Act violations. *See infra*, section I.C. Amarin has also alleged that the Proposed Respondents have imported articles into the United States that are being imported or sold using one or more unfair acts or unfair methods of competition. *See* Complaint, § VI.B. These allegations, like the Lanham Act allegations, are "in addition to" the FDCA and satisfy Section 337(a)(1)(A) as an independent causes of action. 19 U.S.C. § 1337(a)(1)(A).

By contrast, FDA has no authority to interpret or enforce either the Lanham Act or Section 337. Nonetheless FDA's letter objects that the alleged falsehoods in Proposed Respondents' statements are based on the definitions of different types of FDA-regulated products in the FDCA. According to FDA, Amarin's claims under the Lanham Act and Section

337 are barred because there is no private right of action under the FDCA. As discussed in detail below, that position is nothing more than an attempt to resurrect the type of field preclusion argument that was soundly rejected by the Supreme Court in *POM Wonderful*. *See POM Wonderful*, 134 S.Ct. at 2241. As discussed at length in Amarin's previous jurisdiction briefs, the Supreme Court found that neither the text of the FDCA, nor the text of the Lanham Act, precludes Lanham Act claims challenging labels regulated by FDA. *See id.* at 2237. Similarly, nothing in the text of the FDCA, nor the text of Section 337, forecloses the use of Section 337 to remedy harm from unfair methods of competition or unfair acts in the importation of articles that are false and misleading.

It is not by happenstance that Congress directed the Commission to investigate properly pled complaints in addition to any other law, while enacting no contradictory provision in the FDCA. Congress's grant of jurisdiction to the Commission to investigate violations of Section 337 "in addition to any other law" is designed to reflect the unique role the Commission plays in policing unfair trade practices in international trade. As the Federal Circuit has explained:

> As a trade statute, the purpose of Section 337 is to regulate international commerce. . . . Section 337 necessarily focuses on commercial activity related to cross-border movement of goods. . . . While Congress has addressed domestic commercial practices under various statutory regimes, such as antitrust (15 U.S.C. §§ 1-38), patent (35 U.S.C. §§ 1-390), and copyright (19 U.S.C. §§ 1-1332), it has established a distinct legal regime in Section 337 aimed at curbing unfair trade practices that involve the entry of goods into the U.S. market via importation. In sum, Section 337 is an enforcement statute enacted by Congress to stop at the border the entry of goods, *i.e.*, articles, that are involved in unfair trade practices.

Suprema, Inc. v. Int'l Trade Comm'n, 796 F.3d 1338, 1344-45 (Fed. Cir. 2015). *See also Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F. 2d. 1471, 1488 (Fed. Cir. 1986) (stating that [a]lthough it is true that private rights may be affected by section 337 determinations, the thrust of the

statute is directed towards the protection of the public interest from unfair trade practices in international commerce.").

2. Congress requires FDA to cooperate with the Commission's Section 337 investigation, not impede it.

Congress emphasized the importance and primacy of Section 337 investigations when it enacted Section 334 of the Tariff Act, 19 U.S.C. § 1334. Section 334 states, in relevant part, that the "[C]ommission shall in appropriate matters act in conjunction and cooperation with . . . any other department . . . of the Government, and such departments . . . shall cooperate fully with the [C]ommission for the purposes of aiding and assisting in its work . . . ." 19 U.S.C. § 1334. In other words, Congress directed FDA to cooperate with the Commission's investigation of unfair acts and unfair methods of competition, including those based on violations of Section 43(a) of the Lanham Act. FDA's October 6 Letter, which asks the Commission to "decline to initiate the requested investigation," directly contradicts Congress's mandate and goes against the statutory scheme. *See* FDA's October 6 Letter, at 1. Nothing in the FDCA relieves FDA from its obligation to "cooperate fully with the [C]ommission for purposes of aiding and assisting in its work" or allows FDA to impede the work of the Commission.

Similarly, Section 337, the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551-559, which governs Section 337 proceedings, and the Commission Rules have extensive procedures designed to protect the rights of both the parties and FDA. The statute and regulations provide for pleadings, institution, motions, discovery, the submission of relevant evidence, the creation of an administrative record, the cross-examination of fact and expert witnesses during a hearing, review by the Commission, and further review to the Federal Circuit. For example, once facts come to light in discovery, the Commission will be in a position to request cooperation and

assistance from FDA under Sections 334 and 337(b)(2).[2] The statute and regulations are clear, however, that these procedures are to be pursued only after the investigation has been instituted.[3] To allow FDA to circumvent these procedures would violate the APA and deny Amarin the ability to develop the record, present evidence, cross examine witnesses, and generally protect its interests in an adversarial proceeding. FDA's position that the Commission lacks jurisdiction effectively nullifies all of these statutory and regulatory protections and eliminates the Commission's role as an independent factfinder.

Significantly, the statute and regulations also protect FDA's interests. In fact, Commission Rule 210.37(c) is designed to deal with the concerns presented by FDA. Under that rule, "[a]ny documents, papers, books, physical exhibits, or other materials or information obtained by the Commission under any of its powers [including the power to consult with FDA] may be disclosed by the Commission investigative attorney when necessary in connection with investigations and may be offered in evidence by the Commission investigative attorney." 19

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[2] If any doubt remains as to the existence of the Commission's jurisdiction, evidence adduced during the investigation also will assist the Commission making this determination. *See Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990) ("As is very common in situations where a tribunal's subject matter jurisdiction is based on the same statute which gives rise to the federal right, the jurisdictional requirements of section 1337 mesh with the factual requirements necessary to prevail on the merits. In such a situation, the Supreme Court has held that the tribunal should assume jurisdiction and treat (and dismiss on, if necessary) the merits of the case.").

[3] As established in Amarin's Reply Brief on Jurisdiction, Congress and the Commission's rules do not provide for any pre-institution submissions by FDA on the Commission's jurisdiction. The only pre-institution submissions contemplated by the Commission Rules are public interest comments. 19 C.F.R. § 210.8(c). Public interest comments are solicited to provide the Commission with sufficient information to determine whether to delegate the public interest to the ALJ as an issue on which to adduce evidence for purposes of her recommended determination under Commission Rule 210.42(a)(1)(ii) on remedy, bonding, and the public interest. 19 C.F.R. § 210.50(b)(1). Nothing in the statute or the Commission's Rules invites comments from members of the public on the Commission's jurisdiction for purposes of advocating against institution of the investigation. Indeed, the statute authorizing the Commission to consult with FDA states that such consultation occur "during the course of each investigation." 19 U.S.C. § 1337(b)(2). Until such time as an investigation has been instituted, there is no authority for FDA's unprecedented request.

C.F.R. 210.37(c). Accordingly, if FDA wants evidence to be considered on the issues it has raised in its letter, it can provide that information or advice to the Commission, and the Office of Unfair Import Investigations ("OUII") can make that information part of the administrative record to be considered by the Administrative Law Judge ("ALJ") and the Commission.

3. The Tariff Act empowers the President to resolve inter-agency conflicts during a Presidential review period.

Congress further protected the interests of FDA by authorizing the President to mediate interagency conflicts through the Presidential review process. Under the statute, all Commission Decisions finding a violation of Section 337 are submitted to the President for review during a 60-day period following the conclusion of the investigation. 19 U.S.C. § 1337(j)(1). The President may disapprove of any Commission Decision for "policy reasons," in which case the Commission decision will have no force or effect. *Id.* § 1337(j)(2). As the head of the Executive Branch, the President has broad and unfettered discretion under this provision to mediate any inter-agency disputes between FDA and the Commission over the Commission's mandate. If the President believes the Commission has exceeded its statutory mandate, or that its mandate should not be implemented in a particular case for "policy reasons, he can vindicate FDA's jurisdictional objections at that time. In fact, the President previously has used this statutory provision on two separate occasions to mediate interagency conflicts. *See* PRESIDENTIAL DETERMINATION OF APRIL 22, 1978; *WELDED STAINLESS STEEL PIPE AND TUBE INDUSTRY*, 43 Fed. Reg. 17789 (Apr. 22, 1978) (disapproving the Commission's cease and desist order in Investigation No. 337-TA-20 in part because "[t]he Treasury Department's determination under the Antidumping Act ... provides adequate protection against unfair trade practices described in [the complainant's] petition."); DETERMINATION OF THE PRESIDENT REGARDING *CERTAIN ALKALINE BATTERIES*, 50 Fed. Reg. 1655 (Jan. 11, 1985) (disapproving the Commission's determination in Investigation No. 337-TA-165 on the ground that the Commission's

interpretation of the gray market goods provision of the Lanham Act conflicted with the Treasury Department's interpretation of the statute). In the event FDA eventually formulates a position on the issues presented in this case (or reverses its 15-year old position), the statutory provision for Presidential review will ensure that inter-agency conflicts are appropriately mediated.

4. Congress provided for post-investigation modification or rescission of an exclusion order based on changed circumstances.

In the event that FDA resolves one of the issues raised in its October 6 letter after the Commission concludes its investigation and issues an exclusion order, FDA, or one of the Proposed Respondents benefitting from a favorable FDA decision with respect to its products, can pursue post-investigation modification or rescission of the exclusion order and cease and desist order through Commission modification proceedings. 19 U.S.C. § 1337(k); 19 C.F.R. § 210.76(a) ("Whenever any person believes that changed conditions of fact or law, or the public interest, require that an exclusion order, cease and desist order, or consent order be modified or set aside, in whole or in part, such person may file with the Commission a petition requesting such relief"). These procedural provisions ensure that FDA's concerns about future, speculative positional conflicts with the Commission's decision can be addressed at the appropriate time within the existing statutory and regulatory framework for Section 337 investigations. But unless and until such an event materializes, Amarin is entitled to an investigation in this case.

5. Congress expressly exempted specific regulatory schemes from investigation under Section 337, but not the FDCA.

In narrow circumstances, not applicable here, Congress has exempted the administration and enforcement of certain statutes from investigation by the Commission under Section 337, but it has not applied that exemption to FDA's administration and enforcement of the FDCA. For example, Section 337(b)(3) requires the Commission to notify the U.S. Department of Commerce if a matter, in whole or in part, comes within the purview of part II of subtitle IV of the Tariff Act (*i.e.*, the antidumping laws). 19 U.S.C. § 1337(b)(3). If the matter is wholly

within the purview of the antidumping or countervailing duty laws, or relates to certain copyright infringement allegations, Congress directed the Commission not to institute a Section 337 investigation. *Id.* By contrast, if the matter presented to the Commission is based in part on acts within the purview of the antidumping or countervailing duty laws, and in part on acts arising under Section 337, Congress directed the Commission to institute an investigation. *Id.* If a matter falls wholly or partially within the purview of the antidumping or countervailing duty laws, the Commission may suspend its investigation during the time the matter is before Commerce for final decision. *Id. See also* 19 C.F.R. § 210.23.

Congress's statutory exemption for matters within the purview of the antidumping and countervailing duty laws, combined with the absence of an exemption for FDA's administration and enforcement of the FDCA, indicates that Congress did not intend for the Commission to decline institution over properly pled claims involving FDA-regulated products, even if it falls wholly or partly within the purview of the FDCA. *Franklin Nat'l Bank v. New York,* 347 U.S. 373, 378 (1954) (finding "no indication that Congress intended to make this phase of national banking subject to local regulations, as it has done by express language in several other instances."). Rather, Congress set up a different statutory scheme, described above, to address potential conflicts between FDA and the Commission. That scheme involves several procedural protections for FDA, but does not permit the Commission to decline institution. Rather, the Tariff Act makes clear that Congress contemplated where it should exempt the administration and enforcement of other statutory schemes from the operation of Section 337 and elected not to do so with respect to FDA's administration and enforcement of the FDCA.

By contrast, the Commission's consistent line of decisions refusing to stay Section 337 investigations pending *inter partes* review ("IPR") proceedings at the U.S. Patent and Trademark Office ("USPTO") demonstrates that the Commission need not decline to investigate pending

another agency's review of matters that fall within the purview of Section 337. For example, in *Certain Network Devices, Related Software And Components Thereof (II)*, Inv. No. 337-TA-945 (Jul. 21, 2017), the Commission denied the respondent's requests to modify, suspend, or rescind the Commission's remedial orders pending appeal of a final written decision of the Patent Trial and Appeal Board finding that the claims of the asserted patents were unpatentable. The Commission reasoned that "[t]he legal status of the claims at issue will not change unless and until the [USPTO] issues a certificate cancelling the claims following the exhaustion of all appeals." The Commission's decision in *Certain Network Devices*, as well as other cases refusing to stay Section 337 investigations pending IPR proceedings, demonstrates that the Commission need not curtail its investigations out of a concern for potentially conflicting determinations of other governmental agencies until such issues are definitively resolved.

6. The primary jurisdiction doctrine does not authorize an open-ended stay on the Commission's ability to investigate.

FDA cites *Hi-Tech Pharms, Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1331 (N.D. Ga. 2016), to suggest that courts have invoked the doctrine of primary jurisdiction to allow FDA to resolve complex issues before judicial review of matters involving the definitions in the FDCA. FDA's October 6 Letter at 5. Amarin distinguished *Hi-Tech* and other cases cited by both FDA and the Proposed Respondents in its Reply Jurisdictional Brief. *See* Amarin Reply Br. at 27-30. More fundamentally, the doctrine does not authorize the open-ended foreclosure of any review of FDA's actions, even when it is invoked by courts.[4] Nothing in the primary jurisdiction

[4] As demonstrated in Amarin's Initial Jurisdiction Brief and Reply Jurisdiction Brief, primary jurisdiction has no place in inter-agency jurisdictional disputes:

> There exists no legal precedent for expanding th[e] common law doctrine [of primary jurisdiction] beyond its present parameters so as to incorporate those instances where one agency refrains from exercising its own jurisdiction until a second agency first addresses the questions presented. . . . Therefore, [respondents'] assertion that the Customs Service has primary jurisdiction over alleged failures to mark country of origin as well as alleged trademark and

doctrine exempts FDA decisions from judicial review in perpetuity, which is essentially what FDA is asking the Commission to do here. Analogously, even when the Commission suspends a Section 337 investigation under 19 U.S.C. § 1337(b)(2) and 19 C.F.R. § 210.23 because the matter is within the purview of the antidumping or countervailing duty laws, it does not do so in perpetuity. Rather, it suspends the Section 337 investigation for the period required by Commerce to complete the antidumping or countervailing duty investigation or administrative review. And those proceedings are required by statute to be conducted on tight deadlines. 19 U.S.C. §§ 1671d, 1673d. Accordingly, the Commission should reject FDA's appeals to the primary jurisdiction doctrine as a means to foreclose Commission investigation under Section 337 for an open-ended period of time.

Indeed, all indications are that FDA may never reach a decision on certain "dietary ingredient" issues, or if they do, it will not be for a very long time. For example, FDA's letter mentions that it initially published a draft guidance document on "new dietary ingredients," which it claims is relevant here, in 2011. *See* FDA October Letter, at 2-3. As discussed below, FDA revised that draft guidance in 2016. It is unclear when FDA will issue the next document, whether it will be a revised draft guidance or a final guidance, or whether FDA will or will not change any policy positions relevant here. And to the extent FDA does change a relevant policy, the post-investigation modification or rescission of an exclusion order based on changed

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> trade dress violations and that both the Customs Service and the Federal Trade Commission have primary jurisdiction over alleged violations of the Fair Packaging and Labeling Act lacks legal foundation.

Certain Alkaline Batteries, Inv. No. 337-TA-165, Order No. 18 at 2 (Mar. 26, 1984), *accord Certain Light-Emitting Diode Products and Components Thereof*, Inv. No. 337-TA-945, Initial Determination at 422-430 (Sept. 2, 2016) (exercising jurisdiction over complainants' false advertising claims and rejecting respondents' primary jurisdiction defense).

circumstances provided for by Congress are ideally suited to address any such circumstances should they arise. *See* 19 U.S.C. § 1337(k); 19 C.F.R. § 210.76(a).

C. The Commission historically has investigated violations of Section 337 and the Lanham Act when the alleged unfair trade practices involved reliance on other agency's regulations.

As demonstrated in Amarin's Initial and Reply Jurisdiction Briefs, the Commission has a long history of investigating violations of Section 337 and the Lanham Act when the alleged unfair trade practice involves reliance on standards principally administered by other agencies. *See, e.g., Certain Light Emitting Diode Products*, Inv. No. 337-TA-947, Initial Determination (Sept. 2, 2016) ("it is evident that the Lanham Act/unfair trade practices questions at issue fall clearly within both the expertise of the Commission by statutory mandate and, accordingly, within the discretion of the Commission"); *Periodontal Laser Devices,* Inv. No. 337-TA-1070, 82 Fed. Reg. 43401 (Sep. 15, 2017) (instituting an investigation based on alleged violations of the Lanham Act and federal common law of unfair competition involving allegations that respondents' periodontal laser devices did not have FDA clearance for claiming periodontal tissue regeneration, but nevertheless advertised its product as being FDA-cleared for this indication); *Potassium Chloride*, Inv. No. 337-TA- 1013, 81 Fed. Reg. 49623 (Jul. 27, 2016) (instituting an investigation of a Lanham Act claim that involved allegations that an FDA-regulated product was mislabeled based on allegations that the respondents were (1) selling a potassium chloride product — an unapproved "new drug" — with misleading labeling and other promotional materials that suggested the product was an FDA-approved generic drug, and (2) misleading Customs and Border Protection officials during the import process by misrepresenting the product as a "*dietary supplement.*"). *See also, Certain Motorized Self-Balancing Vehicles*, Inv. No. 337-TA-1000, 81 Fed. Reg. 33548 (May 26, 2016) (instituting an investigation for violations of Section 337 and the Lanham Act based on allegations that

Respondents' hoverboards were falsely certified as compliant with safety standards promulgated by Underwriters Laboratories, a global independent safety science company).

The Commission's institution decision in *Certain Alkaline Batteries* is especially instructive. The Commission instituted an investigation into allegations of multiple unfair acts involved in the importation of alkaline batteries, including false representation and designation of geographic origin, failure to mark country of origin, and violation of the Fair Packaging and Labeling Act. INSTITUTION OF SECTION 337 INVESTIGATION OF *CERTAIN ALKALINE BATTERIES,* Docket No. 965, USITC GC-G-230 (Sept. 9, 1983) (recommendation of institution of the investigation by the General Counsel). The General Counsel's memorandum recognized that

> An argument could be made that the Commission should not institute an investigation under section 337 for failure to mark the country of origin on imported products because the Customs Service can deal with such a matter under 19 U.S.C. § 1304. Section 337(a), however, provides that unfair methods of competition and unfair acts are declared unlawful 'in addition to any other provisions of law. . . .' Moreover, stated Congressional policy is that section 337 relief be provided expeditiously. Thus, even though alternative relief may be available to complainant under another statute, such as 19 U.S.C. § 1304, this fact should not preclude complainant from obtaining expeditious alternative relief under section 337.

Id. at 3.[5] Much like FDA's argument that it has responsibility for the administration and enforcement of the FDCA, the General Counsel's memorandum recognized that another agency of government — Customs — has responsibility for the administration and enforcement of a statute — 19 U.S.C. § 1304 — but still recommended proceeding with "expeditious alternative relief under section 337. The Commission instituted the investigation on September 21, 1983. *Certain Alkaline Batteries*, Inv. No. 337-TA-165, Comm'n Pub. 1616 (1984).

[5] The General Counsel's memorandum also recommended institution of an investigation based on allegations of violation of the Fair Labeling and Packaging Act, 15 U.S.C. § 1451 *et seq.* because respondents' products allegedly failed to identify the name or place of business of the manufacturer or distributor, or the quantity of the contents of the packages. *Id.*

D. The Commission's non-institution decisions are rare and distinguishable.

Commission decisions not to institute an investigation under Section 337 are exceedingly rare. In over 1,000 Section 337 cases instituted at the Commission, only a handful have not been instituted. For example, the Commission declined to institute an investigation based on allegations that were wholly within the purview of the antidumping laws and, therefore, were expressly precluded by 19 U.S.C. § 1337(b)(3). *Syntex Agribusiness, Inc. v. U.S. Int'l Trade Comm'n*, 659 F.2d 1038 (C.C.P.A. 1981). The Commission also declined to institute an investigation based on a subsequent complaint filed by the same complainant that merely substituted the antidumping allegations for allegations of predatory pricing, but without factual support. *Id.* The Commission also declined to institute an investigation in *Certain Anhydrous Ammonia from Mexico* based on allegations that were factually unsupported, barred by the Act of State Doctrine, partially within the purview of the antidumping laws, and contradicted the antitrust law. GENERAL COUNSEL MEMORANDUM REGARDING COMPLAINT FILED IN DOCKET N. 891, *CERTAIN ANHYDROUS AMMONIA FROM MEXICO*, 1983 WL 207055 (1983). These cases are all distinguishable. Amarin's complaint is factually supported, does not allege violations of the antidumping laws, is not barred by the Act of State doctrine, and is not contrary to the antitrust laws.

Finally, the Commission did not institute an investigation in *Hydroxyprogesterone Caproate*, ITC Docket No. 2919 ("*HPC*") As demonstrated in Amarin's Initial and Reply Jurisdiction Briefs, *HPC* creates no categorical rule that forecloses investigation of unfair trade practices involving FDA-regulated products. The Commission provided scant explanation for its *HPC* decision, and developments in the law superseded what explanation it did provide. First, unlike Amarin, the complainant in *HPC* did not allege a Lanham Act violation in its complaint, and *HPC* was decided before *POM Wonderful* made clear that Lanham Act claims may be brought against FDA-regulated products with misleading labels and other promotional materials.

The complainant in *HPC* sought to enforce the FDCA directly. By contrast, Amarin seeks to use Section 337 as an unfair trade practice statute to vindicate competitor interests under the Lanham Act and Section 337 using the *POM Wonderful* rubric.

Second, the one case cited in support of the Commission's decision — *KV Pharmaceutical Co. v. FDA*, 1:12-cv-001105-ABJ (D.D.C. 2012) — was vacated and remanded on appeal. *See KV Pharmaceutical Co. v. FDA*, 2014 WL 68499 (D.C. Cir. 2014). The D.C. Circuit recognized that, in some instances, FDA's enforcement discretion was not unfettered, particularly when imported drugs are at issue. *Id.* To the extent the Commission relied on the lower court's decision in *KV Pharma*, its reliance is no longer viable.

Third, FDA declined to enforce the Orphan Drug provisions at issue in *HPC* against the compounding pharmacies, whereas in this case, FDA has not refused to enforce the FDCA against the importers of the synthetically produced omega-3 products at issue here. Rather, for more than 15 years, FDA has consistently found that these types of synthetic substances do not fall under the "dietary ingredient" definition. *See* Complaint ¶¶ 67. In other words, the requested action in *HPC* would have conflicted with an express FDA determination. Here, there has been no express FDA determination. Moreover, Amarin's requested action would not conflict with existing FDA policy. Rather, the action is consistent with existing FDA policy. FDA's October 6 Letter does not change that. As mentioned, the question for the Commission is not whether FDA might at some point change regulatory expectations in a way that would affect this case. Instead, the question is whether the statements being made by the Proposed Respondents are false in a manner that is causing competitive harm today. Accordingly, *HPC* is entitled to no weight in this matter.

II. Amarin Is Not Attempting An Unlawful Private Enforcement Of The FDCA, Nor Is It Asking The Commission To Break New Ground Or To Act Outside Of Its Expertise Or Authority

Contrary to FDA's assertions, Amarin is not attempting an unlawful private enforcement of the FDCA. Rather, the company is seeking the remedies that Congress authorized under the Lanham Act and Section 337. The Commission has ample authority and capacity to determine whether the synthetically produced omega-3 products at issue are falsely labeled or promoted in the marketplace in violation of the Lanham Act and Section 337. The Commission may look to the statutory definition of "dietary supplement" and "drug," and the case-specific facts, to determine whether the products at issue are "drugs" that have been improperly labeled and promoted as "dietary supplements." That would not require any special scientific expertise or judgment. Nor would it intrude on FDA's distinct sphere of regulatory responsibility. It would merely exercise the authority that Congress directed the Commission to exercise to protect against competitive injuries. If the Commission determines that the products are mislabeled, then the relevant product labeling and promotional materials are literally false.

A. Amarin is not attempting an unlawful private enforcement action.

FDA's October 6 Letter argues that Amarin's claims under the Lanham Act and Section 337 are barred because there is no private right of action under the FDCA. FDA's October 6 Letter, at 4-6. The position that FDA has taken is akin to Coca-Cola's field preclusion argument that was soundly rejected by the Supreme Court in *POM Wonderful*, with regard to the Lanham Act. *See POM Wonderful*, 134 S.Ct. at 2241. *See also Thompson Medical Company, Inc. v. Federal Trade Comm'n*, 791 F.2d 189 (D.C. Cir. 1986) ("We find no evidence in the regulatory scheme that Congress has fashioned for over-the-counter medications that the FTC is indefinitely barred from all regulatory authority over drug advertising while the FDA conducts its comprehensive review of drug safety."). As discussed at length in Amarin's previous jurisdiction briefs, the Supreme Court in that case found that neither the text of the FDCA, nor

the text of the Lanham Act, precludes Lanham Act claims challenging labels regulated by FDA. *See POM Wonderful*, 134 S.Ct. at 2237. Analogously, nothing in the text of the FDCA, nor the text of Section 337, should foreclose the use of Section 337 to remedy harm from unfair methods of competition or unfair acts in the importation of articles that violate the standards established by the FDCA.

Regardless, FDA claims that the FDCA would preclude a case that required the Commission to "directly apply, enforce, or interpret" the FDCA. FDA's October 6 Letter, at 5. This claim appears to be based on a statement by the Commission's Staff that was taken out of context,[6] and therefore, that statement is not meaningful here. In any event, Amarin has not asked the Commission to "directly apply," "enforce," or "interpret" the FDCA. Rather, it has asked the Commission to determine whether the Proposed Respondents' false statements are false and misleading to various marketplace actors in violation of the Lanham Act and Section 337, invoking the Commission's authority to redress competitive injury. *See, e.g., TianRui Group Co., Ltd. v. U.S. Int'l Trade Comm'n*, 661 F.3d 1322, 1327 (Fed. Cir. 2011) ("The question under Section 337 is ... whether goods imported from abroad should be excluded because of a violation of the congressional policy of protecting domestic industries from unfair competition...."); *accord*, H.R. Rep. No. 67-1223 at 146 ("[t]he Senate Amendment [to Section 316 of the Tariff Act of 1922, the precursor of Section 337] inserts a new section making unlawful unfair methods of competition and unfair acts in the importation of merchandise into the United States, which threatens the stability or existence of American industry").

[6] FDA's citation to the Commission Staff's statement in *Potassium Chloride* 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" is taken out of context. *See* FDA's October 6 Letter at 5. The Commission Staff made that statement in the context of a case where the Commission had not been called upon to "directly apply, enforce, or interpret the FDCA." Therefore, the statement does not indicate that the Commission Staff in *Potassium Chloride* believed that a case that does call upon the Commission to interpret the FDCA is precluded by the FDCA.

It makes no difference that the Commission might take account of the commonly accepted definitions of "dietary supplements" and "drugs" set forth in the FDCA. *See Certain Universal Transmitters for Garage Door Openers*, Inv. No. 337-TA-497, OUII Br. On Jurisdiction at 6 (Sept. 16, 2003) ("In a Section 337 investigation, the Commission looks to other statutes, like the Patent Act or Lanham Act, or the common law or other indicia of public policy, to determine the standards by which to judge if acts and practices involving import trade are unfair; but the Commission does not enforce those laws *per se*, it only enforces the provisions of Section 337"); *see also, Codonics, Inc. v. Datcard Systems, Inc.*, Case No. 1:08-CV-1885, No. 62-1 at 7-8, 2009 WL 2382567, at *4 (July 31, 2009) (N.D. Ohio) (Lanham Act claims can move forward where "the plaintiff can prove the falsity of the advertising through reference to an unambiguous FDA definition.").

Moreover, in *POM Wonderful,* the Court emphasized that the Lanham Act subjects any person who misrepresents the "*nature*, characteristics, qualities, or geographic origin" of a product to suit, and the Court notes that neither the text in the Lanham Act, nor the FDCA forbids or limits these types of claims. *POM Wonderful,* 134 S.Ct. at 2237 (emphasis supplied). *POM Wonderful* thus confirms that Amarin is entitled to challenge Proposed Respondents for misrepresenting the *nature* of their products. Analogously, Section 337 subjects importers who engage in unfair trade practices that injure a domestic industry to suit, and nothing in the FDCA specifically limits those types of claims. Therefore, Amarin should not be precluded from bringing a case, like this, that challenges Proposed Respondents for engaging in unfair trade practices – even if the challenge requires the Commission to look to certain provisions in the FDCA in conjunction with case-specific facts.

As explained below, the ITC is fully equipped to look to statutes that are primarily administered by other agencies. For example, *Certain Light Emitting Diode Products*, Inv. No.

337-TA-947, Initial Determination (Sept. 2, 2016), presented a similar issue —namely whether the Commission could look to certification standards administered by the Environmental Protection Agency and the Department of Energy in deciding a case. *Certain Light Emitting Diodes* at 426-27. The ALJ in that case found that looking to those standards in the context of Lanham Act and unfair trade practice allegations was within both the expertise of the Commission and its statutory mandate. *See id.*

Amarin is not asking the Commission to do anything different here. Amarin is asking the Commission to call balls and strikes based on definitions in the FDCA and previous FDA interpretations. Moreover, as discussed below, it is not asking FDA to interpret the statute in a way that would be inconsistent with existing FDA policies.

Finally, FDA's citation to *Hi-Tech Pharmaceuticals, Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1332 (N.D. Ga. 2016) and *JHP Pharmaceuticals LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992 (C.D. Cal. 2014), *etc.*, do nothing to advance their argument. Amarin has already distinguished those cases from this one in its Reply Brief on Jurisdiction. *See* Amarin's Reply Br. on Juris. at 27-29. Simply put, Amarin agrees that FDA should have primary jurisdiction over the determination of whether a "drug" is "*new*" — namely whether it is generally recognized as safe and effective by qualified experts because that decision is akin to determining whether a "drug" should be approved.[7] But, there is no reason that the Commission should not

[7] If a product meets the definition of "drug" – it is presumed to be a "new drug" – if FDA has not approved the specific product. This presumption is based on the 1973 Supreme Court decision in *Weinberger v. Hynson, Wescott & Dunning Inc.*, 412 U.S. 609, 632 (1973). In that case, the Supreme Court found that the only way a "drug" can avoid meeting the definition of "new drug," is for the sponsor to show that there is a consensus of expert opinion that a drug is safe and effective based on "substantial evidence." *See Hynson*, 412 U.S. at 632 (citing 21 U.S.C. 355(d)). This "substantial evidence" standard is the same evidentiary standard required for NDA approval. 21 U.S.C. § 355(d)(5). In other words, to either get FDA approval (i.e., because the drug is "new") — or to show that a product does not need FDA approval (i.e., because the drug is "not new") — the sponsor has to provide "substantial evidence" that a product is efficacious for its intended use. As a practical matter, therefore, it is not easier to show that a product is "not new" than to go through the drug approval process. So, virtually all

be able to rely on the FDCA's definition of "dietary supplement," and the FDA's related interpretations, as well as the FDCA's definition of "drug," when deciding this case. *See* Amarin's Reply Br. on Jurisdiction, at 9-30.[8] Resolving those issues does not require scientific expertise of judgment.

Indeed, neither the courts, nor the Commission should be precluded by the FDCA from looking to definitions in the FDCA to determine whether a Proposed Respondent is mislabeling a product in violation of the Lanham Act and Section 337. *See generally*, Amarin Reply Br. There is no reason for the Commission to treat the FDA and FDCA differently from all other agencies and statutes.

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prescription drug manufacturers concede that their "drugs" are "new" and go through the drug approval process. *See* David G. Adams, et al., Food and Drug Law and Regulation (3d. 2015), at p. 298, Complaint Exhibit 54. Only in very limited and unique circumstances, when all parties agree that the product at issue is a "drug" in the first place, does the issue of whether the product is a "*new* drug" ever arise. *See Weinberger v. Bentex Pharmaceuticals*, 412 U.S. 645 (1973). In *Bentex*, for example, all parties agreed that a product that was already on the market was a "drug." *See id.* Although the "drug" had not originally been subject to FDA's drug approval process, the FDCA was amended in 1962 in a manner that suddenly required the sponsors of the "drug" at issue to show that the "drug" was effective by going through the drug approval process. *See id.* The plaintiffs in that case argued that the "drug" did not have to go through the "drug" approval process because it was "not *new*" – meaning that it was already recognized as safe and effective by qualified experts. *See id.* Observing that the same data is required to show that a "drug" is "not new" that is required for drug approval, and that FDA has the scientific expertise and scientific judgement to determine whether such data is sufficient to approve a "drug"– the Court determined that FDA, not the courts, should also determine whether a "drug" is "not *new*." *See id.*

[8] The holding in *Bentex* has no bearing on a court's ability, or indeed the ITC's ability, to rely on the "drug" definition when reviewing case-specific facts. To determine whether a product is a "drug," a manufacturer, a court, or the ITC need only evaluate the facts (e.g., the chemical components of the products at issue and the promotional materials for those products) to determine whether the product is (1) recognized in a drug compendium listed in the statute, (2) intended to affect the structure/function of the body, (3) intended to affect disease, or (4) intended to be a component in a "drug." 21 U.S.C. § 321(g)(1). Nor does the holding in *Bentex* have any bearing on a court's ability, or the ITC's ability, to rely on the definition of "dietary supplement" when reviewing case-specific facts.

B. The issues presented in this case can only be resolved by the Commission.

FDA cannot dispute that it lacks the resources, expertise, and authority to police competitive injuries caused by the unlawful actions of companies that are improperly and falsely marketing products as "dietary supplements." *See* Frontline: Supplements and Safety, PBS and The New York Times, Complaint Exhibit 29 (noting that FDA has only about 25 people in the division that oversees products positioned as "dietary supplements," and more than 85,000 of these products are sold each year. As reported in that program, "[FDA] target[s] companies they consider the most risky, but agree[s] the problem remains much bigger than that"). Instead, FDA argues that the Commission should not institute an investigation because the issues are purportedly "complex" and require "case-specific" analysis. In FDA's view, the Commission cannot do the job that Congress intended without a scientific understanding of a product's chemical structure and marketing history, and even consultations with FDA are not "adequate." FDA's October 6 Letter, at 3.

FDA fundamentally misunderstands both the Commission's expertise and the nature of its inquiry. Many statutes are "complex" and involve scientific and technical issues, but that does not prevent the Commission from conducting the investigations that Congress required. The Commission is well equipped — indeed, it is designed — to assess complex issues based on "case-specific" facts and the law at hand. *See, e.g., Certain Light Emitting Diode Products*, Inv. No. 337-TA-947, Initial Determination a 426-27 (Sept. 2, 2016) ("The Commission, by virtue of the history of the opinions it has issued for at least the past 30 years has proven its irrefutable capability to deal with complexity").

Moreover, resolving the issues in this case would not involve complex scientific and technical issues falling within FDA's exclusive purview. There is nothing particularly special about this investigation — it turns on well-settled principles of false advertising law, and the Commission can conduct this investigation to completion without interfering in any way with

FDA. The issue of whether the molecular structure of synthetically produced omega-3 products is different from the molecular structure of natural fish oil can be resolved by expert testimony, and the issue of whether one type of product has been marketed before another can be resolved based on facts collected during discovery. There is no reason for the Commission to treat these inquiries differently than it treats inquires posed by other statutes, such the Patent Act.

C. Amarin's Lanham Act and Section 337 claims are straight-forward.

Amarin has alleged that certain competitor products violate both the Lanham Act and Section 337 because their labeling and promotional materials are literally false for two reasons: (1) the products are falsely labeled and promoted as "dietary supplements," and (2) the labeling and promotional materials for the products fail to disclose the material fact that the products are "drugs." Amarin Compl. ¶ 60. Notably, Amarin need only prove that these promotional materials are literally false for one of those reasons, in addition to the other elements of a Lanham Act claim and a Section 337 claim, to win its case.

Amarin's claims under the Lanham Act are straight-forward. The definitions of "dietary supplement" and "drug" in the FDCA establish certain marketplace expectations about the nature of products designated as one or the other. All of the players in the chain of distribution of the synthetically produced omega-3 products at issue here rely upon those expectations, including the distributors selling the products to pharmacies and physicians, the pharmacies and physicians themselves, and consumers. When those players are misled, they are harmed, as are companies that sell competing products lawfully.

Amarin's Section 337 claims are equally straight-forward in that they merely ask the Commission to look at the FDCA, as it would other statutes, like the Patent Act, "or the common law, or other indicia of public policy, to determine the standards by which to judge if acts and

practices involving import trade are unfair." *Certain Universal Transmitters for Garage Door Openers*, Inv. No. 337-TA-497, OUII Br. On Jurisdiction at 6 (Sept. 16, 2003). As OUII has observed, when the Commission looks to these standards, the "Commission does not enforce those laws *per se*; it only enforces the provisions of section 337." *Id.*

D. The FDA policies at issue here are well-settled, and the fact that FDA might or might not change them in the future should not affect this case.

In addition, FDA suggests that the Commission should not take this case because there are "open" questions of policy regarding the definition of "dietary ingredient" that FDA has not yet found time to address. *See* FDA's October 6 Letter, at 2-3. For example, FDA appears to suggest that the Commission should not take this case because there are "open" questions regarding whether synthetically produced substances do not fall under subsections 201(ff)(1)(E) and (F) of the definition of "dietary ingredient." FDA's October 6 Letter, at 2-3.

But that is not true. The statute defines what products qualify as "dietary supplements," and products qualify only if they contain one or more of the types of "dietary ingredients" that are enumerated in the statute. 21 U.S.C. § 321(ff)(1). These definitions reflect common and well-settled understandings that market participants have in the marketplace. Indeed, for more than 15 years, it has been well-recognized that synthetically produced substances, such as those at issue here, are not "dietary ingredients." Amarin Compl., ¶¶ 67-68. In fact, as noted in the complaint, FDA has already determined that synthetic fatty acid esters derived from fish oil "do not fit within the statutory definition of 'dietary ingredient' because they are not constituents of a dietary substance for use by man under section 201(ff)(1)(F)." FDA Letter to AIBMR Life Sciences, Inc., dated March 19, 2014 (emphasis added), Complaint Exhibit 33.

Yet, FDA appears to suggest that its settled interpretation may change by mentioning that it is currently in the process of developing guidance for industry on when a "dietary supplement"

ingredient is a "new dietary ingredient" and "related issues." *See* FDA October 6 Letter, at 2. But, the draft guidance does not give any indication that FDA intends to change its policy on whether synthetically produced substances are "dietary ingredients." Although the draft guidance reiterates the position the agency has taken over the last fifteen years it does not ask stakeholders whether the issue should be reconsidered. *See* Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry (Draft), August 2016 ("Draft NDI Guidance"), at 41. Moreover, as FDA itself noted, the agency has been developing the Draft NDI Guidance since 2011. *See* FDA's October 6 Letter, at 2. Even though Congress required FDA to issue that guidance no later than 180 days after January 4, 2011, in the Food Safety Modernization Act of 2011, Pub. L. 111-353, 124 Stat. 3885, 3921 (Jan. 5, 2011), that guidance still has not been finalized. In fact, five years after issuing the first draft guidance, in 2011, FDA issued a revised draft guidance. It is not clear at this point whether FDA plans to issue another revised draft guidance or a final guidance. Nor is it clear how long it will take FDA to issue the next document or whether the next document will reverse FDA's current stance that synthetically produced substances do not automatically fall under subsections 201(ff)(1)(E) and (F).

In addition, FDA also appears to suggest that the Commission needs to resolve the issue of whether the synthetically produced omega-3 products at issue here are "new" "dietary ingredients" or "old" "dietary ingredients," and that the Commission cannot do so because the agency is currently developing policy in that area. *See* FDA's October 6 Letter, at 3. But, that also is not true.

As discussed in Amarin's Reply Brief on Jurisdiction, based on the relevant statutory language and existing policy, the substances at issue here are not "dietary ingredients" at all and

therefore, they cannot be classified as "old" or "new" "dietary ingredients." Amarin's Reply Br. on Juris., at 30-31. Thus, Amarin did not argue that the substances at issue here are "new dietary ingredients" in its complaint.

The question of whether a "dietary ingredient" is "new" or "old" is only relevant when a manufacturer is trying to determine whether it should submit a "new dietary ingredient" notification ("NDI notification") to FDA 75 days before it markets the "dietary ingredient" or a "dietary supplement" containing the "dietary ingredient." *See* 21 U.S.C. § 350b(a). Section 413(d) of the FDCA defines the term "new dietary ingredient" in pertinent part as "a dietary ingredient that was not marketed in the United States before October 15, 1994," the date on which the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. 103-417, 108 Stat. 4325 (1994), was enacted.

It is true that FDA is evaluating how to document that a "dietary ingredient" is "old," among other things, 82 Fed. Reg. 42098, 42099 (Sept. 6, 2017), and that during this exercise, it could potentially change its interpretation of the definition of "dietary ingredient" such that the term could encompass the synthetically produced omega-3 products at issue here. But, the possibility that FDA could change its interpretation of "dietary ingredient" in the future does not suggest that the Commission should decline to institute this case.

As a general matter, the question for the Commission is not whether FDA might at some point change the regulatory requirements or expectations in a way that might render the products at issue here "dietary ingredients," such that it could be lawful to promote them as "dietary supplements" under the Lanham Act and Section 337. Instead, the question is whether the statements being made today violate those statutes in a manner that is causing competitive harm. Indeed, as explained above, if FDA resolves one of the issues raised in its October 6 letter after

the Commission concludes its investigation and issues an exclusion order, FDA, or one of the Proposed Respondents benefitting from a favorable FDA decision, can pursue post-investigation modification or rescission of the exclusion order and cease and desist order through Commission modification proceedings. 19 U.S.C. § 1337(k); 19 C.F.R. § 210.76(a).

E. The Commission's decisions in the present case would not intrude on FDA's distinct sphere of authority.

FDA's statutory mission is to (1) "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner," and (2) "protect the public health by ensuring that," among other things, foods (including "dietary supplements") are safe and properly labeled and drugs are safe and effective. 21 U.S.C. § 393(b)(1)-(2).

In keeping with FDA's mission to "promote" the public health, the agency serves in the role of "gatekeeper" for the entry of "drugs" into the marketplace. The FDCA provides that "new drugs" may not be introduced or delivered for introduction into interstate commerce without an *FDA-approved new drug application* ("NDA"). *See* 21 U.S.C. § 355(a). For a product to be subject to the drug approval process, the product must be: (1) a "drug," (i.e., a product that is recognized in a drug compendium listed in the statute, a product that is intended to affect the structure/function of the body or to affect disease, or a product intended to be a component in a "drug"), *id.* § 321(g)(1), *and* (2) a "new drug" (i.e., a "drug" that is *not* generally recognized as safe and effective for its intended uses by qualified experts), *id.* § 321(p).

Nothing in the statute gives FDA exclusive jurisdiction or primary jurisdiction to determine whether a product is a "drug," or a "new drug." The terms are defined in the definition section of the statute, consistent with common understandings in the marketplace. *See id.* § 321(g), (p). In fact, it is the *manufacturer — not FDA* — that in the first instance determines whether a product is a "drug." If a manufacturer determines that its product is a

"drug," the manufacturer must comply with FDA's regulations for investigational "new drugs"[9] as it tests the product for safety and efficacy, and then must submit an NDA with that data to FDA for drug approval. *See generally,* Susan Thaul, How FDA Approves Drugs and Regulates Their Safety and Effectiveness, Congressional Research Service, June 25, 2012, Complaint Exhibit 53. There is no dispute here that FDA has authority to review scientific information to determine whether a product is safe and efficacious.

There is no such approval process, however, for "dietary supplements." Products that meet the definition of "dietary supplement" in the FDCA, 21 U.S.C. § 321(ff), may proceed to market without FDA weighing in and without FDA's knowledge of the existence of the product. In fact, FDA estimates that between 1994 and 2012, the number of products sold as "dietary supplements" increased from 4,000 to 55,600, and that FDA was made aware of only 750 of these products pre-market. *See* Draft NDI Guidance, at 12.

FDA's ability to ensure that "dietary supplements" are safe and properly labeled in accordance with its statutory mission is limited to post-market tools, primarily the adulteration and misbranding provisions in the statute. 21 U.S.C. §§ 342, 343. In addition, if FDA becomes aware of the fact that a product sold as a "dietary supplement" is actually an unapproved "new drug," then the agency may decide whether it has the resources to pursue the violation through mechanisms such as warning letters or working with the Department of Justice ("DOJ") to bring enforcement actions. FDA prioritizes spending its resources based on the most pressing public health needs at a given time.

Accordingly, the statutory scheme complements Congress's objective to protect against unfair competition and deceptive advertising. If a *manufacturer* decides that its product is not a

[9] As mentioned, if a product meets the definition of "drug" – it is presumed to be a "new drug" — if FDA has not approved the specific product. *See Hynson,* 412 U.S. at 632.

"drug" and that it is a "dietary supplement," it does not submit the product to FDA for pre-marketing approval and can sell its product without asking permission. If it mislabels an unapproved "new drug" as a "dietary supplement," however, the manufacturer faces potential consequences under the FDCA, the Lanham Act, and Section 337. If FDA detects the violation and has the resources, it may choose to issue a warning letter or work with the DOJ to bring an enforcement action designed to protect the public. Moreover, if the products are falsely labeled and cause competitive harm, competitors have the right to seek separate remedies from this Commission under the Lanham Act and Section 337.

III. FDA's Request Intrudes Upon The Commission's Jurisdiction And Attempts To Eliminate A Remedy That Congress Provided To Competitors And The Domestic Industry Under The Lanham Act And Section 337

FDA's request is particularly troubling for a number of reasons. As mentioned, if the Commission were to abdicate its jurisdiction in this matter, and in all matters affecting FDA-regulated products as FDA requests, then it would not only subvert Congress's objectives in enacting Section 337 and the Lanham Act, but also effectively provide a shield for wrong-doing. Amarin's competitive interests, as well as the competitive interests of countless others — and "indirectly the public at large" — would be substantially harmed. *See POM Wonderful*, 134 S.Ct. at 2239 (observing that if Lanham Act claims challenging food and beverage labeling were precluded, commercial interests and "indirectly the public at large" would be less protected than in other industries). As the Supreme Court observed in *POM Wonderful*, "[i]t is unlikely that Congress intended the FDCA's protection of health and safety to result in less policing of misleading food and beverage labels." *Id.* at 2239. The same is true here — it is unlikely that Congress intended for the FDCA to result in less policing of false and misleading labeling for products sold as "dietary supplements," or indeed, in less policing of unfair trade practices

engaged in by companies selling products falsely labeled as "dietary supplements" than by companies selling products in other industries.

Moreover, as mentioned, FDA's assertions are overbroad, and if the agency is suggesting that courts cannot look to the standards established in the FDCA in private actions, it could affect countless tort cases and other actions proceeding under state law. As discussed at length in Amarin's Reply Brief on Jurisdiction, the government recently took a wholly different position in *Allergan, Inc. v. Athena Cosmetics, Inc. et al.*, 738 F.3d 1350 (Fed. Cir. 2013), which required a court to determine whether a product was a "drug," and thus a "new drug." In that case, the Federal Circuit upheld a district court decision that a purported "cosmetic" marketed for eyelash growth was actually an unapproved "new drug" under the California FDCA analog (which uses the same definitions of "drug" and "new drug" as the FDCA, *compare* Cal. Health Code § 109925(c), *with* 21 U.S.C. § 321(g)(1)(C)). *See id.* Significantly, when the defendant in that case sought *certiorari* review in the U.S. Supreme Court on preemption grounds, the U.S. Solicitor General asked the Supreme Court to deny *certiorari*, stating among other things that:

> Respondent's state-law suit to enjoin the sale of an unapproved drug does not compromise FDA's objectives. While FDA is well-equipped to decide the adequacy of pre-market [drug] submissions actually filed with the agency . . . this Court has noted FDA's "limited resources to monitor" the thousands of drugs on the market after they have been approved [citation omitted]. The agency's capacity to police the vast marketplace of consumer products that have never been submitted to FDA for pre-market approval is even more constrained.

Athena Cosmetics, Inc. v. Allergan, Inc., No. 13-1379, Brief for the United States as Amicus Curiae, at 10-14 (attached to Amarin Reply Br.). These statement are relevant because, as the Supreme Court has observed, preemption principles are instructive for preclusion analysis

"insofar as they are designed to assess the interaction of laws that bear on the same subject." *POM Wonderful*, 134 S.Ct. at 2236.

Further, as discussed at length, the FDCA, the Lanham Act, and Section 337 can work together. *See POM Wonderful*, 134 S.Ct. at 2238-39; *see also* Amarin's Br. on Juris., at 6; Amarin's Reply Br. on Juris., at 2-9. While FDA has important role in protecting public health and consumer safety, the Lanham Act has a different function — it is designed to protect against competitive harms caused when communications in the marketplace are false. As the Supreme Court has recognized, Congress established the Lanham Act's remedies to protect competitive interests and that statute complements the FDCA, as both statutes provide incentives for manufacturers to "behave well" and, in this way, produce "regulatory synergies." *POM Wonderful*, 134 S.Ct. at 2239. Section 337, which Congress also designed to protect the competitive interests of U.S. domestic industries, provides these same "regulatory synergies" when it is permitted to operate alongside the FDCA.

CONCLUSION

For the foregoing reasons, Amarin respectfully request that the Commission institute an investigation into this matter under Section 337 of the Tariff Act. Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 13, 2017 a copy of the foregoing **AMARIN'S RESPONSE TO FDA'S OCTOBER 6, 2017 SUBMISSION** was served to the following parties as indicated below:

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