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APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2018-1247

[Filed May 1, 2019]

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LTD.,
Appellants

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

ROYAL DSM NV, DSM MARINE LIPIDS PERU S.A.C., DSM NUTRITIONAL PRODUCTS LLC, DSM NUTRITIONAL PRODUCTS CANADA, INC., PHARMAVITE LLC, NORDIC NATURALS, INC., NORDIC PHARMA, INC.,
Intervenors

Appeal from the United States International Trade Commission in Investigation No. 337-TA-3247.

2018-114

IN RE: AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LTD., *Petitioners*	)

On Petition for Writ of Mandamus to the United States International Trade Commission in No. 337-TA-3247.

Decided: May 1, 2019

ASHLEY CHARLES PARRISH, King & Spalding LLP, Washington, DC, argued for appellants and petitioners. Also represented by LISA MOLOT DWYER, JESSE SNYDER, JEFFREY MARK TELEP.

HOUDA MORAD, Office of the General Counsel, United States International Trade Commission, Washington, DC, argued for appellee and respondent. Also represented by DOMINIC L. BIANCHI, WAYNE W. HERRINGTON.

MARK S. DAVIES, Orrick, Herrington & Sutcliffe LLP, Washington, DC, argued for intervenors Royal DSM NV, DSM Marine Lipids Peru S.A.C., DSM Nutritional Products LLC, DSM Nutritional Products Canada, Inc., Pharmavite LLC. Also represented by JORDAN COYLE, THOMAS KING-SUN FU; ANDREW D. SILVERMAN, New York, NY; ANNETTE LOUISE HURST, ROBERT SHWARTS, San Francisco, CA.

JOSEPH FORREST BUSA, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC, argued for amicus curiae United States. Also represented by JOSEPH H. HUNT, SCOTT R. MCINTOSH.

ANDREW F. PRATT, Venable LLP, Washington, DC, for intervenors Nordic Naturals, Inc., Nordic Pharma, Inc.

DEANNA TANNER OKUN, Adduci, Mastriani & Schaumberg, LLP, Washington, DC, for amici curiae Council for Responsible Nutrition, Global Organization for EPA and DHA Omega-3S. Also represented by ASHA ALLAM, PAUL M. BARTKOWSKI, PAULINA MARIA STAROSTKA.

Before PROST, *Chief Judge,* WALLACH and HUGHES, *Circuit Judges*.

Opinion for the court filed by *Chief Judge* PROST.

Dissenting opinion filed by *Circuit Judge* WALLACH.

PROST, *Chief Judge*.

Amarin Pharma, Inc. ("Amarin") appeals the decision of the International Trade Commission ("Commission"), which determined not to institute an investigation and, accordingly, dismissed Amarin's complaint. The Commission held that Amarin's complaint failed to allege a cognizable claim based on an unfair method of competition or unfair act under 19 U.S.C. § 1337(a)(1)(A). We affirm.

I

Amarin markets Vascepa® capsules, a prescription drug that consists of 1 gram of eicosapentaenoic acid (the omega-3 acid commonly known as "EPA") in a 1-gram capsule. The EPA in Vascepa® is in ethyl ester form and is synthetically produced from fish oil. Amarin obtained approval from the Food and Drug Administration ("FDA") to market and sell Vascepa®, which is designed to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Vascepa® is the only purified ethyl ester E-EPA product sold in the United States as an FDA-approved drug.

On August 30, 2017, Amarin filed under oath a complaint alleging violations under § 337 of the Tariff Act of 1930, as amended. J.A. 4–114 (Compl.). The complaint alleges that certain companies were falsely labeling and deceptively advertising their imported synthetically produced omega-3 products as (or for use in) "dietary supplements," where the products are actually "new drugs" as defined in the Food, Drug, and Cosmetic Act ("FDCA") that have not been approved for sale or use in the United States. J.A. 9 ¶ 1.

Specifically, Amarin articulated two claims in its complaint: (1) that the importation and sale of the articles is an unfair act or unfair method of competition under § 337 because it violates § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), *see* J.A. 31–56 ¶¶ 53–105; and (2) that importation of the articles violates the Tariff Act "based upon the standards set forth in the FDCA," *see* J.A. 56 ¶ 106. By way of relief, Amarin's complaint seeks an order under § 337(d) that would exclude synthetically produced omega-3 products from entry

into the United States, as well as a cease-and-desist order under § 337(f) to prohibit the proposed respondents from importing, using, or selling synthetically produced omega-3 products. J.A. 112–13 ¶¶ D–F.

After Amarin filed its complaint, the FDA submitted a letter urging the Commission not to institute an investigation and instead to dismiss Amarin's complaint. J.A. 627–37. In the FDA's view, the FDCA prohibits private enforcement actions, including unfair trade practice claims that seek to enforce the FDCA. J.A. 630. The FDA contended that the FDCA precludes any claim that would "require[] the Commission to directly apply, enforce, or interpret the FDCA." J.A. 631. The FDA further contended that the Commission should decline to institute an investigation based on principles of comity to the FDA. J.A. 629.

On October 27, 2017, the Commission issued its decision declining to institute an investigation and dismissing the complaint. J.A. 1–3. The Commission reasoned that Amarin's allegations are precluded by the FDCA. *Id.*; *see also POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014) ("Private parties may not bring [FDCA] enforcement suits." (citing 21 U.S.C. § 337)).

In December 2017, Amarin filed in this court a petition for review and, separately, a petition for a writ of mandamus. We consolidated the two cases. Royal DSM NV, DSM Marine Lipids Peru S.A.C., DSM Nutritional Products LLC, and Pharmavite LLC (collectively, "DSM"); and Nordic Natural, Inc. and

Nordic Pharma, Inc. (collectively, "Nordic") (both, "the Intervenors") intervened in the appeal. ECF Nos. 14, 23, 25, 49.

II

At the outset, we begin by confirming that we have jurisdiction to review the Commission's decision in this case. We then address Amarin's argument that the Commission has a mandatory, non-discretionary duty to institute an investigation when presented with a complaint under oath. Finally, we address whether the Commission correctly determined that Amarin's allegations are precluded by the FDCA.

A

Amarin contends that we have appellate jurisdiction under 28 U.S.C. § 1295(a)(6), but the Intervenors and the Commission disagree.

Our jurisdictional statute gives this court exclusive jurisdiction "to review the final determinations of the United States International Trade Commission relating to unfair practices in import trade, made under section 337 of the Tariff Act of 1930 (19 U.S.C. [§] 1337)." § 1295(a)(6). "Final determinations appealable under § 1295(a)(6) are specified in § 1337(c) . . . ." *Crucible Materials Corp. v. ITC*, 127 F.3d 1057, 1060 (Fed. Cir. 1997).

The Intervenors and the Commission argue that the only "final determinations" subject to appellate review are those listed in § 1337(c). Intervenors' Br. 18–19; Commission's Br. 52–56. And these decisions, according

to the Intervenors, can only be made "as a result of an investigation." Intervenors' Br. 19.

The question as to our jurisdiction in this case is resolved by our decision in *Amgen Inc. v. ITC*, 902 F.2d 1532 (Fed. Cir. 1990). In *Amgen*, the complainant alleged that a company violated § 337 by importing articles made by a patented process. *See* 19 U.S.C. § 1337(a)(1)(B)(ii). The Commission instituted an investigation. *Amgen*, 902 F.2d at 1534. Ultimately, however, the Commission dismissed the complaint because the patent at issue did not contain a process claim, which the Commission considered to be a jurisdictional prerequisite for an investigation under § 1337(a)(1)(B)(ii). *Id.* at 1535.

On appeal in *Amgen*, we first addressed our jurisdiction under 28 U.S.C. § 1295(a)(6). Interpreting 19 U.S.C. § 1337(c), we recognized that § 1337(c) "has been interpreted as requiring a 'final determination decision *on the merits*, excluding or refusing to exclude articles from entry' under section 1337(d), (e), (f) or (g)." *Id.* (quoting *Block v. ITC*, 777 F.2d 1568, 1571 (Fed. Cir. 1985)). But instead of adopting the rigid approach Intervenors argue for in this case, we concluded that the Commission's decision was "intrinsically a final determination, i.e., a determination *on the merits*," thus making it appealable under § 1295(a)(6). *Id.* (emphasis in original).

In reaching that conclusion, we carefully explained the difference between our holding there and our earlier holding in *Block*, a case in which we held that a Commission order was *not* a final determination. In *Block*, the Commission initiated an investigation on its

own motion. The Commission later terminated that investigation after the patent at issue was amended during reexamination. *See id.* As we explained in *Amgen*, "nothing in the termination Order [in *Block*] prejudiced the Commission or any private party in a future proceeding." *Id.* Unlike in *Block*, however, the Commission order in *Amgen* "clearly reach[ed] the merits of [the] complaint and determinatively decide[d] [the complainant's] right to proceed in a section 1337 action." *Id.* We further explained that "any future action brought by [the complainant] would necessarily raise the same issue, and would presumably be dismissed for the same reason." *Id.* at 1536.

As in *Amgen*, the Commission's decision not to institute in this case is "intrinsically a final determination, i.e., a determination *on the merits*." *See id.* at 1535 (emphasis in original). Here, the Commission declined to institute an investigation because the claims were precluded by the FDCA and, therefore, the complaint failed to state a cognizable claim under § 337. *See* J.A 1–3. As in *Amgen*, this decision "clearly reach[ed] the merits of [the] complaint and determinatively decide[d] [Amarin's] right to proceed in a section 1337 action." *See id.*; *see also Import Motors, Ltd., Inc. v. ITC*, 530 F.2d 940, 946–47 (CCPA 1976) (analyzing the right to appeal a Commission order by asking whether the order "has the operative effect of a 'final determination under subsection (d) or (e)'" and noting that "[s]ubstance, not form, must control"). Any future complaint brought by Amarin alleging these same facts "would necessarily raise the same issue" and "would presumably be dismissed for the same reason"—i.e., for lack of a

private right of action to enforce the FDCA. *See Amgen*, 902 F.2d at 1536.[1] In other words, as discussed below, as long as Amarin's complaint is based on proving violations of the FDCA (at least where the FDA has not provided guidance as to whether the articles violate the FDCA), Amarin's claims will be precluded. The Commission's decision is therefore intrinsically a final determination that effectively denies Amarin's request for relief under § 337(d) and (f).[2]

We are unpersuaded by the Intervenors' and the Commission's argument that a final determination can

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[1] The Commission's decision to dismiss the complaint presented a pure question of law regarding FDCA preclusion. Based on that holding, Amarin was in no way free to file another complaint on the same grounds, as the dissent suggests. *See* Dissent at 12. Our recognition of the possibility that Amarin's complaint may not be precluded in the future, under a different set of facts (i.e., where FDA has provided guidance as to whether these particular articles violate the FDCA) does not make the Commission's determination "without prejudice." Indeed, that future possibility would not have existed but for our ability to review and narrow the Commission's even *broader* preclusion holding through this appeal.

[2] The dissent's attempt to characterize the Commission's decision in this case as an order under § 1337(b), rather than as effectively being an order under § 1337(d) or (e), cannot be reconciled with *Amgen*. *Amgen* also did not involve a formal order under § 1337(d), (e), (f), or (g). Regardless, and as the dissent recognizes, *see* Dissent at 11–12, we held in *Amgen* that the substance of the Commission's analysis meant that it "should have dismissed on the merits." 902 F.2d at 1536. But a dismissal on the merits would still not produce a formal order under § 1337(d), (e), (f), or (g). Instead, as our predecessor court emphasized in *Import Motors*, what matters is that the order "ha[s] the same operative effect, . . . as a final determination under subsections (d) and (e). Substance, not form, must control." 530 F.2d at 945–46.

be made only after institution. *See* Intervenors' Br. 3; Commission's Br. 52. Although the decision in *Amgen* occurred after institution, the court's reasoning in that case was not based on that procedural detail. *See Amgen*, 902 F.2d at 1535. Instead, the court's analysis focused on the operative effect of the Commission decision. *See id.*; *Import Motors*, 530 F.2d at 946–47 ("Substance, not form, must control.").

The dissent makes essentially the same argument, contending that a "final determination" can exist only after institution. Dissent at 4–5, 7, 11. But this approach elevates form over substance. The dissent's approach would require the Commission to formally institute an investigation—which requires publication of notice in the Federal Register—just long enough for the Commission to issue the same dismissal order it already issued in this case. There is no indication from the statutory text or context that Congress intended such rigid formality.

Because the Commission's decision is intrinsically a final determination on the merits that has the operative effect of denying Amarin's request for relief under § 337(d) and (f), the decision is a "final determination" under § 337(c). We therefore have jurisdiction to review that decision under 28 U.S.C. § 1295(a)(6).

Having found our jurisdiction proper, we need not address Amarin's alternative argument for

jurisdiction—that we have authority to compel agency action under 5 U.S.C. § 706(1).[3]

B

We next address Amarin's argument that the Commission had a mandatory duty to institute an investigation in this case. Amarin contends that 19 U.S.C. § 1337(b)(1) imposes a non-discretionary duty on the Commission to institute an investigation when presented with a complaint under oath. *See* § 1337(b)(1) ("The Commission shall investigate any alleged violation of this section on complaint under oath or upon its initiative.").

The relevant statutory scheme contemplates certain scenarios in which the Commission need not institute an investigation. *See* § 1337(b)(3) (stating, for example, that the Commission "may institute" under specified circumstances); *see also* § 1330(d)(5) (stating that an investigation shall occur if "one-half of the number of commissioners voting agree that the investigation should be made"). The Commission Rules also contemplate non-institution. Rule 210.10 provides that

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[3] It is unclear whether Amarin is also arguing that we may review the decision via mandamus aside from § 706(1). Indeed, Amarin states that "[t]he judicial review provisions of the Administrative Procedure Act have effectively *displaced* the need for courts to issue writs of mandamus when asked to review agency decisions." Appellant's Br. 26 (emphasis added). Regardless, to the extent Amarin contends that some other basis for mandamus review is warranted, Amarin has failed to explain how it would satisfy the traditional mandamus requirements. *See Cheney v. U.S. Dist. Court for D.C.*, 542 U.S. 367, 380–81 (2004) (listing the three requirements that must be satisfied before a writ may issue).

"[t]he Commission shall determine whether the complaint is *properly filed* and whether an investigation *should be instituted* on the basis of the complaint." 19 C.F.R. § 210.10(a)(1) (emphases added). That Rule further explains that "[i]f the Commission determines not to institute an investigation on the basis of the complaint, the complaint shall be dismissed." 19 C.F.R. § 210.10(c); *see also* 19 C.F.R. § 210.9(a) ("Upon receipt of a complaint alleging violation of section 337 . . . [t]he Commission shall examine the complaint for sufficiency and compliance with the applicable sections of this chapter.").

The question remains, then, in what circumstances may the Commission decline to institute an investigation? Our precedent recognizes at least one such circumstance. *See Syntex Agribusiness, Inc. v. ITC*, 659 F.2d 1038 (CCPA 1981). In *Syntex*, our predecessor court held that the Commission was correct to dismiss a complaint without instituting an investigation where the complaint contained insufficient factual allegations to support a monopolization or conspiracy claim. *Id.* at 1044. The court framed the issue in that case as whether the complaint was a "'complaint' within the meaning of section 337." *Id.* at 1041. Noting the absence of a definition of "complaint," the court recognized that a complaint must comply with then-Commission Rule 210.20, which set forth requirements for a complaint under § 337, including a requirement that the complaint include a statement of the facts constituting the alleged acts of monopolization and conspiracy. *Id.*

at 1042.[4] The court explained that its disposition was based on the complaint's failure to comply with the requirements set forth in that Commission Rule.

Although Amarin appears to raise a broader argument regarding whether the Commission has discretion *generally* not to institute an investigation, we need not address that question here. Instead, we simply hold, consistent with *Syntex*, that the Commission may decline to institute an investigation where a complaint fails to state a cognizable claim under § 337.

The facts alleged as the basis for Amarin's complaint demonstrate that Amarin's allegations are based entirely on violations of the FDCA. As we explain below, claims based on such allegations are precluded by the FDCA, at least where the FDA has not yet provided guidance as to whether violations of the FDCA have occurred. Thus, under the facts of this case, where Amarin's complaint fails to state a cognizable claim for relief, the Commission did not err in its decision not to institute.

C

We next address the Commission's holding that Amarin's complaint "does not allege an unfair method of competition or unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A), as required by the statute and the Commission's rules." J.A. 1. The Commission explained that "the Lanham Act allegations in this case are

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[4] The Commission Rule at issue in *Syntex* has since been re-codified as Commission Rule 210.12.

precluded by the Food, Drug and Cosmetic Act," and that "the Food and Drug Administration is charged with the administration of the FDCA." J.A. 1. As explained below, we agree.

As relevant here, the FDCA authorizes the FDA to regulate drugs and dietary supplements. Introducing a "new drug," 21 U.S.C. § 321(p), into interstate commerce requires FDA approval, *id.* § 355(a). Dietary supplements, however, do not require pre-market approval.

The FDCA provides the United States with "nearly exclusive enforcement authority." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014); *see also* 21 U.S.C. § 337(a) ("Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); *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 medical device provisions . . . ."). Private parties may not bring suits to enforce the FDCA. *POM Wonderful*, 573 U.S. at 109 (citing 21 U.S.C. § 337).

Given the lack of a private right to enforce the FDCA, other circuit courts have grappled with the extent to which private parties' claims under § 43(a) of the Lanham Act are limited by the FDCA. *See PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010); *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934 (8th Cir. 2005); *cf. Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990).

For example, in *PhotoMedex*, the Ninth Circuit affirmed a grant of summary judgment in favor of a defendant as to a Lanham Act false advertising claim based on allegations that the defendant misrepresented that its product had received FDA clearance. 601 F.3d at 922. That case involved the FDCA's 510(k) clearance process, and the court focused heavily on the details of that statutory scheme in reaching its holding. In short, the defendant had received 510(k) clearance for its earlier device, but the plaintiff argued that based on significant changes to the device, the defendant should have made a *new* 510(k) submission to obtain market clearance for the updated product. *Id.* at 926. In reaching its conclusion, the court emphasized that "[i]t is significant that under the regulatory structure established by the FDA for the medical devices at issue in this case, clearance to market a given device did not necessarily require an affirmative statement of approval by the FDA." *Id.* Further, the court explained that even though the FDA had been aware of the alleged need for a new clearance, the FDA had never taken the position that the products had not been properly cleared. In sum, the court held that "[b]ecause the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act *may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation*." *Id.* at 924 (emphasis added).[5]

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[5] The court limited its holding, reasoning that "we do not suggest that the Lanham Act can never support private party claims involving FDA approval or clearance of drugs or medical devices."

The Eighth Circuit employed similar reasoning in *Alpharma*. 411 F.3d at 939–41. There, the district court granted a defendant's motion to dismiss a plaintiff's Lanham Act claim that was based on alleged misrepresentation of the uses for which a drug had been approved. *Id.* at 935–36. The Eighth Circuit reversed, reasoning that because the FDA had given guidance on the precise dispute between the parties, the plaintiff's claim in this particular case did not require a "preemptive determination" of how the FDA would interpret and enforce its own regulations. *Id.* at 940; *see also PhotoMedex*, 601 F.3d at 929 (summarizing *Alpharma* and noting that, there, "FDA explicitly made clear that it had not given the defendant's product the affirmative approval required for expanding its list of permissible uses" and thus "the plaintiff could bring a Lanham Act claim based on the defendant's false statements in its advertisement that the uses had been approved").

In its complaint, Amarin includes two separate bases for its § 337 claims. First, Amarin alleges that respondents' labeling or advertisements about the articles is false or misleading, in violation of § 43(a) of the Lanham Act, such that importation of those articles is an "unfair act" under § 337 of the Tariff Act. *See* J.A. 31–56 ¶¶ 53–105 (Compl.). This claim is based on the

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Id. at 924. Giving an example, the court stated that if "it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued for injuries suffered by a competitor as a result of a false assertion that approval had been granted." *Id.* at 924–25.

allegation that labeling the products as "dietary supplements" is literally false because the products "cannot meet the definition of 'dietary supplement' in Section 201(ff) of the FDCA." J.A. 33 ¶ 60 (Compl.). And, the claim is further based on the allegation that the products "are actually unapproved 'new drugs' under the FDCA." J.A. 47 (Compl.). Amarin's complaint relies on these alleged FDCA violations to support key elements of its Lanham Act false-advertising claim. *See* J.A. 55 ¶¶ 102–03 (applying these allegations to the elements of a false advertising claim). In other words, proving the Lanham Act claim in this case requires proving violations of the FDCA.

The second claim in Amarin's complaint alleges that the respondents' importation and sale of the products constitute unfair acts or unfair methods of competition under § 337 based on the standards set forth in the FDCA. J.A. 56 ¶ 106; *see* J.A. 56–59 (Compl.). For example, Amarin alleges that the products are "misbranded drugs in violation of the standards set forth in Section 502 of the FDCA, [21 U.S.C.] § 352, and adulterated drugs, in violation of Section 501 of the FDCA, *id.* § 351." J.A. 57 ¶ 107. Every allegation supporting this claim rests on an alleged violation of the FDCA.

In sum, Amarin's two § 337 claims are based on the same factual allegations—that respondents' products do not meet the definition of "dietary supplement" in the FDCA, *see* 21 U.S.C. § 321(ff), and are instead unapproved "new drugs" under the FDCA. *E.g.*, J.A. 33–34 ¶¶ 60–61; J.A. 47–49 ¶¶ 84–87; J.A. 56 ¶ 106.

The case before us bears much resemblance to *PhotoMedex*, and we consider the Ninth Circuit's reasoning in that case persuasive. In our case, the alleged violations of § 337 are based entirely on—and could not exist without—the FDCA. Because private parties are prohibited from enforcing the FDCA, the same concerns expressed in *PhotoMedex* apply here. *See PhotoMedex*, 601 F.3d at 924. We note, however, that a major concern of the court in *PhotoMedex* was that proceeding with the Lanham Act claim would "require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." *Id.* The court in *PhotoMedex* appears to have been concerned with adjudicating FDCA violations for the first time via a Lanham Act claim, rather than via the FDA. *See id.*; *id.* at 928 (noting that the court's decision was consistent with other decisions "refusing to allow private actions under the Lanham Act premised on enforcement determinations *that the FDA and other regulatory agencies did not themselves make*" (emphasis added)); *see also Alpharma*, 411 F.3d at 935–37; *Sandoz*, 902 F.2d at 231 (noting that what the FDCA "do[es] not create directly, the Lanham Act does not create indirectly, at least not in cases requiring original interpretation of these Acts or their accompanying regulations").

As in *PhotoMedex* (and unlike in *Alpharma*), affirmative FDA approval is not required in the dietary supplement context. Instead, manufacturers self-police. And as in *PhotoMedex* (and unlike in *Alpharma*), the FDA has not provided guidance as to whether the products at issue in this case should be considered

"new drugs" that require approval. Given this lack of guidance, we see no need to go further than the court in *PhotoMedex* did. We therefore hold that a complainant fails to state a cognizable claim under § 337 where that claim is based on proving violations of the FDCA and where the FDA has not taken the position that the articles at issue do, indeed, violate the FDCA. Such claims are precluded by the FDCA.

We note that this limited holding is consistent with the Commission's arguments in its briefing, which indicated that Amarin's claims are precluded *at least* until the FDA has provided guidance as to whether the products at issue are dietary supplements. *See, e.g.*, Commission's Br. 58 (suggesting that "Amarin is free to file a new complaint once the FDA issues sufficient guidance with respect to the accused products such that the Commission is not required to interpret the FDCA in the first instance and Amarin's claims are otherwise no longer precluded by the FDCA"). We also note that the United States, as amicus, appears to seek a broader ruling—that all such claims are precluded *regardless* of whether the FDA has provided guidance. As explained above, we need not address that broader question here, as the FDA has not provided guidance as to whether the products at issue properly qualify as "dietary supplements."

Despite Amarin's heavy reliance on *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014), that recent decision does not alter our analysis. There, the plaintiff sued a competitor under § 43 of the Lanham Act, alleging that the label on one of the defendant's products was deceptive and misleading. *Id.* at 106. The

product at issue was a juice blend sold with a label featuring the words "pomegranate blueberry" more prominently than the words "flavored blend of 5 juices." *Id.* at 106, 110. Despite the prominence of the names of those two juices, the product actually contained just 0.3% pomegranate juice and 0.2% blueberry juice. *Id.* at 110. The plaintiff alleged that this labeling (and other features) mislead consumers into thinking that the juice blend contained primarily pomegranate and blueberry juices. *Id.* The issue in the case was whether a private party could bring a Lanham Act claim challenging a food label as misleading, where that food label was regulated by the FDCA. The Ninth Circuit held that the plaintiff's Lanham Act claim was precluded by the FDCA, which forbids misbranding of food, including by misleading labeling. *Id.* The Supreme Court reversed, holding instead that the Lanham Act claim in that case was not precluded.

Amarin views *POM Wonderful* as rejecting the view that the FDCA precludes Lanham Act claims. But this reads *POM Wonderful* too broadly. Although *POM Wonderful* held that the FDCA does not categorically preclude a Lanham Act claim based on a product (e.g., a label) that is regulated by the FDCA, the court did not open the door to Lanham Act claims that are based on proving FDCA violations. The allegations underlying the Lanham Act claim in *POM Wonderful* did not require proving a violation of the FDCA itself. *See id.* at 117 ("But POM seeks to enforce the Lanham Act, not the FDCA or its regulations."). This stands in stark contrast to the allegations in our case, which are based solely on alleged violations of the FDCA's requirements.

Amarin also relies on this court's decision in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013). But *Allergan* was a pre-emption case—not a preclusion case. As the Supreme Court explained in *POM Wonderful*, "[i]n pre-emption cases, the question is whether state law is pre-empted by a federal statute, or in some instances, a federal agency action." *POM Wonderful*, 573 U.S. at 111. Meanwhile, in cases where a cause of action under one federal statute is alleged to be precluded by the provisions of another federal statute, "the state-federal balance does not frame the inquiry," and the "'presumption against pre-emption' has no force." *Id.* (internal citation omitted). In *Allergan*, we simply held that the FDCA did not preempt certain state law claims based on violations of state law requirements that paralleled FDCA requirements. *Allergan*, 738 F.3d at 1354–56. That analysis has no bearing on this case.

In short, although Amarin presents its claims as violations of the Tariff Act, in reality those claims constitute an attempt to enforce requirements of the FDCA through the remedies provided under the Tariff Act. Because private parties have no such enforcement authority, Amarin's allegations fail to state a cognizable claim for relief.[6]

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[6] Although the Intervenors argue that the Commission should receive *Chevron* deference for its interpretation of § 337 with respect to the preclusion issue in this case, *see* Intervenors' Br. 54–68, the Commission does not. The United States, as amicus, also does not argue in favor of *Chevron* deference.

III

For the foregoing reasons, we hold that we have appellate jurisdiction to review the Commission's decision not to institute an investigation in this case. Exercising that jurisdiction, we hold that the Commission correctly held that Amarin's complaint fails to present a cognizable claim under § 337. The decision is therefore affirmed and the petition for mandamus is denied as moot.

AFFIRMED

WALLACH, *Circuit Judge*, dissenting.

It is axiomatic that "the power which [C]ongress possess[es] to create [c]ourts of inferior jurisdiction, necessarily implies the power to limit the jurisdiction of those [c]ourts to particular objects." *United States v. Hudson*, 11 U.S. (7 Cranch) 32, 33 (1812); *see Lockerty v. Phillips*, 319 U.S. 182, 187 (1943) (explaining that Congress may "withhold[] jurisdiction from [lower courts] in the *exact degrees and character* which to Congress may seem proper for the public good" (emphasis added) (internal quotation marks and citations omitted)). The statute is clear: Congress limited our subject-matter jurisdiction "to review the *final determinations* of the United States International Trade Commission [('ITC')] . . . made under [19 U.S.C. § 1337 (2012)[1]]," 28 U.S.C. § 1295(a)(6) (2012)

[1] Section 1337 addresses, inter alia, "[u]nfair methods of competition and unfair acts in the importation of articles . . . into the United States." 19 U.S.C. § 1337(a)(1)(A). Section 1337 is part

(emphasis added), by defining an ITC "final determination" as a determination made "*under subsection (d), (e), (f), or (g)* of [§ 1337]," 19 U.S.C. § 1337(c) (emphasis added).

Although I agree with the majority's conclusion that the ITC did not err in declining to institute an investigation into the complaint under § 1337 brought by Appellants-Petitioners Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (together, "Amarin"), *see* J.A. 4–114 (Complaint), I disagree with the majority's approach, for it fails to give due respect to Congress's choice to limit our appellate jurisdiction. As the ITC's decision not to institute was made pursuant to § 1337(b), I believe that we lack appellate jurisdiction; however, I would instead exercise mandamus jurisdiction and conclude that Amarin has not demonstrated that the "extraordinary remedy" of issuing a writ of mandamus is appropriate. *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 289 (1988). Because I would dismiss Amarin's appeal and deny its petition for a writ of mandamus, I respectfully dissent.

DISCUSSION

I. Congress Limited Our Appellate Jurisdiction

Congress conferred upon us exclusive jurisdiction "to review the final determinations of the [ITC] relating to unfair practices in import trade, made under [§ 1337]." 28 U.S.C. § 1295(a)(6). Relevant here,

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of the Tariff Act of 1930 ("Tariff Act"). *See* Pub. L. No. 71-361, § 337, 46 Stat. 590, 703–04 (codified at 19 U.S.C. §§ 1304 et seq.).

§ 1337(c) employs the term "final determination" and states that "[a]ny person adversely affected by a final determination of the [ITC] under subsection (d), (e), (f), or (g) of [§ 1337] may appeal such determination . . . to the United States Court of Appeals for the Federal Circuit." In interpreting these statutes, we have said that "[f]inal determinations appealable under § 1295(a)(6) are specified in § 1337(c)." *Crucible Materials Corp. v. U.S. Int'l Trade Comm'n*, 127 F.3d 1057, 1060 (Fed. Cir. 1997).

II. We Lack Appellate Jurisdiction to Review the ITC's Decision Not to Institute an Investigation

Amarin filed its Complaint, which alleges, inter alia, that Royal DSM NV et al. ("Intervenors") have "falsely labeled[] and/or promoted for use" synthetically produced omega-3 products ("the Accused Products"), labelled "as dietary supplements," even though they "are actually unapproved new drugs under the Federal Food, Drug and Cosmetic Act ('FDCA')," 21 U.S.C. §§ 301 et seq. (2012), thereby violating "Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a) [(2012)], and the standards established by the FDCA," J.A. 9 (internal quotation marks omitted). The Commissioners of the ITC voted not to institute an investigation, *see* J.A. 681, and sent a letter to Amarin's counsel notifying it of that decision, J.A. 1–2; *see* 19 C.F.R. § 210.10(c) (2018) ("If the [ITC] determines not to institute an investigation on the basis of the complaint, the complaint shall be dismissed, and the complainant and all proposed respondents will receive written notice of the [ITC]'s action and the reason(s) therefor."). The ITC stated it "has determined not to institute an investigation based

on the [C]omplaint . . . and has dismissed the [C]omplaint." J.A. 1. According to the ITC, the "[C]omplaint does not allege an unfair method of competition or an unfair act cognizable under . . . § 1337(a)(1)(A), as required by the statute and the [ITC]'s rules." J.A. 1. The ITC reasoned "that the Lanham Act allegations in this case are precluded by the [FDCA]," and that "the Food and Drug Administration [('FDA')] is charged with the administration of the FDCA." J.A. 1.

The ITC's Decision Not to Institute is not an appealable final determination. An appealable final determination is an ITC determination made "under subsection (d), (e), (f), or (g) of [§ 1337]." 19 U.S.C. § 1337(c). Subsections (d)–(g) pertain to determinations on exclusion orders, *see id.* § 1337(d)–(e), (g), and cease-and-desist orders, *see id.* § 1337(f)–(g).[2] Amarin contends that the ITC's Decision Not to Institute is a final determination under either § 1337(d) or (f). *See* Appellants' Br. 20; *see* Oral Arg. at 1:37–55, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2018-1247.mp3 (disclaiming reliance on § 1337(e) or (g)). Each subsection contemplates determinations made by the ITC *post-initiation* of an investigation. Subsection (d) explicitly provides that the ITC's determination to exclude articles will be made "as a result of an investigation." 19 U.S.C. § 1337(d)(1) (emphasis added); *see id.* § 1337(c) (directing that a "determination under subsection (d) or (e) . . . shall be

[2] Section 1337(g) governs determinations rendered pursuant to a default and thereby relates to both exclusion and cease-and-desist orders. *See* 19 U.S.C. § 1337(g)(1)–(2).

made on the record after notice and opportunity for a hearing"). Subsection (f) sets forth that the ITC's determination to issue a cease-and-desist order is "[i]n addition to, or in lieu of, taking action" pursuant to other statutory provisions that involve an initiated investigation, i.e., taking action "under subsection (d)," which involves a completed investigation, "or [subsection] (e)," *id.* § 1337(f)(1), which covers the ITC's determination to exclude articles made "during the course of an investigation," *id.* § 1337(e)(1).

Here, the ITC neither initiated an investigation, decided whether a violation of § 1337 occurred, nor determined whether to issue an exclusion or cease-and-desist order. *See* J.A. 1–2. In *Block v. United States International Trade Commission*, we held that the "ITC's decision to terminate its investigation as 'abated' [was not] an appealable 'final determination.'" 777 F.2d 1568, 1570 (Fed. Cir. 1985); *see id.* at 1571. The ITC terminated the investigation because, following the U.S. Patent and Trademark Office's reexamination relating to an allegedly-infringed patent, the reexamined claims were substantively changed. *Id.* at 1570. There, the ITC's termination decision "did not rule on the merits," so its "action could not intrinsically be a final determination within the meaning of . . . § 1337(c) because it was not a decision *to exclude or refuse to exclude* articles from entry under . . . § 1337(d), (e), or (f)." *Id.* at 1571 (emphasis added). Similarly, the Decision Not to Institute did not render a decision on whether to exclude the allegedly mislabeled products or issue a cease-and-desist order. *See* J.A. 1–2. The ITC refused institution of an

investigation and dismissed the Complaint, without reaching the requested relief. *See* J.A. 1–2.

Rather than placing the ITC's authority to investigate in subsections (d), (e), (f), or (g), of § 1337, Congress located that authority in subsection (b). Section 1337(b) authorizes the ITC to "investigate any alleged violation of [§ 1337] on complaint under oath or upon its initiative," 19 U.S.C. § 1337(b)(1), and contemplates instances where the ITC "shall terminate, *or not institute*, any investigation" or "suspend its investigation," *id.* § 1337(b)(3) (emphasis added); *see VastFame Camera, Ltd. v. Int'l Trade Comm'n*, 386 F.3d 1108, 1112, 1113 (Fed. Cir. 2004) (explaining that § 1337(b) "gives the [ITC] general authority to investigate violations of the statute"). Congress indicated its intent to make § 1337(b) determinations, such as the Decision Not to Institute, non-appealable through its exclusion of subsection (b) from the list of final determinations in § 1337(c). *See Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 392 (2013) ("[T]he *expressio unius, exclusio alterius* canon, . . . instructs that when Congress includes one possibility in a statute, it excludes another by implication."); *cf. United States v. Erika*, 456 U.S. 201, 207 (1982) ("In the context of the statute's *precisely drawn provisions*, this omission provides persuasive evidence that Congress deliberately intended to foreclose further review of such claims." (emphasis added)).[3] Had

[3] Case law, while not expressly deciding the issue, supports this conclusion. *See BASR P'ship v. United States*, 795 F.3d 1338, 1342 (Fed. Cir. 2015) (consulting case law to construe a statute). In *Syntex Agribusiness, Inc. v. United States International Trade*

Congress intended to make non-institution decisions appealable, it merely needed to include them in its list of determinations that would be considered final in § 1337(c). Given that Congress decided not to adopt this "obvious alternative," "the natural implication is that [it] did not intend" for such decisions under § 1337(b) to be appealable. *Lozano v. Montoya Alvarez*, 572 U.S. 1, 16 (2014). "We cannot revisit that choice." *Id.*

The statutory context further reveals that Congress did not contemplate appealability of an ITC non-institution decision. *See Digital Realty Tr., Inc. v. Somers*, 138 S. Ct. 767, 777 (2018) (acknowledging that courts may rely upon a statute's "purpose and design" to "corroborate" their understanding of the statutory text); *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 349 (1984) ("[T]he presumption favoring judicial review of administrative action may be overcome by inferences of intent drawn from the statutory scheme as a whole."). In fact, § 1337(b)(1) covers the procedures for commencing and conducting an investigation, and details that, "[u]pon commencing any such investigation, the [ITC] shall publish notice thereof in the Federal Register." Moreover, "the [ITC] shall, within 45 days *after an investigation is initiated*,

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Commission, the ITC decided not to institute an investigation pursuant to § 1337 and accordingly dismissed a complaint. *See* 659 F.2d 1038, 1040 (CCPA 1981). The complainant first petitioned our predecessor court for a writ of mandamus based on the ITC's refusal to investigate and later filed an appeal from the ITC's decision. *Id.* at 1041. Our predecessor court, by separate order, "dismissed [the complainant's] . . . *appeal* on the ground that there had been *no final determination* by [the] ITC, which is essential for jurisdiction of the court." *Id.* (emphases added).

establish a target date for its *final determination*." 19 U.S.C. § 1337(b)(1) (emphases added). Through this language, Congress established two separate types of ITC determinations—a decision whether to institute an investigation and, separately, a final determination, i.e., those made under subsections (d), (e), (f), or (g)—and clarified that a final determination is rendered *after* an institution decision. *See id.*

Similarly, § 1337(j) provides that, when the ITC "determines that there is a violation of [§ 1337] . . . or . . . [ha]s reason to believe that there is such a violation," it shall, inter alia, "transmit to the President a copy of such determination and the action taken under subsection (d), (e), (f), (g), or (i)[4] of [§ 1337]." *Id.* § 1337(j)(1), (j)(1)(B). The President then has the option "for policy reasons" to "disapprove[of] such determination" within sixty days, *id.* § 1337(j)(2), and, if not disapproved or if approved, the "determination *shall become final*," *id.* § 1337(j)(4) (emphasis added). Such determinations that are submitted to the President become final well after an investigation is complete. *See id.* § 1337(b), (j). Tellingly, Congress has conferred jurisdiction explicitly over certain administrative decisions not to institute an investigation, elsewhere in the Tariff Act. Congress explained that "an interested party . . . may commence an action in the United States Court of International Trade [('CIT')]" challenging "a determination by [the

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[4] Section 1337(i) authorizes the ITC, "[i]n addition to taking action under subsection (d)," to "issue an order providing that any article imported in violation of the provisions of [§ 1337] be seized and forfeited to the United States" in certain situations.

U.S. Department of Commerce] . . . *not to initiate an investigation*" related to antidumping and countervailing duty proceedings. 19 U.S.C. § 1516a(a)(1), (a)(1)(A) (emphasis added); *see* 28 U.S.C. § 1581(c) (conferring the CIT with "exclusive jurisdiction" over actions commenced pursuant to § 1516a). Congress did not confer such jurisdiction in § 1337.

The legislative history does not support the majority's conclusion. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207, 209–12 (1994) (consulting legislative history for statutory interpretation). Although the original version of § 1337 did not define an ITC final determination by reference to specific subsections, *see* Tariff Act § 337, 46 Stat. at 703–04, Congress amended § 1337(c) and added that "[a]ny person adversely affected by a final determination of the [ITC] under subsection (d) or (e) may appeal such determination," Trade Act of 1974, Pub. L. No. 93-618, § 341(a), 88 Stat. 1978, 2054.[5] When Congress inserted this language, the Senate Finance Committee recognized it was "extend[ing] the right to judicial review of final [ITC] determinations." S. Rep. No. 93-1298, at 197 (1974) (Conf. Rep.). It provided that "[b]y *final determination*, as used in this section, *the Committee means a*[*n ITC*] *determination which has been referred to the President under* [*the predecessor to current § 1337(j)*], and has been approved by the

[5] Congress later amended this language to include additional subsections under the definition of an ITC final determination. *See, e.g.*, Trade Agreements Act of 1979, Pub. L. No. 96-39, § 1105(c), 93 Stat. 144, 311 (adding subsection (f)).

President or has not been disapproved . . . after referral of the determination." *Id.* (emphases added). This appears to be the only time in the legislative history Congress expounded its understanding of the term final determination in § 1337. Nowhere does Congress equate a non-institution decision to a final determination. *See id.*

While this court has acknowledged that § 1337 "provides for judicial review of both positive and negative determinations," we should be careful not to expand the scope of the term final determination to include determinations beyond those contemplated by Congress. *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1535 (Fed. Cir. 1990) (footnote omitted); *see Imp. Motors, Ltd. v. U.S. Int'l Trade Comm'n*, 530 F.2d 940, 945 (CCPA 1976) (explaining that § 1337(c) "indicate[s] an intent to provide appeal of such an unfavorable decision"). I find no support for the proposition that Congress intended a non-institution decision to be an appealable final determination. Accordingly, I do not believe that the ITC's Decision Not to Institute is a final determination under § 1337(c).

Apparently recognizing that it is not a final determination as defined by § 1337(c), the majority sweeps the ITC's Decision Not to Institute under our jurisdiction by holding that it is *intrinsically* a final determination, based on *Amgen*. *See* Maj. Op. 6–9. In *Amgen*, the ITC dismissed a complaint for lack of subject-matter jurisdiction because the patent-at-issue did "not contain any process patent claims," which the ITC considered "a jurisdictional prerequisite." 902 F.2d

at 1535. We exercised appellate jurisdiction and vacated and remanded the ITC's dismissal, determining that the dismissal "should have been phrased as a dismissal on the merits." *Id.* at 1537.[6] There, the ITC's determination that the patent's claims "do not, in fact, cover a process [as required by statute] . . . clearly reache[d] the merits of [the] complaint and determinatively decide[d the complainant's] right to proceed in a [§] 1337 action." *Id.* at 1535. The court recognized that "the jurisdictional requirements of [§] 1337 mesh with the factual requirements necessary to prevail on the merits," and explained that "the fact that [the complainant] was later unable to sustain these allegations [regarding whether its patent covered a process] is not material to the issue of *jurisdiction*." *Id.* at 1536.

The majority's reliance on *Amgen* is misplaced. *Amgen* did not involve a determination made pursuant

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[6] *Amgen*'s statement that "when a decision is intrinsically a final determination, i.e., a determination on the merits, then that decision is appealable under [§] 1337(c)," traces back to our predecessor court's decision in *Import Motors*. *Amgen*, 902 F.2d at 1535 (emphasis omitted) (citing, inter alia, 530 F.2d at 944). Even under this interpretation of "final determination," the ITC's determination must be made "under subsection (d), (e), (f), or (g)" because the statutory language cabins the *types* of final determinations that are appealable. 19 U.S.C. § 1337(c); *see Import Motors*, 530 F.2d at 944 (recounting that an earlier version of § 1337, "[s]trictly interpreted[,] . . . refers to a final administrative decision on the merits, excluding or refusing to exclude articles from entry under subsection (d) or (e)"). *Amgen* does not expand our jurisdiction to determinations made under different subsections of § 1337, nor could it. *See Lozano*, 572 U.S. at 16 (recognizing that we are bound by Congress's choice).

to § 1337(b); instead, the ITC in that case "conduct[ed] a full investigation" before dismissing the complaint. *Id.* at 1534. The majority dismisses this fact by stating "the court's reasoning in [*Amgen*] was not based on that procedural detail" but "focused on the operative effect of the [ITC] decision." Maj. Op. 8. That is hardly a procedural detail; this fact, coupled with § 1337(c)'s precise definition of a final determination, fundamentally limits *Amgen*'s holding. *See* 19 U.S.C. § 1337(c). The majority criticizes "this approach [as] elevat[ing] form over substance." Maj. Op. 9. There is a "general principle that agencies with statutory enforcement responsibilities enjoy broad discretion in allocating investigative and enforcement resources." *Torrington Co. v. United States*, 68 F.3d 1347, 1351 (Fed. Cir. 1995). The majority fails to give due respect to Congress's choice, thereby placing "this court in the position of routinely second-guessing the [ITC]'s decisions [on non-institution] . . . , a role for which [we] are ill-suited and one that could be quite disruptive of [the ITC]'s effort to establish enforcement priorities." *Id.*

In addition, *Amgen* determined that the ITC improperly characterized its dismissal as jurisdictional on the process patent claim issue, but we explained that the substance of its analysis meant it "should have dismissed on the merits." 902 F.2d at 1536 (footnote omitted). By contrast, the ITC's two-page Decision Not to Institute, which dismissed on jurisdictional grounds, does not purport to, nor in fact does, reach the merits of Amarin's Complaint; rather, it recognizes that the FDCA vests the FDA with primacy over such claims. *See* J.A. 1–2. Amarin is not barred from seeking relief;

for instance, the ITC did not find that Amarin failed to "pro[ve] . . . an element of the cause of action," such as finding the Intervenors did not falsely label their accused products and therefore did not commit an unfair act under § 1337(a). *Engage Learning, Inc. v. Salazar*, 660 F.3d 1346, 1354 (Fed. Cir. 2011) (citation omitted); *see Block*, 777 F.2d at 1571 (dismissing for lack of appellate jurisdiction where the ITC did not make a "finding as to whether . . . § 1337 was violated"); J.A. 1–2. As in *Block*, the ITC's Decision Not to Institute is not "the equivalent of a final determination," as it was "without prejudice," because it did not make findings on the merits, and Amarin is "free to" file another complaint. 777 F.2d at 1571; *see id.* (rejecting the argument that the ITC's "order . . . involved the denial of substantive rights"); *Amgen*, 902 F.2d at 1535 (distinguishing *Block* and recognizing there that the court "found the *lack of any findings* by the [ITC] to be critical; nothing in the termination [o]rder prejudiced the [ITC] or any private party in a future proceeding" (emphasis added) (citation omitted)). Indeed, the ITC represents, on appeal, that its dismissal is "without prejudice." Appellee's Br. 57. The ITC notes that "Amarin is free to file a new complaint once the FDA issues sufficient guidance with respect to the [A]ccused [P]roducts such that the [ITC] is not required to interpret the FDCA in the first instance and Amarin's claims are otherwise no longer precluded by the FDCA." *Id.* at 58 (footnote omitted); *see Imp. Motors*, 530 F.2d at 947 & n.13 (relying on an ITC representation made on appeal regarding whether a party could participate in the second stage of a § 1337 investigation). The majority implicitly recognizes that Amarin may eventually re-file. *See* Maj. Op. 7–8 ("[A]s

long as Amarin's [C]omplaint is based on proving violations of the FDCA (*at least where the FDA has not provided guidance as to whether the articles violate the FDCA*), Amarin's claims will be precluded." (emphasis added)).[7] Accordingly, I conclude that the ITC's Decision Not to Institute is not an appealable final determination within the meaning of § 1337(c).

III. We Should Exercise Mandamus Jurisdiction and Deny Amarin's Petition

Intervenors argue that we lack mandamus jurisdiction to review Amarin's Petition, *see* Intervenors' Br. 34–37, because we may not "use mandamus to obtain jurisdiction over agency decisions otherwise beyond [our] reach," *id.* at 36. Amarin and the ITC contend that we have mandamus jurisdiction. *See* Appellants' Br. 25–27; Appellee's Br. 51–52. I agree with Amarin and the ITC.

Pursuant to the All Writs Act, we "may issue all writs necessary or appropriate in aid of" our jurisdiction. 28 U.S.C. § 1651(a). Therefore, our "authority to issue writs of mandamus is restricted by statute to those cases in which the writ is in aid of [appellate] jurisdiction." *Roche v. Evaporated Milk Ass'n*, 319 U.S. 21, 25 (1943). "The authority is not limited to issuance of the writ where the court already had jurisdiction on appeal; rather, the authority

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[7] Because the dismissal is without prejudice and Amarin can re-file, the majority need not be concerned that the ITC would unnecessarily be required "to formally institute . . . just long enough . . . to issue the same dismissal order it already issued in this case." Maj. Op. 9.

extends to those cases which are within its appellate jurisdiction although no appeal has been perfected." *In re Princo Corp.*, 478 F.3d 1345, 1351 (Fed. Cir. 2007) (internal quotation marks and citation omitted).

I believe we have jurisdiction to consider Amarin's Petition, which seeks mandamus relief. Section 1295(a) gives us "exclusive jurisdiction . . . (6) to review the final determinations of the [ITC] . . . made under [§ 1337]." *See* 19 U.S.C. § 1337(c) (defining "a final determination"). If the ITC were to erroneously refuse to initiate an investigation, we might consequently be divested of appellate jurisdiction over a matter which we should have had jurisdiction following ITC's institution and final determination. *See id.*; 28 U.S.C. § 1295(a)(6). Review over such matters is necessary as an exercise of "limited judicial power to preserve th[is] court's jurisdiction." *FTC v. Dean Foods Co.,* 384 U.S. 597, 604 (1966). Amarin's Petition asks whether the ITC is required to initiate an investigation under the governing statute. *See, e.g.*, Appellants' Br. 38 ("The Tariff Act imposes a non-discretionary duty on the [ITC] to institute investigations into alleged unfair trade practices and methods of competition."); *see id.* at 39 (relying on § 1337(b)). Accordingly, we retain mandamus jurisdiction, which, under these circumstances, is "necessary to protect [our] prospective jurisdiction." *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 76 (D.C. Cir. 1984); *see, e.g., Syntex*, 659 F.2d at 1041 (considering, but ultimately denying, a petition for writ of mandamus where petitioner sought "to compel [the] ITC to institute an investigation"); *cf. In re Cypress Semiconductor Corp.*, 321 F. App'x 964, 965 (Fed. Cir.

2009) (exercising jurisdiction over, but ultimately denying, a petition for writ of mandamus seeking to compel the ITC "to halt its investigation").

Heckler v. Chaney does not require a different result. *See* 470 U.S. 821 (1985); *see also* Intervenors' Br. 26–27, 35 (citing *Heckler* to argue the ITC's Decision Not to Institute is immune from judicial review). Although *Heckler* held that "an agency's decision not to take enforcement action should be presumed immune from judicial review," 470 U.S. at 832, the Supreme Court did not address "a refusal by the agency to institute proceedings based solely on the belief that it lacks jurisdiction," *id.* at 833 n.4, or a "decision [that] is predicated solely on the agency's interpretation of a statute," *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. v. Brock*, 783 F.2d 237, 245 n.10 (D.C. Cir. 1986). However, as discussed above, the Petition challenges the ITC's interpretation of § 1337 and the FDCA, *see* Appellants' Br. 38–39, 50, and the ITC refused to institute because it lacked jurisdiction over Amarin's Complaint, *see* J.A. 1. Thus, I would exercise mandamus jurisdiction over Amarin's Petition, but agree with the majority's conclusion that Amarin has failed to demonstrate that it is entitled to the extraordinary relief of mandamus. *See* Maj. Op. 9 n.3, 9–18.[8]

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[8] To the extent there remains a question about whether we have mandamus jurisdiction, the ITC's failure to institute an investigation would not evade judicial review. Instead, the Administrative Procedure Act ("APA"), 60 Stat. 237 (1946) (codified in scattered sections of 5 U.S.C. (2012)), provides that "[a] person . . . adversely affected" by "final agency action[s] for which there is no other adequate remedy in a court" may seek review of that

CONCLUSION

Through § 1337(c), Congress expressly defined a final determination of the ITC and thereby precisely drew the limits of our appellate jurisdiction. The majority disregards the text of the statute and Congress's intent by holding that a § 1337(b) non-institution determination is appealable, even though Congress expressly defined a final determination as one made under § 1337(d)–(g). Because I believe we must follow Congress's directive, I respectfully dissent.

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action, 5 U.S.C. §§ 702, 704. Under this type of action, a reviewing court may "compel agency action unlawfully withheld," *id.* § 706(1), for example the ITC's failure to institute an investigation. Therefore, if appellate and mandamus jurisdiction are lacking in this court, Amarin may be able to raise an APA challenge in district court. *See Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004) (holding "a claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*"). It is useful to note that § 1337(c) expressly contemplates APA review of certain types of determinations. *See* 19 U.S.C. § 1337(c) (stating that ITC "determinations under subsections (d), (e), (f), and (g) . . . with respect to its findings on the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, the amount and nature of bond, or the appropriate remedy shall be reviewable in accordance with [§] 706" and "[d]eterminations . . . under subsections (e), (f), and (j) . . . with respect to forfeiture of bonds and under subsection (h) . . . with respect to the imposition of sanctions for abuse of discovery or abuse of process shall also be reviewable in accordance with [§] 706").

APPENDIX B

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, D.C. 20436

October 27, 2017

Jeffrey M. Telep, Esq.
KING & SPALDING LLP
1700 Pennsylvania Avenue, NW
Suite 200
Washington, DC 20006-4706

Re: Complaint Filed by Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. Concerning Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form (Docket No. 3247)

Dear Mr. Telep:

Under Commission Rules 210.9, 210.10 and 210.12(a)(2), (3) and (8), 19 C.F.R. §§ 210.9, 210.10, 210.12(a)(2), (3) and (8), the Commission has determined not to institute an investigation based on

the complaint filed on behalf of Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively "Amarin") concerning Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form, and has dismissed the complaint.

Amarin's complaint does not allege an unfair method of competition or an unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A), as required by the statute and the Commission's rules. The Commission notes that the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act ("FDCA"). The Commission also notes that the Food and Drug Administration is charged with the administration of the FDCA.

Documents relating to this institution determination, including comments from the complainant, proposed respondents, and the public, can be found on the Commission's Electronic Document Information System (EDIS) under Docket Number 3247.

Sincerely,

/s/ Lisa R. Barton
Lisa R. Barton
Secretary to the Commission

cc: Proposed respondents

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, DC 20436

CO84-PP-001

October 27, 2017

CONCURRING MEMORANDUM

TO: THE SECRETARY[1]

FROM: Commissioner Meredith M. Broadbent MMB

SUBJECT: Complaint of Amarin Pharma, Inc. concerning Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-Esterified Triglyceride Form (Docket No. 3247)

Commissioner Broadbent concurs with the Commission's finding that Amarin's complaint does not allege an unfair method of competition or an unfair act

[1] This is a public document to be filed in EDIS.

under section 337(a)(1)(A) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(a)(1)(A). She notes, however, that she does not reach the issue of whether properly pleaded claims based on the Food, Drug, and Cosmetic Act may be cognizable under section 337(a)(1)(A).

APPENDIX C

15 U.S.C. § 1125. False designations of origin, false descriptions, and dilution forbidden

(a) Civil action

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which--

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

(2) As used in this subsection, the term "any person" includes any State, instrumentality of a State or employee of a State or instrumentality of a

State acting in his or her official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this chapter in the same manner and to the same extent as any nongovernmental entity.

(3) In a civil action for trade dress infringement under this chapter for trade dress not registered on the principal register, the person who asserts trade dress protection has the burden of proving that the matter sought to be protected is not functional.

(b) Importation

Any goods marked or labeled in contravention of the provisions of this section shall not be imported into the United States or admitted to entry at any customhouse of the United States. The owner, importer, or consignee of goods refused entry at any customhouse under this section may have any recourse by protest or appeal that is given under the customs revenue laws or may have the remedy given by this chapter in cases involving goods refused entry or seized.

(c) Dilution by blurring; dilution by tarnishment

(1) Injunctive relief

Subject to the principles of equity, the owner of a famous mark that is distinctive, inherently or through acquired distinctiveness, shall be entitled to an injunction against another person who, at any time after the owner's mark has become famous, commences use of a mark or trade name in commerce that is likely to cause dilution by blurring or dilution by tarnishment of the famous mark,

regardless of the presence or absence of actual or likely confusion, of competition, or of actual economic injury.

(2) Definitions

(A) For purposes of paragraph (1), a mark is famous if it is widely recognized by the general consuming public of the United States as a designation of source of the goods or services of the mark's owner. In determining whether a mark possesses the requisite degree of recognition, the court may consider all relevant factors, including the following:

(i) The duration, extent, and geographic reach of advertising and publicity of the mark, whether advertised or publicized by the owner or third parties.

(ii) The amount, volume, and geographic extent of sales of goods or services offered under the mark.

(iii) The extent of actual recognition of the mark.

(iv) Whether the mark was registered under the Act of March 3, 1881, or the Act of February 20, 1905, or on the principal register.

(B) For purposes of paragraph (1), "dilution by blurring" is association arising from the similarity between a mark or trade name and a famous mark that impairs the distinctiveness of

the famous mark. In determining whether a mark or trade name is likely to cause dilution by blurring, the court may consider all relevant factors, including the following:

(i) The degree of similarity between the mark or trade name and the famous mark.

(ii) The degree of inherent or acquired distinctiveness of the famous mark.

(iii) The extent to which the owner of the famous mark is engaging in substantially exclusive use of the mark.

(iv) The degree of recognition of the famous mark.

(v) Whether the user of the mark or trade name intended to create an association with the famous mark.

(vi) Any actual association between the mark or trade name and the famous mark.

(C) For purposes of paragraph (1), "dilution by tarnishment" is association arising from the similarity between a mark or trade name and a famous mark that harms the reputation of the famous mark.

(3) Exclusions

The following shall not be actionable as dilution by blurring or dilution by tarnishment under this subsection:

(A) Any fair use, including a nominative or descriptive fair use, or facilitation of such fair use, of a famous mark by another person other than as a designation of source for the person's own goods or services, including use in connection with--

(i) advertising or promotion that permits consumers to compare goods or services; or

(ii) identifying and parodying, criticizing, or commenting upon the famous mark owner or the goods or services of the famous mark owner.

(B) All forms of news reporting and news commentary.

(C) Any noncommercial use of a mark.

(4) Burden of proof

In a civil action for trade dress dilution under this chapter for trade dress not registered on the principal register, the person who asserts trade dress protection has the burden of proving that--

(A) the claimed trade dress, taken as a whole, is not functional and is famous; and

(B) if the claimed trade dress includes any mark or marks registered on the principal register, the unregistered matter, taken as a whole, is famous separate and apart from any fame of such registered marks.

(5) Additional remedies

In an action brought under this subsection, the owner of the famous mark shall be entitled to injunctive relief as set forth in section 1116 of this title. The owner of the famous mark shall also be entitled to the remedies set forth in sections 1117(a) and 1118 of this title, subject to the discretion of the court and the principles of equity if--

(A) the mark or trade name that is likely to cause dilution by blurring or dilution by tarnishment was first used in commerce by the person against whom the injunction is sought after October 6, 2006; and

(B) in a claim arising under this subsection--

(i) by reason of dilution by blurring, the person against whom the injunction is sought willfully intended to trade on the recognition of the famous mark; or

(ii) by reason of dilution by tarnishment, the person against whom the injunction is sought willfully intended to harm the reputation of the famous mark.

(6) Ownership of valid registration a complete bar to action

The ownership by a person of a valid registration under the Act of March 3, 1881, or the Act of February 20, 1905, or on the principal register under this chapter shall be a complete bar to an

action against that person, wit respect to that mark, that--

(A) is brought by another person under the common law or a statute of a State; and

(B)(i) seeks to prevent dilution by blurring or dilution by tarnishment; or

(ii) asserts any claim of actual or likely damage or harm to the distinctiveness or reputation of a mark, label, or form of advertisement.

(7) Savings clause

Nothing in this subsection shall be construed to impair, modify, or supersede the applicability of the patent laws of the United States.

(d) Cyberpiracy prevention

(1)(A) A person shall be liable in a civil action by the owner of a mark, including a personal name which is protected as a mark under this section, if, without regard to the goods or services of the parties, that person--

(i) has a bad faith intent to profit from that mark, including a personal name which is protected as a mark under this section; and

(ii) registers, traffics in, or uses a domain name that--

(I) in the case of a mark that is distinctive at the time of registration of

the domain name, is identical or confusingly similar to that mark;

(II) in the case of a famous mark that is famous at the time of registration of the domain name, is identical or confusingly similar to or dilutive of that mark; or

(III) is a trademark, word, or name protected by reason of section 706 of Title 18 or section 220506 of Title 36.

(B)(i) In determining whether a person has a bad faith intent described under subparagraph (A), a court may consider factors such as, but not limited to--

(I) the trademark or other intellectual property rights of the person, if any, in the domain name;

(II) the extent to which the domain name consists of the legal name of the person or a name that is otherwise commonly used to identify that person;

(III) the person's prior use, if any, of the domain name in connection with the bona fide offering of any goods or services;

(IV) the person's bona fide noncommercial or fair use of the mark in a site accessible under the domain name;

(V) the person's intent to divert consumers from the mark owner's online location to a site accessible under the

domain name that could harm the goodwill represented by the mark, either for commercial gain or with the intent to tarnish or disparage the mark, by creating a likelihood of confusion as to the source, sponsorship, affiliation, or endorsement of the site;

(VI) the person's offer to transfer, sell, or otherwise assign the domain name to the mark owner or any third party for financial gain without having used, or having an intent to use, the domain name in the bona fide offering of any goods or services, or the person's prior conduct indicating a pattern of such conduct;

(VII) the person's provision of material and misleading false contact information when applying for the registration of the domain name, the person's intentional failure to maintain accurate contact information, or the person's prior conduct indicating a pattern of such conduct;

(VIII) the person's registration or acquisition of multiple domain names which the person knows are identical or confusingly similar to marks of others that are distinctive at the time of registration of such domain names, or dilutive of famous marks of others that are famous at the time of registration of such domain names, without regard to the goods or services of the parties; and

(IX) the extent to which the mark incorporated in the person's domain name registration is or is not distinctive and famous within the meaning of subsection (c).

(ii) Bad faith intent described under subparagraph (A) shall not be found in any case in which the court determines that the person believed and had reasonable grounds to believe that the use of the domain name was a fair use or otherwise lawful.

(C) In any civil action involving the registration, trafficking, or use of a domain name under this paragraph, a court may order the forfeiture or cancellation of the domain name or the transfer of the domain name to the owner of the mark.

(D) A person shall be liable for using a domain name under subparagraph (A) only if that person is the domain name registrant or that registrant's authorized licensee.

(E) As used in this paragraph, the term "traffics in" refers to transactions that include, but are not limited to, sales, purchases, loans, pledges, licenses, exchanges of currency, and any other transfer for consideration or receipt in exchange for consideration.

(2)(A) The owner of a mark may file an in rem civil action against a domain name in the judicial district in which the domain name registrar, domain name registry, or other domain name authority that

registered or assigned the domain name is located if--

> **(i)** the domain name violates any right of the owner of a mark registered in the Patent and Trademark Office, or protected under subsection (a) or (c); and
>
> **(ii)** the court finds that the owner--
>
> > **(I)** is not able to obtain in personam jurisdiction over a person who would have been a defendant in a civil action under paragraph (1); or
> >
> > **(II)** through due diligence was not able to find a person who would have been a defendant in a civil action under paragraph (1) by--
> >
> > > **(aa)** sending a notice of the alleged violation and intent to proceed under this paragraph to the registrant of the domain name at the postal and e-mail address provided by the registrant to the registrar; and
> > >
> > > **(bb)** publishing notice of the action as the court may direct promptly after filing the action.

(B) The actions under subparagraph (A)(ii) shall constitute service of process.

(C) In an in rem action under this paragraph, a domain name shall be deemed to have its situs in the judicial district in which--

(i) the domain name registrar, registry, or other domain name authority that registered or assigned the domain name is located; or

(ii) documents sufficient to establish control and authority regarding the disposition of the registration and use of the domain name are deposited with the court.

(D)(i) The remedies in an in rem action under this paragraph shall be limited to a court order for the forfeiture or cancellation of the domain name or the transfer of the domain name to the owner of the mark. Upon receipt of written notification of a filed, stamped copy of a complaint filed by the owner of a mark in a United States district court under this paragraph, the domain name registrar, domain name registry, or other domain name authority shall--

(I) expeditiously deposit with the court documents sufficient to establish the court's control and authority regarding the disposition of the registration and use of the domain name to the court; and

(II) not transfer, suspend, or otherwise modify the domain name during the pendency of the action, except upon order of the court.

(ii) The domain name registrar or registry or other domain name authority shall not be liable for injunctive or monetary relief under this paragraph except in the case of bad faith

or reckless disregard, which includes a willful failure to comply with any such court order.

(3) The civil action established under paragraph (1) and the in rem action established under paragraph (2), and any remedy available under either such action, shall be in addition to any other civil action or remedy otherwise applicable.

(4) The in rem jurisdiction established under paragraph (2) shall be in addition to any other jurisdiction that otherwise exists, whether in rem or in personam.

19 U.S.C. § 1334. Cooperation with other agencies

The commission shall in appropriate matters act in conjunction and cooperation with the Treasury Department, the Department of Commerce, the Federal Trade Commission, or any other departments, or independent establishments of the Government, and such departments and independent establishments of the Government shall cooperate fully with the commission for the purposes of aiding and assisting in its work, and, when directed by the President, shall furnish to the commission, on its request, all records, papers, and information in their possession relating to any of the subjects of investigation by the commission and shall detail, from time to time, such officials and employees to said commission as he may direct.

19 U.S.C. § 1337. Unfair practices in import trade

(a) Unlawful activities; covered industries; definitions

(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:

(A) Unfair methods of competition and unfair acts in the importation of articles (other than articles provided for in subparagraphs (B), (C), (D), and (E)) into the United States, or in the sale of such articles by the owner, importer, or consignee, the threat or effect of which is--

(i) to destroy or substantially injure an industry in the United States;

(ii) to prevent the establishment of such an industry; or

(iii) to restrain or monopolize trade and commerce in the United States.

(B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that--

(i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under Title 17; or

(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

(C) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that infringe a valid and enforceable United States trademark registered under the Trademark Act of 1946.

(D) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of a semiconductor chip product in a manner that constitutes infringement of a mask work registered under chapter 9 of Title 17.

(E) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consigner, of an article that constitutes infringement of the exclusive rights in a design protected under chapter 13 of Title 17.

(2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.

(3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned--

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing.

(4) For the purposes of this section, the phrase "owner, importer, or consignee" includes any agent of the owner, importer, or consignee.

(b) Investigation of violations by Commission

(1) The Commission shall investigate any alleged violation of this section on complain t under oath or upon its initiative. Upon commencing any such investigation, the Commission shall publish notice thereof in the Federal Register. 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. To promote expeditious adjudication, the Commission shall, within 45 days after an investigation is initiated, establish a target date for its final determination.

(2) During the course of each investigation under this section, the Commission shall consult with, and

seek advice and information from, the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and such other departments and agencies as it considers appropriate.

(3) Whenever, in the course of an investigation under this section, the Commission has reason to believe, based on information before it, that a matter, in whole or in part, may come within the purview of part II of subtitle IV of this chapter, it shall promptly notify the Secretary of Commerce so that such action may be taken as is otherwise authorized by such part II. If the Commission has reason to believe that the matter before it (A) is based solely on alleged acts and effects which are within the purview of section 1671 or 1673 of this title, or (B) relates to an alleged copyright infringement with respect to which action is prohibited by section 1008 of Title 17, the Commission shall terminate, or not institute, any investigation into the matter. If the Commission has reason to believe the matter before it is based in part on alleged acts and effects which are within the purview of section 1671 or 1673 of this title, and in part on alleged acts and effects which may, independently from or in conjunction with those within the purview of such section, establish a basis for relief under this section, then it may institute or continue an investigation into the matter. If the Commission notifies the Secretary or the administering authority (as defined in section 1677(1) of this title) with respect to a matter under this paragraph, the Commission may suspend its

investigation during the time the matter is before the Secretary or administering authority for final decision. Any final decision by the administering authority under section 1671 or 1673 of this title with respect to the matter within such section 1671 or 1673 of this title of which the Commission has notified the Secretary or administering authority shall be conclusive upon the Commission with respect to the issue of less-than-fair-value sales or subsidization and the matters necessary for such decision.

(c) Determinations; review

The Commission shall determine, with respect to each investigation conducted by it under this section, whether or not there is a violation of this section, except that the Commission may, by issuing a consent order or on the basis of an agreement between the private parties to the investigation, including an agreement to present the matter for arbitration, terminate any such investigation, in whole or in part, without making such a determination. Each determination under subsection (d) or (e) shall be made on the record after notice and opportunity for a hearing in conformity with the provisions of subchapter II of chapter 5 of Title 5. All legal and equitable defenses may be presented in all cases. A respondent may raise any counterclaim in a manner prescribed by the Commission. Immediately after a counterclaim is received by the Commission, the respondent raising such counterclaim shall file a notice of removal with a United States district court in which venue for any of the counterclaims raised by the party would exist

under section 1391 of Title 28. Any counterclaim raised pursuant to this section shall relate back to the date of the original complaint in the proceeding before the Commission. Action on such counterclaim shall not delay or affect the proceeding under this section, including the legal and equitable defenses that may be raised under this subsection. Any person adversely affected by a final determination of the Commission under subsection (d), (e), (f), or (g) may appeal such determination, within 60 days after the determination becomes final, to the United States Court of Appeals for the Federal Circuit for review in accordance with chapter 7 of Title 5. Notwithstanding the foregoing provisions of this subsection, Commission determinations under subsections (d), (e), (f), and (g) with respect to its findings on the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, the amount and nature of bond, or the appropriate remedy shall be reviewable in accordance with section 706 of Title 5. Determinations by the Commission under subsections (e), (f), and (j) with respect to forfeiture of bonds and under subsection (h) with respect to the imposition of sanctions for abuse of discovery or abuse of process shall also be reviewable in accordance with section 706 of Title 5.

(d) Exclusion of articles from entry

(1) If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating

the provision of this section, be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. The Commission shall notify the Secretary of the Treasury of its action under this subsection directing such exclusion from entry, and upon receipt of such notice, the Secretary shall, through the proper officers, refuse such entry.

(2) The authority of the Commission to order an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that--

(A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons; or

(B) there is a pattern of violation of this section and it is difficult to identify the source of infringing products.

(e) Exclusion of articles from entry during investigation except under bond; procedures applicable; preliminary relief

(1) If, during the course of an investigation under this section, the Commission determines that there is reason to believe that there is a violation of this

section, it may direct that the articles concerned, imported by any person with respect to whom there is reason to believe that such person is violating this section, be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. The Commission shall notify the Secretary of the Treasury of its action under this subsection directing such exclusion from entry, and upon receipt of such notice, the Secretary shall, through the proper officers, refuse such entry, except that such articles shall be entitled to entry under bond prescribed by the Secretary in an amount determined by the Commission to be sufficient to protect the complainant from any injury. If the Commission later determines that the respondent has violated the provisions of this section, the bond may be forfeited to the complainant.

(2) A complainant may petition the Commission for the issuance of an order under this subsection. The Commission shall make a determination with regard to such petition by no later than the 90th day after the date on which the Commission's notice of investigation is published in the Federal Register. The Commission may extend the 90-day period for an additional 60 days in a case it designates as a more complicated case. The Commission shall publish in the Federal Register

its reasons why it designated the case as being more complicated. The Commission may require the complainant to post a bond as a prerequisite to the issuance of an order under this subsection. If the Commission later determines that the respondent has not violated the provisions of this section, the bond may be forfeited to the respondent.

(3) The Commission may grant preliminary relief under this subsection or subsection (f) to the same extent as preliminary injunctions and temporary restraining orders may be granted under the Federal Rules of Civil Procedure.

(4) The Commission shall prescribe the terms and conditions under which bonds may be forfeited under paragraphs (1) and (2).

(f) Cease and desist orders; civil penalty for violation of orders

(1) In addition to, or in lieu of, taking action under subsection (d) or (e), the Commission may issue and cause to be served on any person violating this section, or believed to be violating this section, as the case may be, an order directing such person to cease and desist from engaging in the unfair methods or acts involved, unless after considering the effect of such order upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such order should not be issued. The Commission may at any time, upon such notice and in such manner as it

deems proper, modify or revoke any such order, and, in the case of a revocation, may take action under subsection (d) or (e), as the case may be. If a temporary cease and desist order is issued in addition to, or in lieu of, an exclusion order under subsection (e), the Commission may require the complainant to post a bond, in an amount determined by the Commission to be sufficient to protect the respondent from any injury, as a prerequisite to the issuance of an order under this subsection. If the Commission later determines that the respondent has not violated the provisions of this section, the bond may be forfeited to the respondent. The Commission shall prescribe the terms and conditions under which the bonds may be forfeited under this paragraph.

(2) Any person who violates an order issued by the Commission under paragraph (1) after it has become final shall forfeit and pay to the United States a civil penalty for each day on which an importation of articles, or their sale, occurs in violation of the order of not more than the greater of $100,000 or twice the domestic value of the articles entered or sold on such day in violation of the order. Such penalty shall accrue to the United States and may be recovered for the United States in a civil action brought by the Commission in the Federal District Court for the District of Columbia or for the district in which the violation occurs. In such actions, the United States district courts may issue mandatory injunctions incorporating the relief sought by the Commission as they deem

appropriate in the enforcement of such final orders of the Commission.

(g) Exclusion from entry or cease and desist order; conditions and procedures applicable

(1) If--

(A) a complaint is filed against a person under this section;

(B) the complaint and a notice of investigation are served on the person;

(C) the person fails to respond to the complaint and notice or otherwise fails to appear to answer the complaint and notice;

(D) the person fails to show good cause why the person should not be found in default; and

(E) the complainant seeks relief limited solely to that person;

the Commission shall presume the facts alleged in the complaint to be true and shall, upon request, issue an exclusion from entry or a cease and desist order, or both, limited to that person unless, after considering the effect of such exclusion or order upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, the Commission finds that such exclusion or order should not be issued.

(2) In addition to the authority of the Commission to issue a general exclusion from entry of articles when a respondent appears to contest an investigation concerning a violation of the provisions of this section, a general exclusion from entry of articles, regardless of the source or importer of the articles, may be issued if--

(A) no person appears to contest an investigation concerning a violation of the provisions of this section,

(B) such a violation is established by substantial, reliable, and probative evidence, and

(C) the requirements of subsection (d)(2) are met.

(h) Sanctions for abuse of discovery and abuse of process

The Commission may by rule prescribe sanctions for abuse of discovery and abuse of process to the extent authorized by Rule 11 and Rule 37 of the Federal Rules of Civil Procedure.

(i) Forfeiture

(1) In addition to taking action under subsection (d), the Commission may issue an order providing that any article imported in violation of the provisions of this section be seized and forfeited to the United States if--

(A) the owner, importer, or consignee of the article previously attempted to import the article into the United States;

(B) the article was previously denied entry into the United States by reason of an order issued under subsection (d); and

(C) upon such previous denial of entry, the Secretary of the Treasury provided the owner, importer, or consignee of the article written notice of--

(i) such order, and

(ii) the seizure and forfeiture that would result from any further attempt to import the article into the United States.

(2) The Commission shall notify the Secretary of the Treasury of any order issued under this subsection and, upon receipt of such notice, the Secretary of the Treasury shall enforce such order in accordance with the provisions of this section.

(3) Upon the attempted entry of articles subject to an order issued under this subsection, the Secretary of the Treasury shall immediately notify all ports of entry of the attempted importation and shall identify the persons notified under paragraph (1)(C).

(4) The Secretary of the Treasury shall provide--

(A) the written notice described in paragraph (1)(C) to the owner, importer, or consignee of any article that is denied entry into the United

States by reason of an order issued under subsection (d); and

(B) a copy of such written notice to the Commission.

(j) Referral to President

(1) If the Commission determines that there is a violation of this section, or that, for purposes of subsection (e), there is reason to believe that there is such a violation, it shall--

(A) publish such determination in the Federal Register, and

(B) transmit to the President a copy of such determination and the action taken under subsection (d), (e), (f), (g), or (i), with respect thereto, together with the record upon which such determination is based.

(2) If, before the close of the 60-day period beginning on the day after the day on which he receives a copy of such determination, the President, for policy reasons, disapproves such determination and notifies the Commission of his disapproval, then, effective on the date of such notice, such determination and the action taken under subsection (d), (e), (f), (g), or (i) with respect thereto shall have no force or effect.

(3) Subject to the provisions of paragraph (2), such determination shall, except for purposes of subsection (c), be effective upon publication thereof in the Federal Register, and the action taken under

subsection (d), (e), (f), (g), or (i), with respect thereto shall be effective as provided in such subsections, except that articles directed to be excluded from entry under subsection (d) or subject to a cease and desist order under subsection (f) shall, until such determination becomes final, be entitled to entry under bond prescribed by the Secretary in an amount determined by the Commission to be sufficient to protect the complainant from any injury. If the determination becomes final, the bond may be forfeited to the complainant. The Commission shall prescribe the terms and conditions under which bonds may be forfeited under this paragraph.

(4) If the President does not disapprove such determination within such 60-day period, or if he notifies the Commission before the close of such period that he approves such determination, then, for purposes of paragraph (3) and subsection (c) such determination shall become final on the day after the close of such period or the day on which the President notifies the Commission of his approval, as the case may be.

(k) Period of effectiveness; termination of violation or modification or rescission of exclusion or order

(1) Except as provided in subsections (f) and (j), any exclusion from entry or order under this section shall continue in effect until the Commission finds, and in the case of exclusion from entry notifies the Secretary of the Treasury, that the conditions which

led to such exclusion from entry or order no longer exist.

(2) If any person who has previously been found by the Commission to be in violation of this section petitions the Commission for a determination that the petitioner is no longer in violation of this section or for a modification or rescission of an exclusion from entry or order under subsection (d), (e), (f), (g), or (i)--

(A) the burden of proof in any proceeding before the Commission regarding such petition shall be on the petitioner; and

(B) relief may be granted by the Commission with respect to such petition--

(i) on the basis of new evidence or evidence that could not have been presented at the prior proceeding, or

(ii) on grounds which would permit relief from a judgment or order under the Federal Rules of Civil Procedure.

(l) Importation by or for United States

Any exclusion from entry or order under subsection (d), (e), (f), (g), or (i), in cases based on a proceeding involving a patent, copyright, mask work, or design under subsection (a)(1), shall not apply to any articles imported by and for the use of the United States, or imported for, and to be used for, the United States with the authorization or consent of the Government. Whenever any article would have been excluded from

entry or would not have been entered pursuant to the provisions of such subsections but for the operation of this subsection, an owner of the patent, copyright, mask work, or design adversely affected shall be entitled to reasonable and entire compensation in an action before the United States Court of Federal Claims pursuant to the procedures of section 1498 of Title 28.

(m) "United States" defined

For purposes of this section and sections 1338 and 1340 of this title, the term "United States" means the customs territory of the United States as defined in general note 2 of the Harmonized Tariff Schedule of the United States.

(n) Disclosure of confidential information

(1) Information submitted to the Commission or exchanged among the parties in connection with proceedings under this section which is properly designated as confidential pursuant to Commission rules may not be disclosed (except under a protective order issued under regulations of the Commission which authorizes limited disclosure of such information) to any person (other than a person described in paragraph (2)) without the consent of the person submitting it.

(2) Notwithstanding the prohibition contained in paragraph (1), information referred to in that paragraph may be disclosed to--

(A) an officer or employee of the Commission who is directly concerned with--

(i) carrying out the investigation or related proceeding in connection with which the information is submitted,

(ii) the administration of a bond posted pursuant to subsection (e), (f), or (j),

(iii) the administration or enforcement of an exclusion order issued pursuant to subsection (d), (e), or (g), a cease and desist order issued pursuant to subsection (f), or a consent order issued pursuant to subsection (c),

(iv) proceedings for the modification or rescission of a temporary or permanent order issued under subsection (d), (e), (f), (g), or (i), or a consent order issued under this section, or

(v) maintaining the administrative record of the investigation or related proceeding,

(B) an officer or employee of the United States Government who is directly involved in the review under subsection (j), or

(C) an officer or employee of the United States Customs Service who is directly involved in administering an exclusion from entry under subsection (d), (e), or (g) resulting from the investigation or related proceeding in connection with which the information is submitted.

21 U.S.C. § 321. Definitions; generally

For the purposes of this chapter--

(a)(1) The term "State", except as used in the last sentence of section 372(a) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any

of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c),

and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic

Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the

labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means--

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has

not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q)(1)(A) Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is

included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 348(h)(6) of this title, and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on

food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any substance from such definition.

(2) The term "pesticide chemical residue" means a residue in or on raw agricultural commodity or processed food of--

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance

from the definition of "pesticide chemical" or "pesticide chemical residue" if--

(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this chapter other than sections 342(a)(2)(B) and 346a of this title.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific

procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include--

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act or the Meat Inspection Act of March 4, 1907, as amended and extended;

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term "color additive" means a material which--

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part

thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe" as used in paragraph (s) of this section and in sections 348, 360b, 360ccc, and 379e of this title, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,--

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the

labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

(w) The term "animal feed", as used in paragraph (w)[1] of this section, in section 360b of this title, and in provisions of this chapter referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

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[1] So in original. Probably should be "paragraph (v)".

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of Title 5 and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which

shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under section 355(j) of this title for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and--

(1) in the case of section 335a of this title, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 335b and 335c of this title, includes any supplement to such an application.

(bb) The term "knowingly" or "knew" means that a person, with respect to information--

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 335a of this title, the term "high managerial agent"--

(1) means--

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for--

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 335a and 335b of this title, the term "drug product" means a drug subject to regulation under section 355, 360b, or 382 of this title or under section 262 of Title 42.

(ee) The term "Commissioner" means the Commissioner of Food and Drugs.

(ff) The term "dietary supplement"--

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that--

(A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title;

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does--

(A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of Title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include--

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of Title 42, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a

food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.[2]

Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.

(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

(ii) The term "compounded positron emission tomography drug"--

(1) means a drug that--

(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) has been compounded by or on the order of a practitioner who is licensed by a State to

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[2] So in original. Provision probably should be set flush with subpar. (B).

compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

(jj) The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(kk) Priority supplement

The term "priority supplement" means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

(*ll*)(1) The term "single-use device" means a device that is intended for one use, or on a single patient during a single procedure.

(2)(A) The term "reprocessed", with respect to a single-use device, means an original device that has

previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

(B) A single-use device that meets the definition under clause (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term "recycled" rather than the term "reprocessed".

(3) The term "original device" means a new, unused single-use device.

(mm)(1) The term "critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

(2) The term "semi-critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(nn) The term "major species" means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to this definition by regulation.

(oo) The term "minor species" means animals other than humans that are not major species.

(pp) The term "minor use" means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

(qq) The term "major food allergen" means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

(B) A food ingredient that is exempt under paragraph (6) or (7) of section 343(w) of this title.

(rr)(1) The term "tobacco product" means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

(2) The term "tobacco product" does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 353(g) of this title.

(3) The products described in paragraph (2) shall be subject to subchapter V of this chapter.

(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this chapter (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).

APPENDIX D

UNITED STATES INTERNATIONAL TRADE COMMISSION

Investigation No. 337-TA- ___

[Filed August 30, 2017]

In The Matter Of	)
	)
Certain Synthetically Produced,	)
Predominantly EPA Omega-3	)
Products In Ethyl Ester Or	)
Re-esterified Triglyceride Form	)
	)

VERIFIED COMPLAINT UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

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I. INTRODUCTION

1. Amarin Pharma, Inc. ("Amarin Pharma") and Amarin Pharmaceuticals Ireland Ltd. ("Amarin Ireland") (collectively, "Amarin" or "Complainants") file this Complaint pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337"). Amarin manufactures and markets Vascepa® capsules, a drug approved by the Food and Drug Administration ("FDA") consisting of 1 gram of eicosapentaenoic acid (the omega-3 acid commonly known as "EPA") in a 1-gram capsule. The EPA in Vascepa® is in ethyl ester form and is synthetically produced. Amarin respectfully requests that the U.S. International Trade Commission (the "ITC" or "Commission") commence an investigation into the unlawful importation or sale in the United States of synthetically produced omega-3 products that are predominantly comprised of EPA in either ethyl ester ("EE") or re-esterified ("rTG") form and are falsely labeled, and/or promoted for use as, or in "dietary supplements" (the "Synthetically Produced Omega-3 Products" (as defined with more particularity in paragraph 8, below)). **Exhibits 1-12.** These products are cloaked as "dietary supplements" but are actually unapproved "new drugs" under the Federal Food, Drug and Cosmetic Act ("FDCA"). The false labeling or promotion of these products constitutes an unfair act and/or unfair method of competition under Section 337 because, among other things, these acts violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and the standards established by the FDCA.

2. A large majority of omega-3 products that are imported or sold in the United States are legally marketed "dietary supplements" comprised of common fish oil. *See* Global Organization for EPA and DHA Omega-3s ("GOED") Blog, June 5, 2014, (noting that, for example, "[e]thyl esters represented 12% of the US dietary supplement market in 2013"), **Exhibit 13.** Common fish oil typically includes a mixture of saturated and unsaturated fats, including a variety of omega fatty acids in their natural triglyceride ("nTG") form. *See* R. Preston Mason and Samuel C.R. Sherratt, Omega-3 fatty acid fish oil dietary supplements contain saturated fats and oxidized lipids that may interfere with their intended biological benefits, Biochemical and Biophysical Research Communications (2016), **Exhibit 14**. Common fish oil is not synthetically produced. Amarin is not alleging that the import or sale in the United States of common fish oil, *i.e.,* for use in, or as "dietary supplements," violates Section 337, or other U.S. laws *per se,* and Amarin is not requesting an investigation into the import or sale of those natural products. Nor is Amarin requesting an investigation into synthetically produced omega-3 products in EE or rTG form that are not predominantly comprised of the omega-3 acid, EPA.

3. The Synthetically Produced Omega-3 Products are being sold in the United States as ingredients for finished products, and as finished products themselves. Certain of the Proposed Respondents are selling synthetically produced omega-3 oil, or encapsulated synthetically produced omega-3 oil, *for use in or as* finished products marketed as "dietary supplements"– namely:

- Royal DSM NV ("DSM NV"), **Exhibit 1**;
- DSM Marine Lipids Peru S.A.C. ("DSM-Peru"), **Exhibit 1**;
- DSM Nutritional Products LLC in the United States ("DSM-US"), **Exhibit 1**;
- DSM Nutritional Products Canada Inc., ("DSM-Canada"), **Exhibit 1**;
- Ultimate Biopharma Corp. ("Ultimate"), **Exhibit 2**;
- Marine Ingredients AS, **Exhibit 3**;
- Marine Ingredients LLC, **Exhibit 3**;
- Golden Omega S.A., **Exhibit 4**;
- Golden Omega USA LLC, **Exhibit 4**;
- Nordic Pharma Inc., **Exhibit 5**;
- Croda Europe Ltd., **Exhibit 6**;
- Croda, Inc., **Exhibit 6**; and
- Technologica de Alimentos S.A., **Exhibit 7**

(collectively the "Manufacturers").

4. The other Proposed Respondents are selling finished products containing synthetically produced omega-3 oil *as* "dietary supplements" directly to consumers – namely:

- The Nature's Bounty Co. ("Nature's Bounty"), **Exhibit 8**;
- Nordic Naturals, **Exhibit 9**;

- Pharmavite LLC, **Exhibit 10**;
- Innovix Pharma Inc. ("Innovix Pharma"), **Exhibit 11**; and
- J. R. Carlson Laboratories ("Carlson"), **Exhibit 12**

(collectively, the "Distributors").

5. The Synthetically Produced Omega-3 Products, like Vascepa®, are derived from common fish oil. Common fish oil includes omega-3 fatty acids in their natural triglyceride form ("nTG-OM3"), such as EPA (eicosapentaenoic acid) in its natural triglyceride form ("nTG-EPA") and docosahexaenoic acid ("DHA") in its natural triglyceride form ("nTG-DHA"). Although the Synthetically Produced Omega-3 Products are derived from common fish oil, they are not the same as common fish oil. As discussed in more detail in paragraphs 42-51, typically, common fish oil is extracted from oily fish by using physical, not chemical processes, such that no chemical bonds are broken or created.

6. Depending upon the fish from which the oil was extracted and the environmental conditions in which the fish were raised, the ratio of nTG-EPA and nTG-DHA can differ. However, typically, 30% of common fish oil by weight is nTG omega-3 fatty acids, or nTG-OM3. The remaining 70% of the oil has other constituents, most predominantly, saturated fat, other omega-3 fatty acids, and omega-6 and omega-9 fatty acids. *See* Figure 1 (below).

Figure 1. Leading Common Fish Oil Supplement with 30% nTG-OM3*

* *See* R. Preston Mason and Samuel C.R. Sherratt, Omega-3 fatty acid fish oil dietary supplements contain saturated fats and oxidized lipids that may interfere with their intended biological benefits, Biochemical and Biophysical Research Communications (2016), 1-5. **Exhibit 14.**

7. It is not possible to produce natural marine oil with a collective concentration of nTG-EPA and nTG-DHA that is greater than approximately 30% by weight of the oil. Oils with a higher collective concentration of EPA and DHA must be chemically synthesized, *i.e.,* synthetically produced. Many of the Synthetically Produced Omega-3 Products are chemically altered to deliver heightened levels of EPA and/or DHA – well beyond the levels that are found in nature, *see, e.g.,* **Exhibits 8-I, 9-T, 9-V, 11-A, 12-D**. Some are also chemically altered to remove less valuable or unwanted components of common fish oil, such as saturated fat. *See* Figure 2 (below).

8. Common molecular forms and mixtures of Synthetically Produced Omega-3 Products include the following:

(i) purified EPA in its ethyl ester form ("E-EPA"),

(ii) purified EPA in its re-esterified form ("rTG-EPA"),

(iii) omega-3 mixtures in their ethyl ester form ("E-OM3"), and

(ii) omega-3 mixtures in their re-esterified form ("rTG-OM3").

Amarin believes that all of the Synthetically Produced Omega-3 Products identified in this complaint contain E-EPA, rTG-EPA, E-OM3 (where E-EPA is the predominant component), or rTG-OM3 (where rTG-EPA is the predominant component). Exhibits 8-A – **12-M**[1]; *see also* Section VII.

9. To synthesize omega-3 fatty acid mixtures, or their EPA or DHA components, from their natural triglyceride form into their ethyl ester form, the natural triglyceride molecules undergo chemical reactions. First, the glycerol backbone of each triglyceride molecule in the common fish oil is removed. Second, the resulting free fatty acids are reacted with ethanol through a process known as esterification. This ethyl ester form allows for the substantial heightening of the level of the E-EPA and/or E-DHA in the synthetically produced oil. The manufacturer can choose which fatty acid levels to heighten, and either to

[1] Throughout this document, when a range of exhibits is given, it refers to all like subparts within the given range, unless otherwise noted.

manipulate the ratio of E-EPA to E-DHA or to purify the product into E-EPA or E-DHA.

10. The differences between the complex mixture of multiple constituents that comprise common fish oil products and the various pharmacologically designed and chemically synthesized products is illustrated by comparing Figure 1 (above) to Figure 2 (below).

Figure 2. Vascepa® (Purified E-EPA)*

*Vascepa® Full Prescribing Information, **Exhibit 15** (reflecting that FDA has labeled Vascepa® 1 gram capsules as containing 1 gram of E-EPA. The capsules also contain trace amounts of inactive ingredients including, tocopherol, an anti-oxidation agent designed to protect the fragile active ingredient).

11. Vascepa®, the product highlighted in Figure 2, is the only drug approved by the FDA that contains purified E-EPA. *See* List of FDA-Approved Icosapent Ethyl (E-EPA) Drugs in Orange Book, **Exhibit 16** (icosapent ethyl is an alternate name for eicosapentaenoic acid in ethyl ester form). Vascepa® is manufactured and marketed by Amarin. There are also branded and generic FDA-approved drugs that contain

omega-3 mixtures in their ethyl ester form (E-OM3). *See* List of FDA-Approved Omega-3 Ethyl Ester Drugs in the Orange Book, **Exhibit 17**. FDA has approved these drugs for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. *See, e.g.,* Vascepa® Full Prescribing Information, **Exhibit 15**; Lovaza® Full Prescribing Information, **Exhibit 18**. Severe hypertriglyceridemia (too much fat in the blood) is a disease that can lead to inflammation of the pancreas, which can cause life-threatening complications. *See* Pancreatitis, Patient Care & Health Information, Mayo Clinic (accessed August 4, 2017), **Exhibit 19**. Severe hypertriglyceridemia can also raise or indicate increased risk of heart disease. *See* High Cholesterol-Medicines To Help You, FDA Website (accessed August 4, 2017) (noting that "[t]riglycerides are another form of fat in your blood that can raise your risk for heart disease"), **Exhibit 20.**

12. Since the launch of these FDA-approved drugs, companies have been increasingly falsely labeling and promoting products that contain chemically heightened levels of EPA as "dietary supplements." *See* Jennifer Grebow, Ultra-High Concentrates and the Next Omega-3, Supply Side West Report, Nutritional Outlook, Oct. 14, 2015, **Exhibit 21** ("Omega-3 suppliers . . . are now taking omega-3 concentrates for dietary supplements into near-pharmaceutical territory . . . . "); *see also* Hank Schultz, EPA-only nutraceuticals ride pharma's coattails into marketplace, NUTRA Ingredients-usa.com, Oct. 21, 2013, **Exhibit 22**. This recent free-riding is not surprising, and it is likely that it has occurred ever

since E-EPA first gained recognition in the marketplace as a "drug" in the mid-1980s, as discussed in paragraphs 80-83.

13. The ethyl ester components of the FDA-approved drugs (*i.e.,* E-OM3, E-EPA, and E-DHA) can also be *further* chemically altered into the re-esterified triglyceride (rTG) form using enzymes in a chemical process called glycerolysis. Food-grade enzymes separate the ethanol molecule from the fatty acid, creating a free fatty acid ("FFA") molecule and a free ethanol molecule. When glycerol is reintroduced to the solution, the enzymes then re-esterify the fatty acids back onto a glycerol backbone, creating re-esterified triglyceride (rTG) oil. The molecular distinctions between omega-3 fatty acids in their natural triglyceride forms (*e.g.,* nTG-OM3 and nTG-EPA), in their ethyl ester forms (*e.g.,* E-OM3 and E-EPA), and in their re-esterified forms (*e.g.,* rTG-OM3 and rTG-EPA) are further explained in paragraphs 49-50, and in Figure 3, in Section IV.

14. The Proposed Respondents are falsely labeling and/or promoting Synthetically Produced Omega-3 Products for use in, or as "dietary supplements." **Exhibits 1-B – 7-B, 8-A-ii – 12-M-ii**. As explained in paragraphs 58-105, labeling and/or promoting these products as "dietary supplements" is false because E-OM3, E-EPA, rTG-OM3, and rTG-EPA do not meet the definition of "dietary supplement" in the FDCA, 21 U.S.C. § 321(ff), and these products are actually unapproved "new drugs" under the FDCA. This false labeling and/or promotion of the Synthetically Produced Omega-3 Products constitute

unfair trade practices or unfair methods of competition in violation of Section 337 because they deceive or have the capacity to deceive a substantial segment of potential consumers, and that deception is material to purchasing decisions in violation of Section 43(a) of the Lanham Act. False labeling and/or promotion also misbrands the products under the standards set forth in Section 502 of the FDCA. 21 U.S.C. § 352.

15. Moreover, such false labeling and/or promotion is unfair to Amarin and other pharmaceutical companies that have invested the necessary resources to bring competing drug products to market, and it serves as a disincentive for drug companies to invest resources in drug development in the future. In particular, falsely labeling and/or promoting products as "dietary supplements" enables the Proposed Respondents to avoid the drug approval process and the associated time and investment necessary to conduct clinical trials to show that their products are safe and effective for each intended use and to obtain FDA approval for each intended use. *See* 21 U.S.C. § 355. Disregarding the FDA drug approval process also enables the Proposed Respondents to avoid the following: (i) limiting the indications for their products to those that have been approved by FDA, *see id.* § 355(a); (ii) applicable user fee costs associated with manufacturing drugs, *id.* § 379h; and (iii) applicable costs associated with complying with FDA's drug registration, *id.* § 360, listing, *id.,* and labeling and manufacturing requirements, *id.* §§ 502(f), 501(a)(2)(B). In addition, it allows the Distributors to avoid the need to sell their products pursuant to a

prescription by a licensed healthcare professional, *see id.* § 353(b).

16. Amarin has a domestic industry. Amarin specializes in developing effective therapies, approved by FDA, to treat disease, with a focus on hypertriglyceridemia and cardiovascular disease. Amarin developed Vascepa®, a prescription drug that lists icosapent ethyl as the drug's active pharmaceutical ingredient ("API") – legally – by investing the necessary resources to conduct clinical trials to show that the drug is safe and effective. Amarin then obtained FDA approval for the drug. *See* List of FDA-Approved Icosapent Ethyl Drugs (E-EPA) in Orange Book, **Exhibit 16**. Icosapent ethyl, Vascepa®'s API, is the ethyl ester form of EPA, namely E-EPA. The FDA approved Vascepa® for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. *See* Vascepa® Full Prescribing Information, **Exhibit 15**. Amarin markets and sells Vascepa® in the United States as a prescription drug. Vascepa® is the only FDA-approved purified E-EPA mixture on the United States market. *See* List of FDA-Approved Icosapent Ethyl Drugs (E-EPA) in Orange Book, **Exhibit 16**. Vascepa® is a low-cost drug from a consumer perspective. According to Amarin's records, on average, the monthly cost of Vascepa® is typically less than $200, and this cost is mostly covered by insurance plans. **Exhibit** 23. In addition, the majority of patients covered by insurance who obtain prescriptions for Vascepa® pay a monthly co-pay charge of $9.99 or less. **Confidential Exhibit 24.** In fact, a consumer with commercial insurance can pay as little as $9.00 for a

90-day supply prescription of Vascepa®. **Exhibit 25.** Finally, Amarin makes substantial investments in encapsulation, packaging, logistics, sales and marketing, along with substantial investments in labor conducting clinical trials in support of Vascepa®. **Exhibit 23**.

17. The Synthetically Produced Omega-3 Products compete with Vascepa® and injure Amarin because, like Vascepa®, they are chemically modified to deliver heightened levels of EPA. **Exhibits 9-O, 9-V, 9-T, 11-A, 12-D**. Indeed, all the Synthetically Produced Omega-3 products in ethyl ester form (*i.e.,* E-OM3 and E-EPA) actually contain E-EPA – Vascepa's active ingredient. Moreover, the Synthetically Produced Omega-3 Products are often marketed and used to treat the same diseases for which Vascepa® has been, and is being, developed. *See* **Tables 1 and 2.** The Proposed Respondents' importation and sale of Synthetically Produced Omega-3 Products has injured and/or threatened Amarin with substantial injury by (i) damaging the Vascepa® brand by exploiting Vascepa®'s status as an FDA-approved drug, (ii) causing lost sales and market share to Vascepa, and (iii) diminishing profitability and eroding prices. Amarin also has the capacity and/or inventory to supply the entire U.S. market demand for the Synthetically Produced Omega-3 Products (and similarly situated products), and Proposed Respondents' unfair acts prevent Amarin from making these sales, as discussed in paragraphs 225-229.

18. Finally, because false labeling and promotion enables purported "dietary supplement" products to

evade the drug approval process, it also endangers the public health. Indeed, former-Attorney General Lynch observed the following with regard to "dietary supplements":

> What many Americans don't know is that dietary supplements are *not* subject to testing [by FDA] before they reach the store shelves – meaning that every day, millions of Americans are ingesting substances whose safety and efficacy are not guaranteed. Some of these supplements are simply a waste of money, promising results that they can't deliver or advertising ingredients that they don't contain. And too often, these supplements don't just abuse consumer trust – they also endanger public health. Some contain harmful ingredients, causing consumers to fall ill. Others falsely claim to cure illness and disease, leading patients to use them as a substitute of proven therapies they may need. But whether these supplements are deceptive or dangerous, the fact remains that too many companies are making profits by misleading – and in some cases harming – American consumers.

Former-Attorney General Lynch Discusses Department's Efforts to Protect Consumers From Unsafe Dietary Supplements, Department of Justice, Office of Public Affairs, March 8, 2016 (emphasis added), **Exhibit 26**. Then-Attorney General Lynch's remarks were in reference to the Department of Justice's ("DOJ's") "dietary supplement" enforcement sweep in November 2015, which it conducted with the

FDA and other federal partners. *See* Justice Department and Federal Partners Announce Enforcement Actions of Dietary Supplement Cases, Nov. 18, 2015, **Exhibit 27**.

19. Although Section 337 and the Lanham Act are both designed to protect commercial interests against unfair methods of competition by authorizing private parties to sue competitors – they can also indirectly protect the public, particularly where FDA and other government entities have not acted, or have not acted to the full extent of their authority. Given the government's limited resources, it simply cannot pursue all deceptively labeled and deceptively promoted products.

20. Indeed, FDA has primary responsibility for policing the "labeling" of "dietary supplements" and the "labeling" and "advertising" of unapproved "new drugs." *See* Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, 225-71-8003, Sept. 9, 1971, **Exhibit 28**; *see also* 21 U.S.C. § 321(m) (defining "labeling"); 21 C.F.R. § 202.1(1) (providing examples of "labeling" and "advertising"). Yet, according to a recent PBS "Frontline" documentary, produced in collaboration with *The New York Times,* 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 the problem remains much bigger than that." *See* Frontline: Supplements and Safety, PBS and *The New York Times,* **Exhibit 29**; *see also*

Complainant's Brief On Jurisdiction, **Confidential Exhibit 30**.

II. COMPLAINANTS

21. Complainant Amarin Pharma is incorporated under the laws of Delaware with its primary office located at 1430 Route 206, Bedminster, NJ 07921. Amarin Pharma runs Amarin's United States operations, including sales, marketing, research and development, and regulatory affairs, among other things.

22. Complainant Amarin Ireland is organized under the laws of the Republic of Ireland with its principal offices at 2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2 Ireland. Amarin Ireland is a biopharmaceutical company specializing in developing effective, approved therapies to improve cardiovascular health. Amarin Ireland and Amarin Pharma are both wholly owned subsidiaries of Amarin Corporation plc, a public limited liability company organized under the laws of England and Wales.

23. Amarin developed Vascepa®, a prescription drug that lists icosapent ethyl as the drug's APL Icosapent ethyl is another name for E-EPA. Amarin Ireland is the holder of NDA No. 202057 for Vascepa® (icosapent ethyl) Capsules, for oral use. The FDA approved Vascepa® for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Amarin markets and sells Vascepa® in the United States as a prescription drug.

III. PROPOSED RESPONDENTS

A. Manufacturers/Importers

24. Proposed Respondent Royal DSM NV ("DSM NV") is a manufacturer of Synthetically Produced Omega-3 Products. DSM NV's headquarters are located at Het Overloon 1 6411 TE, Heerleen, The Netherlands.

25. Proposed Respondent DSM Marine Lipids Peru S.A.C. ("DSM-Peru") is a manufacturer of Synthetically Produced Omega-3 Products. DSM-Peru's headquarters are located at Calle Principal S/N Caserio la Legua, Catacaos Piura, Peru.

26. Proposed Respondent DSM Nutritional Products LLC ("DSM-US") is a manufacturer of Synthetically Produced Omega-3 Products. DSM-US's headquarters are located at 45 Waterview Blvd., Parsippany, NJ 07054.

27. Proposed Respondent DSM Nutritional Products Canada, Inc. ("DSM-Canada") is a manufacturer of Synthetically Produced Omega-3 Products. DSM-Canada is located at 105 Neptune Crescent, Dartmouth, NS B2Y4T6.

28. Proposed Respondent Ultimate Biopharma (Zhongshan) Corporation ("Ultimate") is a Chinese foreign joint venture limited company that manufactures softgel capsules containing Synthetically Produced Omega-3 Products. Ultimate's headquarters are located at 10 Jiankang Road, National Health Technology Park, Zhongshan, Guandong, People's Republic of China.

29. Proposed Respondent Marine Ingredients AS is a manufacturer of Synthetically Produced Omega-3 Products. Marine Ingredients AS's headquarters are located at Strandgata 60, 6270 Brattvag, Norway.

30. Proposed Respondent Marine Ingredients LLC is a U.S. importer of Synthetically Produced Omega-3 Products. Its headquarters are located at 794 Sunrise Blvd., Mt. Bethel, Pennsylvania 18343.

31. Proposed Respondent Golden Omega S.A. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Avenida Apoquindo Ote. 5550, Piso 8, Las Condes, Santiago, Chile.

32. Proposed Respondent Golden Omega USA LLC is a U.S. importer of Synthetically Produced Omega-3 Products. Its headquarters are located at 65 Enterprise, Aliso Viejo, California, 92656.

33. Proposed Respondent Nordic Pharma, Inc. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Ropnesveien 71, 9107 Kvaløya, Norway.

34. Proposed Respondent Croda Europe Ltd. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Cowick Hall, Snaith Goole, East Yorkshire DN14 9AA, United Kingdom.

35. Proposed Respondent Croda Inc. is a U.S. importer of Synthetically Produced Omega-3 Products. Its headquarters are located at 300-A Columbus Circle, Edison, NJ 08837.

36. Proposed Respondent Tecnologica de Alimentos S.A. is a manufacturer of Synthetically Produced Omega-3 Products. Its headquarters are located at Las Begonias 441, Of. 352, San Isidro, Lima 27, Peru.

B. Distributors

37. Proposed Respondent The Nature's Bounty Co. ("Nature's Bounty"), is a U.S. distributor of imported Synthetically Produced Omega-3 Products. In 2010, a Nature's Bounty subsidiary acquired Ultimate. **Exhibit 2-E-ii**. Nature's Bounty's headquarters are located at 2100 Smithtown Avenue, Ronkonkoma, New York 11779.

38. Proposed Respondent Nordic Naturals, Inc. is a U.S. distributor of imported Synthetically Produced Omega-3 Products. Nordic Naturals' headquarters are located at 111 Jennings Drive, Watsonville, California 95076.

39. Proposed Respondent Pharmavite LLC is a U.S. distributor of Nature Made-branded imported Synthetically Produced Omega-3 Products. Its headquarters are located at 8510 Balboa Blvd. # 100, Northridge, California 91325.

40. Proposed Respondent Innovix Pharma Inc. is a U.S. distributor of OmegaVia-branded imported Synthetically Produced Omega-3 Products. Its headquarters are located at 26500 Agoura Road, Suite 102790, Calabasas, CA 91302.

41. Proposed Respondent J.R. Carlson Laboratories, Inc. is a U.S. distributor of imported

Synthetically Produced Omega-3 Products. Its headquarters are located at 600 W. University Dr., Arlington Heights, Illinois, 60004.

IV. THE PRODUCTS AT ISSUE

42. The Proposed Respondents' Synthetically Produced Omega-3 Products that are the subject of this investigation contain derivatives of naturally occurring omega-3 fatty acids. Omega-3 fatty acids are a category of polyunsaturated fatty acids that include EPA and DHA. Omega-3 fatty acids are marketed, legally and illegally, in the United States in a number of different mixtures and molecular forms. Common mixtures and molecular forms include the following: (i) common fish oil (*i.e.,* a natural omega-3 mixture ("nTG-OM3")), (ii) purified EPA mixtures in their ethyl ester form ("E-EPA"), (iii) purified EPA mixtures in their re-esterified form ("rTG-EPA"), (iv) omega-3 mixtures in their ethyl ester form ("E-OM3"), and (v) omega-3 mixtures in their re-esterified form ("rTG-OM3"). Although common fish oil contains omega-3 fatty acids in their natural triglyceride form (nTG-OM3) – E-EPA, rTG-EPA, E-OM3, and rTG-OM3 are synthetically produced through processes involving a number of chemical reactions.

43. Upon information and belief, all of the Synthetically Produced Omega-3 Products identified in this complaint contain E-EPA, rTG-EPA, E-OM3 (where the predominant component is E-EPA) or rTG-OM3 (where the predominant component is rTG-EPA). **Exhibits 8-A – 12-M**; *see also* Section VII.

44. Omega-3 fatty acids are found in fish and are most prevalent in oily fish, such as salmon, tuna, lake trout, mackerel, menhaden, sardines, anchovies, and herring. Oil in these fatty acids can be extracted by: (1) cooking and pressing the fish to separate the water and oil from the proteins and solids, (2) removing the water from the oil, and (3) polishing the oil (*i.e.,* deacifying, degumming, and washing the oil several times). When this oil is used for human consumption, it is also bleached and deodorized. At this point, the nTG-OM3 has been extracted from the fish through physical processes only – no chemical bonds have been broken or created. The resulting oil is common fish oil in nTG form, and depending upon the fish from which the oil was derived and the environmental conditions in which the fish were raised, the ratio of nTG-EPA and nTG-DHA can differ. Before it is sold, however, common fish oil is generally blended and standardized to contain approximately 180 mg of nTG-EPA and 120 mg of nTG-DHA per gram (1000 mg) of oil. Though the ratio of EPA to DHA may vary slightly, this oil is often referred to as 18:12 fish oil. The numbers 18:12 represent the approximate ratio of nTG-EPA to nTG-DHA by weight: 18% of the oil, by weight, is nTG-EPA; and 12% of the oil, by weight, is nTG-DHA (therefore, 30% of the oil, by weight is nTG omega-3 fatty acids). The remaining 70% of the oil has other constituents, typically, most predominantly, saturated fat, other omega-3 fatty acids, and omega-6 and omega-9 fatty acids. *See* Figure 1 (in Section I, and repeated below).

45. It is not possible to produce natural marine oil with a collective concentration of nTG-EPA and nTG-DHA that is greater than approximately 30% by

weight of the oil. Oils with a higher concentration of EPA and DHA than approximately 30% must be chemically synthesized. Synthetic oils with higher concentrations of EPA and/or DHA that are available today are commonly in either the ethyl ester form or the re-esterified triglyceride form.

46. The first step in the process of synthesizing common fish oil to yield higher concentrations of EPA and DHA involves a chemical reaction wherein the glycerol backbone of each triglyceride molecule in the fish oil is removed, resulting in "free fatty acids" ("FFA"), including FFA-EPA and FFA-DHA, and a "free glycerol" molecule. The FFA-EPA and FFA-DHA are then chemically reacted with ethanol through a process known as esterification. Esterification changes the fatty acids into ethyl ester form, such that FFA-EPA becomes E-EPA, and FFA-DHA becomes E-DHA.

47. The resulting ethyl ester form allows for substantial heightening of the level of the E-EPA or other components. The fatty acid level can be heightened using a number of different physical procedures, the two most common of which are molecular distillation and supercritical fluid technology. These technologies allow the manufacturer to choose which fatty acid levels to heighten, and to either manipulate the ratio of E-EPA to E-DHA or to purify the product into substantially only E-EPA.

48. Synthetically produced ethyl ester fatty acids, such as E-EPA, can also be chemically converted to the re-esterified triglyceride form using enzymes in a chemical process called glycerolysis. Food-grade enzymes separate the ethanol molecule from the fatty

acid, creating a FFA and a free ethanol molecule. When glycerol is reintroduced to the solution, the enzymes then re-esterify the fatty acids back onto a glycerol backbone, creating re-esterified triglyceride (rTG) oil.

49. Omega-3 mixtures in their ethyl ester form, regardless of whether they are characterized as E-OM3 mixtures or more purified E-EPA or E-DHA mixtures, are different from omega-3 mixtures in their natural triglyceride, or nTG, form in a number of ways. For example, the ratio of EPA to DHA in ethyl ester mixtures is often significantly different from the ratio in naturally occurring (nTG) mixtures. In addition, the EPA and DHA levels in the ethyl ester mixtures typically are much higher than they are in natural mixtures. Also, the E-EPA and E-DHA molecules are chemically altered from the nTG-EPA and nTG-DHA molecules and become chemically distinct as a result of such alteration. These types of differences are material because they can affect the efficacy and safety of the ethyl ester mixture, compared to the nTG mixture (*e.g.,* concentration can lead to greater efficacy and, for example, higher levels of DHA have been associated with certain unwanted effects, particularly in diseased patients with severely high levels of triglycerides in the blood). The differences between the complex mixture of multiple constituents that comprise common fish oil products and the pharmacologically designed highly pure synthesized E-EPA product, Vascepa®, are illustrated in Figures 1 and 2. The differences between the E-OM3 and nTG-OM3 molecules, and their components, are illustrated in Figure 3.

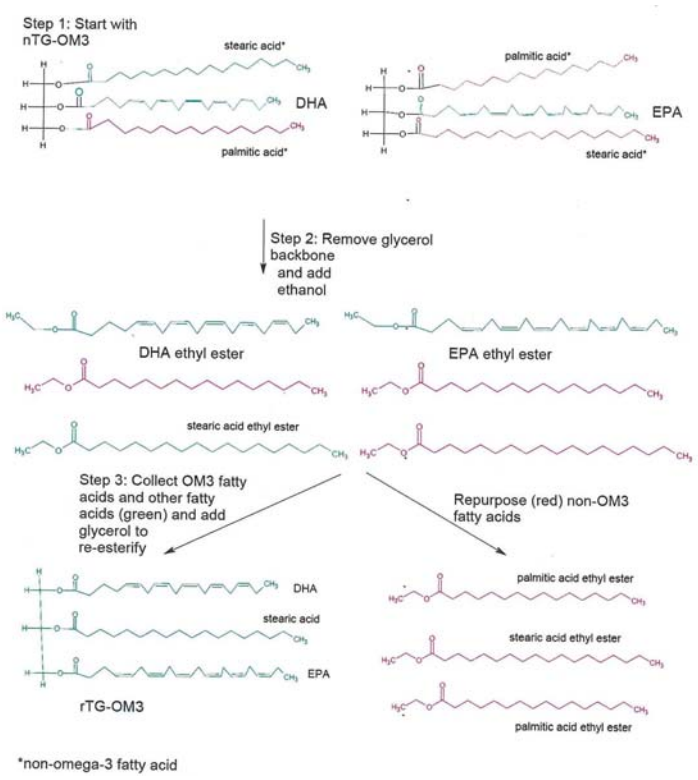
Figure 1. Leading Common Fish Oil Supplement with 30% nTG-OM3.*

* *See* R. Preston Mason and Samuel C.R. Sherratt, Omega-3 fatty acid fish oil dietary supplements contain saturated fats and oxidized lipids that may interfere with their intended biological benefits, Biochemical and Biophysical Research Communications (2016), 1-5. **Exhibit 14.**

Figure 2. Vascepa® (E-EPA)*

*Vascepa®, Full Prescribing Information, **Exhibit 15** (reflecting that FDA has labeled Vascepa® 1 gram capsules as containing 1 gram of E-EPA. The capsules also contain trace amounts of inactive ingredients including, tocopherol, an anti-oxidation agent designed to protect the fragile active ingredient).

Figure 3. Conversion of nTG-OM3 to E-OM3 to rTG-OM3



Disclaimer - The triglyceride molecules shown in the scheme are merely representative of certain molecular species that would be expected to be present in both natural fish oil and rTG oil. They do not represent the only molecular species in these mixtures. These mixtures would contain a variety of fatty acid residues, in addition to DHA, EPA, stearic and palmitic acid. The scheme is intended to represent, qualitatively, the type of chemical transformation that occurs in each step.

50. Omega-3 mixtures in their rTG form, regardless of whether they are characterized as rTG-OM3 mixtures or the more purified rTG-EPA or rTG-DHA mixtures, are also different from omega-3 mixtures in their natural triglyceride, or nTG, form in a number of ways. For example, the ratio of EPA to DHA in rTG-OM3 mixtures is often different from the ratio in naturally occurring (nTG) mixtures. In addition, the EPA and DHA levels in the rTG mixtures are typically much higher than they are in natural mixtures. This is because the re-esterification process adds, on average, one extra fatty acid to each triglyceride molecule. Further, nTG and rTG typically have different molecular structures. When the EPA, DHA, and other fatty acids, are re-attached to the glycerol molecule, during the chemical re-esterification process, they randomly attach to one of three different points on the glycerol molecule: SN-1, SN-2, or SN-3. Even though the pattern of attachment is random, based on statistical probability, more EPA, DHA, and other fatty acids attach to the SN-1 and SN-3 points than the SN-2 point. In nTG, however, the EPA and DHA are typically bound to the SN-2 position. Finally, during the re-esterification process, not all fatty acids, such as EPA and DHA, reattach to the glycerol molecule as triglycerides. Thus, large percentages of the oil, often approximately 40%, are in di-glyceride or mono-glyceride form. Notably, di-glycerides and mono-glycerides are not components of natural fish oil, nTG, at all. In nTG-OM3 mixtures (common fish oil), 100% of the oil is in triglyceride form. As described above, these types of differences are material because they can affect the efficacy and safety of the rTG mixture, compared to the nTG mixture (*e.g.,* concentration can

lead to greater efficacy and, for example, higher levels of DHA have been associated with unwanted effects, particularly in some diseased patients with abnormally high levels of triglycerides in the blood). The differences between the rTG-EPA and nTG-EPA molecules, as well as the differences between the rTG-DHA and nTG-DHA molecules are illustrated in Figure 3.

51. Upon information and belief, all of the Proposed Respondents' Synthetically Produced Omega-3 Products contain E-EPA, rTG-EPA, E-OM3, or rTG-OM3. **Exhibits 1 – 12**. Upon information and belief, all of these products are synthesized (*i.e.,* chemically altered) using the same basic chemical processes described above, and as such, they are distinct from common fish oil, *i.e.,* nTG-OM3.

V. JURISDICTION

52. The Commission had jurisdiction over this investigation for the reasons set forth in Complainant's Brief On Jurisdiction. **Exhibit 30**.

VI. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENTS

A. Proposed Respondents' Importation And Sale Of The Synthetically Produced Omega-3 Products Violate The Lanham Act

53. The Proposed Respondents' importation and sale of the Synthetically Produced Omega-3 Products, and their false or misleading representations about those products, constitute unfair acts or unfair methods

of competition under Section 337, and violate Section 43(a) of the federal Lanham Act, 15 U.S.C. § 1125(a), and the federal common law of unfair competition.

54. Section 43(a) of the Lanham Act provides that:

> [a]ny person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which – . . . (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a).

55. The elements of a false advertising/promotion claim under the Lanham Act are (i) a false or misleading statement of fact is being made by the defendant about a product; (ii) the statement is deceiving or has the capacity to deceive a substantial segment of potential consumers; (iii) the deception is material, in that it is likely to influence a purchasing decision; (iv) the defendant is causing the false statement to enter interstate commerce; and (v) the

complainant has been or is likely to be injured as a result of the statement. *See Hewlett-Packard Co. v. NU-Kate Int'l, Inc.,* 155 F.3d 571 (Fed. Cir. 1998) (*citing Southland Sod Farms v. Stover Seed Co.,* 108 F.3d 1134, 1139 (9th Cir. 1997)); *see also Marcinkowska v. IMG Worldwide, Inc.,* 342 F. App'x 632, 636 (Fed. Cir. 2009) (*citing Scotts Co. v. United Indus. Corp.,* 315 F.3d 264, 272 (4th Cir.2002)).

56. When a complainant can show that a statement is "literally false," or false on its face, however, the consumer deception is presumed, such that proving the third element is not necessary. *See Clock Spring, L.P. v. Wrapmaster, Inc.,* 560 F.3d 1329, n. 10 (Fed. Cir. 2009). A statement may be "literally false" due to a material omission, among other reasons. *See, e.g., Pfizer Inc. v. Miles Inc.,* 868 F.Supp. 437 (D. Ct. 1994) (holding that an omission that is likely to deter physicians from using an FDA approved drug is material and makes the advertisement's statement "a literal falsity").

57. In addition, parties other than those making false statements can be contributorily liable for Lanham Act violations. *See, e.g., Duty Free Ams., Inc. v. Estee Lauder Co.,* 797 F.3d 1248, 1273 (11th Cir. 2015); *Merck Eprova AG v. Gnosis S.p.A.,* 901 F. Supp. 436, 456 (S.D.N.Y. 2012) (finding company liable to Merck for contributory false advertising). The elements of a contributory false advertising/promotion claim include showing that (1) a third party directly engaged in false advertising/promotion that injured the plaintiff and (2) the respondent at issue contributed to that conduct by knowingly inducing or causing the conduct,

or by materially participating in it. *See Duty Free Ams.*, 797 F.3d at 1277.

1. Proposed respondents are making false statements about the Synthetically Produced Omega-3 Products by labeling and/or promoting them as "dietary supplements" when they are actually unapproved "new drugs"

58. The Distributors of the Synthetically Produced Omega-3 Products are unlawfully importing or selling their products with labeling, advertising and/or other promotional materials ("Promotional Materials") that are literally false. Among other things, the labeling for all of the Distributors' Synthetically Produced Omega-3 Products falsely asserts that the products are "dietary supplements," or it falsely implies that they are "dietary supplements" by using some modification of that term (*e.g.,* "Omega-3 Supplement"). **Exhibits 8-A-ii – 12-M-ii**. Indeed, the term "dietary supplement" or a modification of that term using the name of the ingredient in the product is required to appear on "dietary supplement" labeling by law. 21 U.S.C. §§ 321(ff)(2)(C), 343(s)(2)(B).

59. In addition, all of the Manufacturers (except Ultimate) are unlawfully importing or selling their products with Promotional Materials that are literally false because they assert that the products are for use in, or as "dietary supplements." **Exhibits 1-B – 7-B**.

60. Labeling and/or promoting Synthetically Produced Omega-3 Products for use in, or 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) and (ii) are being referred to as "dietary supplements" to hide the fact that they are actually unapproved "new drugs."

a. The Synthetically Produced Omega-3 Products cannot meet the definition of "dietary supplement" in the FDCA

61. None of the Synthetically Produced Omega-3 Products meets the definition of "dietary supplement" in the FDCA because none of the products bears or contains a "dietary ingredient." 21 U.S.C. § 321(ff)(1). Moreover, although the failure to bear or contain a "dietary ingredient" is sufficient to preclude a product from being a "dietary supplement," the Synthetically Produced Omega-3 Products that emphasize E-EPA in their manufacture or marketing are also excluded from the definition of "dietary supplement" by the definition's "exclusionary clause." *See id.* § 321(ff)(3)(B).

i. The Synthetically Produced Omega-3 Products do not meet the definition of "dietary supplement" because they do not bear or contain a "dietary ingredient"

62. The definition of "dietary supplement" in the FDCA applies only to products that, among other things, bear or contain one or more of the following "dietary ingredients": "(A) a vitamin, (B) a mineral,

(C) an herb or other botanical, (D) an amino acid, (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." 21 U.S.C. § 321(ff)(1). Products marketed with ingredients that do not fall within the categories of "dietary ingredients" listed in Section 201(ff)(1) of the FDCA, 21 U.S.C. § 321(ff)(1), cannot be marketed as, or for use in, "dietary supplements." *See id.*

63. The Synthetically Produced Omega-3 Products are not "dietary supplements" because E-EPA, rTG-EPA, E-OM3, and rTG-OM3 do not fall into any of the categories of "dietary ingredients" under the Section 201(ff)(1) of the FDCA. As an initial matter, E-EPA, rTG-EPA, E-OM3, E-EPA, and rTG-OM3 are not vitamins, minerals, herbs, or other botanicals, and therefore, they do not fall under subsections 201(ff)(1)(A)-(D). Moreover, they do not fall under subsections 201(ff)(1)(E) or (F) either.

a) The Synthetically Produced Omega-3 Products do not fall under subsection 201(ff)(1)(E) of the "dietary ingredient" definition

64. Unlike nTG-OM3 and nTG-EPA, which naturally occur in fish oil, E-EPA, rTG-EPA, E-OM3, and rTG-OM3 do not fall under subsection (E). They are not "dietary substance[s] for use by man to supplement the diet by increasing the total dietary intake." 21 U.S.C. § 321(ff)(1)(E). According to FDA,

when the chemical structure of a dietary ingredient is altered, for example, by the "addition of new chemical groups as in *esterification,"* it:

> creates a new substance that is different from the original dietary ingredient. The new dietary ingredient is not considered to be a dietary ingredient merely because it has been altered from a substance that is a dietary ingredient, and therefore, is in some way related to the dietary ingredient.

Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry (Draft), August 2016 (NDI Guidance), at 41 (emphasis added), **Exhibit 31**. This is a well-settled FDA policy that previously has been articulated in Federal Register notices and implemented in rejections of new dietary ingredient notifications. *See, e.g.,* 81 Fed. Reg. 61700, 61702 (Sept. 7, 2016), **Exhibit 32**, (noting that vinpocetine "is a synthetic compound, derived from vincamine, an alkaloid found in the *Vinca minor* plant" because it undergoes transesterification and/or dehydration of vincamine in ethanol); FDA Letter to AIBMR Life Sciences, Inc., dated March 19, 2014, **Exhibit 33** (finding that synthetic fish oil fatty acid esters were "not constituents of a dietary substance for use by man under Section 201 (ff)(1)(F)").

65. FDA refers to these chemically altered ingredients – these new substances – as "synthetic" or "synthetically produced" ingredients, and it uses those terms interchangeably to refer to ingredients that are synthesized from natural starting materials as well as

unnatural starting materials. *See, e.g.,* NDI Guidance, at 37-41, **Exhibit 31**; *see also* 81 Fed. Reg. at 61702, **Exhibit 32**; FDA Warning Letter to Quincy Bioscience Manufacturing Inc., dated Oct. 16, 2012, **Exhibit 34** (concluding that synthetic apoaequorin manufactured from "rapidly dividing host cells," which are natural materials, is not a "dietary ingredient"); FDA Letter to Syntech (SSPF) International, dated December 6, 2004, **Exhibit 35** (finding that betaphrine, an ingredient chemically synthesized from substances that are themselves "dietary ingredients," is not a "dietary ingredient" under any subsection in Section 201(ff)(1)(A)-(F) of the Act).

66. Because E-EPA, rTG-EPA, E-OM3, and rTG-OM3 are each chemically altered, or synthesized from common fish oil, they are synthetically produced, or synthetic. As such, they cannot fall under subsection 201(ff)(1)(E), unless they themselves are commonly used in conventional food.

67. For more than 15 years, FDA has consistently found that synthetic substances do not fall under subsection 201(ff)(1)(E), or subsections 201(ff)(1)(C) and (F) of the "dietary ingredient" definition for that matter, unless the synthetic substance itself is commonly used in conventional food. And when purported "dietary supplements" have contained a synthetic ingredient that is not common in conventional foods, FDA has taken action. For example, the agency has

(i) brought enforcement actions on this basis, *see, e.g.,* 69 Fed. Reg. 6787, 6793 (Feb. 11, 2004),

Exhibit 36 (citing *United States v. 1009 Cases* *** No. 2:01CV-820C (D. Utah filed October 22, 2001));

(ii) denied citizen petitions on this basis, *see, e.g.,* Letter from FDA to Ullman, Shapiro, & Ullman LLP, Docket No. FDA-2009-P-0298, dated Feb. 23, 2011, **Exhibit 37** (citizen petition response stating that synthetic homotaurine may not be marketed as a "dietary supplement" because it is not a "dietary ingredient");

(iii) advised other federal agencies on this basis, *see, e.g.,* Letter from Dennis E. Baker, Associate Commissioner of Regulatory Affairs, FDA, to Laura M. Nagel, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, June 21, 2001 (Nagel Letter), **Exhibit 38** (concluding that synthetic ephedrine alkaloids are not "dietary ingredients");

(iv) announced in the Federal Register that certain ingredients cannot be sold as "dietary supplements" on this basis, 69 Fed. Reg. 6793, **Exhibit 36** (acknowledging that synthetic ephedrine hydrochloride "and other synthetic sources of ephedrine cannot be dietary ingredients because they are not constituents or extracts of a botanical, nor do they qualify as any other type of dietary ingredient");

(v) issued warning letters on this basis, *see, e.g.,* FDA Warning Letter to ATS Labs, LLC, dated February 3, 2016, **Exhibit 39** (finding that 1,3-dimethylbutylamine ("DMBA") is not a "dietary ingredient" because it is synthetic and to the best of

FDA's knowledge it is not used in conventional foods); FDA Warning Letter to DBM Nutrition, dated Nov. 30, 2015, **Exhibit 40** (finding that picamilon, "a unique chemical entity synthesized from the dietary ingredients niacin and aminobutyric acid" does not fall within any of the "dietary ingredients" categories in the statute, and therefore, is not a "dietary ingredient"); FDA Warning Letter to Quincy Bioscience Manufacturing Inc., dated Oct. 16, 2012, **Exhibit 34** (finding that synthetic apoaequorin is not a "dietary ingredient"); FDA Warning Letter to Supplementstogo.com LLC, dated March 8, 2006, **Exhibit 41** (finding that methasterone, a synthetic steroid, is not a "dietary ingredient"); and

(vi) rejected new dietary ingredient notifications on this basis, *see, e.g.,* FDA Letter to Syntech (SSPF) International, dated December 6, 2004, **Exhibit 35** (finding that betaphrine, a chemically synthesized substance is not a "dietary ingredient"). In addition, FDA recently reiterated this position in 2016 draft guidance on "new dietary ingredients." *See* NDI Guidance at 38, **Exhibit 31**.

68. The FDA's long-standing position is based on a plain language interpretation of the definition of "dietary supplement" in the text in subsection 201(ff)(1)(E) – namely, "a dietary substance for use by man to supplement the diet by increasing the total dietary intake." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**. According to FDA, *Webster's II New Riverside University Dictionary,* provides that the term "dietary" means "of or relating to the diet" and

"diet" means "an organism's usual food and drink." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**. Reading those definitions in conjunction with the phrase, "for use by man," FDA construes the term "dietary substance" to mean "a substance commonly used as human food or drink." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**. FDA also maintains that the last phrase in subsection (E), "to supplement the diet by increasing the total dietary intake," provides further evidence that Congress intended the term "dietary substance" to refer to "foods and food components that humans eat as part of their usual diet" because "[o]ne cannot increase the 'total dietary intake' of something that is not part of the human diet in the first place." *See* NDI Guidance, at 38, **Exhibit 31**; Nagel Letter, **Exhibit 38**.

69. Upon information and belief, E-EPA, rTG-EPA, E-OM3, and rTG-OM3 are not common in conventional food in the United States. Each is synthetically produced.

b) The Synthetically Produced Omega-3 Products do not fall under subsection 201(ff)(1)(F) of the "dietary ingredient" definition

70. Similarly, E-EPA, rTG-EPA, E-OM3, and rTG-OM3 do not fall under subsection 201(ff)(1)(F) because each is a synthetically produced substance, and upon information and belief, none of the ingredients is a concentrate, constituent, extract, or combination of a "dietary substance" that falls under subsection 201(ff)(1)(E), or subsections 201(ff)(1)(A)-(D)

for that matter. Notably, in 2014, FDA specifically rejected a new dietary ingredient notification for a product dubbed "synthetic fish oil fatty acid esters"– in part, because the proponent of the ingredient had not submitted evidence sufficient for FDA to determine whether it met the definition of "dietary ingredient." *See* FDA Letter to AIBMR Life Sciences, Inc., dated March 19, 2014, **Exhibit 33**. In reaching this conclusion, FDA stated that the synthetic fish oil fatty acid esters at issue were "not constituents of a dietary substance for use by man under Section 201(ff)(1)(F)." *Id*. This approach by FDA is consistent with its conclusion that "[o]ne cannot increase the 'total dietary intake' of something that is not part of the human diet in the first place." NDI Guidance, at 38, **Exhibit 31**; Nagel Letter; **Exhibit 38**.

ii. Certain Synthetically Produced Omega-3 Products are excluded from the definition of "dietary supplement" under the exclusionary clause contained in subsection 321(ff)(3)(B) of the FDCA

71. Subsection 201(ff)(3)(B) of the FDCA (*i.e.,* the exclusionary clause) also excludes from the definition of "dietary supplement" any "article" that is approved as a "new drug" or authorized for study as a "new drug" (where substantial clinical investigations have been instituted), that was not before such approval or authorization legally marketed as a "dietary supplement" or as a food. 21 U.S.C. § 321(ft)(3)(B). As

explained below in paragraphs 80-83, E-EPA first gained recognition in the market place by being studied as a drug in the mid-1980s, and upon information and belief it was not legally marketed as a "dietary supplement" or a food prior to that time. Thus, as explained below, E-EPA products, as well as products containing E-OM3 that emphasize E-EPA in the way that they are manufactured or promoted, are excluded from the definition of "dietary supplement" under subsection 201(ft)(3)(B) of the FDCA.

72. The relevant "article" for the purposes of the exclusionary clause is dictated by the circumstances surrounding the manufacture and marketing of the purported "dietary supplements" at issue. *See Pharmanex v. Shalala ("Pharmanex III"),* 2001 WL 741419 (D. Utah 2001), *2, *4-*5 (upholding FDA's administrative determination); FDA Administrative Determination on Cholestin, dated May 20, 1998, at 10, **Exhibit 42**. In the seminal case on the exclusionary clause, Pharmanex, Inc. ("Pharmanex") marketed a product that contained red yeast rice as a "dietary supplement." *See* FDA Administrative Determination on Cholestin, dated May 20, 1998, at 1, **Exhibit 42**. FDA, however, determined that Cholestin was not a "dietary supplement," but rather an unapproved "new drug" under the FDCA. *See id.* FDA reasoned that Cholestin did not meet the definition of "dietary supplement" because Cholestin contained lovastatin, an active ingredient in an FDA-approved drug. *See id.* at 7, 10. As such, products containing lovastatin were excluded from the definition of "dietary supplement" by the exclusionary clause. *See id.* According to FDA, lovastatin was the relevant "article" for the purposes of

the exclusionary clause, as opposed to the finished Cholestin product, because of the "particular circumstances surrounding the Cholestin product, which indicate[d] that Pharmanex, in marketing and manufacturing Cholestin, [was] marketing and manufacturing lovastatin, not the traditional food product red yeast rice." *Id.* at 10.

73. Notably, the Tenth Circuit upheld FDA's determination that an "article" for the purposes of the exclusionary clause can be either a finished drug product or a component of a drug product. *See Pharmanex v. Shalala ("Pharmanex II"),* 211 F.3d 1151 (10th Cir. 2000); FDA Administrative Determination on Cholestin, dated May 20, 1998, **Exhibit 42**. This interpretation ensures that substances that have gained recognition in the marketplace as drugs cannot be marketed as, or incorporated into, "dietary supplements." *See* FDA Administrative Determination on Cholestin, dated May 20, 1998, at 6, **Exhibit 42**.

74. The exclusionary clause encourages and protects investment in drug development and the resulting innovation. The Tenth Circuit and FDA have observed, respectively, that permitting "manufacturers to market dietary supplements with components identical to the active ingredients in prescription drugs" would undermine the FDCA's incentive structures for drug development, *see Pharmanex II,* 211 F.3d at 1159, and it would "serve as a disincentive to the often significant investment needed to gain FDA approval of new drugs." *See* FDA Administrative Determination on Cholestin, dated May 20, 1998, at 4-5, **Exhibit 42**. Protecting drug innovation is such a

critical underpinning of the FDCA that Congress later enacted a separate exclusionary clause to prohibit substances that have gained recognition in the marketplace by being studied as, or approved as drugs, from being incorporated into conventional food as well, unless those substances were first marketed in a food. *See* 21 U.S.C. § 331(ll)).

75. In this case, consistent with the FDA's decision in *Pharmanex* and the underlying principle of the exclusionary clause, E-EPA is the relevant "article" when the purported "dietary supplements" at issue (i) contain E-EPA and (ii) emphasize E-EPA in the way that they are manufactured or promoted. In those instances, it is clear that the Proposed Respondents are importing or selling E-EPA, not common fish oil, or nTG-EPA. To adequately protect investment in drug development and the resulting innovation, E-EPA, which gained recognition in the marketplace as a "new drug", as explained in paragraphs 80-83, cannot be marketed as, or incorporated into, "dietary supplements."

76. The affected products are identified in Exhibits **1-A – 4-A, 6-A – 7-A, 8-A – 8-C, 8-E – 8-F, 8-H – 8-N, 10-A – 10-G, 12-C – 12-F, 12-J – 12-K**. By pharmacological design, EEPA is the most predominant component in these purified E-EPA products and E-OM3 mixtures. *Id.* Upon information and belief, these products are manufactured by following the same basic steps that drug companies follow, as summarized in paragraphs 42-51 of the complaint. In addition, as demonstrated in the attached charts, these products are typically promoted

not just for their EPA content – but for their *chemically concentrated EPA content* – which would not be possible but for the ethyl ester form. **Tables 3 and 4**. The chemical cleaving of the glycerol backbone from the nTG-OM3 and the reaction with the ethanol to form E-EPA or E-OM3 enables EPA to be substantially heightened to a level beyond that which exists in nature. EPA in its natural triglyceride form cannot be heightened to the same level.

77. Moreover, the esterification of EPA – *i.e.,* the ethyl ester form – allows these products to be concentrated and differentiates these products from common fish oil or other natural sources of EPA. A consumer would have to consume a likely intolerable amount of common fish oil or common krill oil in an effort to even get the same dosage of E-EPA in Vascepa®, a highly pure form of E-EPA. For example, a 300 mg capsule of MegaRed® Omega-3 Krill Oil contains approximately 50 mg of natural EPA in each capsule, *see* MegaRed Website, **Exhibit 43**, whereas a 1 gram capsule of Vascepa® contains 1000 mg of E-EPA. *See* Vascepa® Full Prescribing Information. **Exhibit 15**. Given that the FDA-approved dose of Vascepa® to reduce triglyceride levels in adult patients with severe hypertriglyceridemia is 4000 mg per day (*e.g.,* two, 1 gram capsules twice a day), consumers would have to take approximately 80 capsules of MegaRed® Omega-3 Krill Oil daily to get a similar dose of EPA from that product as they would get from four, 1 gram capsules of Vascepa®.

78. For this reason, companies often tout their chemically manipulated products containing E-EPA as

being comparable to drugs that contain E-EPA (*e.g.,* "Most fish oils are not the same as Lovaza. But some Are! A few over-the counter pharmaceutical grade fish oils [sic] are just as potent, pure and effective at reducing triglycerides as Lovaza," *see* Omega Via Website, **Exhibit 44**; *see also* OmegaVia Website 2, **Exhibit 45** (making implicit comparisons of OmegaVia's so-called "pharmaceutical grade fish oil" products to both Vascepa® and Lovaza® (another FDA-approved drug product)).

79. The Synthetically Produced Omega-3 Products that contain E-EPA, and emphasize that component in the manufacture and/or promotion of the product, are excluded from the definition of "dietary supplement" under subsection 201(ff)(3)(B) of the FDCA, 21 U.S.C. § 321(ff)(3)(B), because the relevant "article" – E-EPA – gained recognition in the marketplace by being studied as a "drug," as explained below. And upon information and belief, Synthetically Produced Omega-3 Products that incorporate E-EPA are not saved from exclusion from the "dietary supplement" definition by the "prior market clause" because E-EPA was never legally marketed as food or as a "dietary supplement."

80. E-EPA first gained recognition in the marketplace as a drug when it was clinically studied as a drug in the United States in the mid-1980s, if not earlier. Studies on E-EPA, in E-OM3 mixtures, began to proliferate after the Biomedical Test Materials Program ("BTM Program") was created in 1986. *See* Sylvia B. Galloway, Ph.D., Biomedical Test Materials Program: Drug Master Files for Biomedical Test

Materials, Produced From Refined Menhaden Oil, and Their Placebos, United States Department of Commerce, October 1989 (1989 BTM Report), **Exhibit 46**, at 1-1, 2-1, 2-2. The BTM Program was created by the National Oceanographic and Atmospheric Administration ("NOAA") and the National Institutes of Health ("NIH")/Alcohol, Drug Abuse, and Mental Health Administration ("ADAMHA"), and it provided standardized test materials to help researchers better identify the role of different forms of omega-3 fatty acids on health and disease. *See id.* at 1-1. The standardized test materials included an E-OM3 mixture that contained E-EPA as its principal component. *See id.* at 2-3. Specifically, the E-OM3 mixture contained approximately 80% omega-3 fatty acid ethyl esters, 44% E-EPA and 24% E-DHA, and 10-12% other omega-3 fatty acid ethyl esters, as well as other components. *See id.* Notably, the test materials, by chemically converting the EPA to ethyl ester form, increased the level of EPA in the mixture by approximately 26%. Typically, common fish oil contains 18% EPA. The availability of the test materials was announced on a number of occasions in the NIH Guide for Grants and Contracts, starting on May 29, 1987; requests from researchers were received by June 1987; and the BTM Program began shipping materials by September 1987. *See id.* at 2-1. Notably, in a February 1988 announcement, the program was explicit that "[i]n accordance with federal regulations, an [investigational new drug ("IND")] number will be required for the use of these materials in human studies." NIH Guide for Grants and Contracts, Vol. 17, No. 5, Feb. 12, 1988, **Exhibit 47** at 1; *see also* 1989 BTM Report, **Exhibit 46**, at 2-1. In 1989, the BTM

Program also made purified mixtures of E-EPA and E-DHA available for study. *See* P.H. Fair, Biomedical Test Materials Program: Distribution Management Manual, Department of Commerce, Dec. 1989 (1989 BTM Distribution Manual), **Exhibit 48**. The E-EPA mixture contained >95% ethyl esters (of the ethyl esters, EPA was 97%, other omega-3 fatty acids were <1 % and omega-6 fatty acids were <1%). *See id.* at 5.

81. Upon information and belief, no "dietary supplement" or food containing E-EPA was legally marketed prior to these studies. In the late 1980s, FDA was skeptical that any omega-3 products, even those containing common fish oil (*i.e.,* nTG-OM3), were marketed legally. Many, if not all, of the omega-3 products at the time, were marketed with promotional claims that rendered them unapproved new drugs. In 1988, FDA sent more than 50 letters to manufacturers and distributors of omega-3 products citing them for that illegal practice. *See, e.g.,* FDA Letter to Barth Vitamin Corp., dated April 1988 (and related letters), **Exhibit 49**. For example, an FDA letter to American Health Products stated that the promotional material distributed with a product, known as SuperEPA (i) suggested that the product may be useful in "the prevention or treatment of cancer, arthritis, atherosclerosis, heart disease, platelet aggregation, immune system effects, and the lowering of blood levels of cholesterol and triglycerides" and (ii) rendered the product an unapproved "new drug" under the FDCA. *See* FDA Letter to American Health Products, dated May 18, 1988, **Exhibit 50**.

82. In addition, in the late 1980s and in the 1990s (at least before the Dietary Supplement Health and Education Act of 1994, P.L. 103-417, amended the FDCA), no omega-3 supplements had been authorized for use by FDA as food ingredients, and agency statements reveal that the agency considered them to be unsafe "food additives." *See* 21 U.S.C. §§ 321(s), 342(a)(2)(C). A "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food" that is not (i) generally recognized as safe ("GRAS") or (ii) used in food prior to January 1, 1958, and shown to be safe through scientific procedures or common use. 21 U.S.C. § 321(s). Substances falling within the definition of "food additive" are deemed "unsafe" as a matter of law and marketing them is illegal when FDA has not approved them through regulation. 21 U.S.C. §§ 348(a)(2), 342(a)(1)(C)(i). In 1990, FDA sent a letter to a trade association stating that:

> We have continued concerns about any food use of omega-3 polyunsaturated fatty acids. We are unaware of any history of use of these substances as food ingredients prior to 1958, and FDA has not listed omega-3 polyunsaturated fatty acids as approved food additives or as being generally recognized as safe [GRAS]. Thus, addition of these substances to foods may render those foods adulterated under 21 U.S.C. 342(a)(2)(C).

See FDA Letter to R. William Soller, dated June 20, 1990, **Exhibit 51**. Further, when FDA affirmed natural menhaden oil to be GRAS in 1997, the agency noted that it declined to make the same determination in 1989 because the oil contained high levels of the omega-3 fatty acids, EPA and DHA, which were known to have physiologic effects, such as effects on blood clotting. 62 Fed. Reg. 30751, 30752 (June 5, 1997), **Exhibit 52**. In other words, in 1989, FDA did not believe that nTG-OM3 in menhaden oil, or its components nTG-EPA or nTG-DHA, were GRAS, and as such, nTG-OM3, nTG-EPA, and nTG-DHA could not have avoided the designation of "food additive" at that time. If nTG-OM3, nTG-EPA, and nTG-DHA in menhaden oil could not have avoided the designation of "food additive" until 1997, there is no basis to support the lawful marketing of E-OM3 and E-EPA as GRAS ingredients prior to that time.

83. Accordingly, for purported "dietary supplements" containing E-EPA to be saved from exclusion from the "dietary supplement" definition, a product must be identified that contained E-EPA that (i) was marketed before the proliferation of E-EPA clinical studies in the mid-1980s, (ii) was not an unapproved new drug, based on the manner in which it was promoted, (iii) did not contain an unsafe "food additive," and (iv) was not otherwise illegally marketed. Upon information and belief, no such "unicorn" exists.

b. Synthetically Produced Omega-3 Products are actually unapproved "new drugs" under the FDCA

84. Section 201(g)(1) of the FDCA defines the term "drug" as (A) "articles" recognized in the official United States Pharmacopeia ("USP") or official National Formulary ("NF") (which have now been combined into one publication, the "USP/NF"); (B) "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;" (C) "articles (other than food) intended to affect the structure or any function of the body of man or other animals;" and/or (D) "articles intended for use as a component of any articles specified in clause (A), (B), or (C)." 21 U.S.C. § 321(g)(1)(A)-(D); *see also* 21 C.F.R. § 101.93(f) (further describing "structure/function" claims under subsection (C)), (g) (further describing "disease" claims under subsection (B)).

85. Products that meet the definition of "dietary supplement," however, are subject to a safe harbor – they may be promoted with claims indicating that they are intended to affect the structure or function of the body without invoking drug status. 21 U.S.C. § 321(g)(1). But, because the Synthetically Produced Omega-3 Products are not "dietary supplements," they are not subject to that safe harbor. Thus, the Synthetically Produced Omega-3 Products are "drugs" if they meet any of the four prongs of the "drug" definition contained in Section 201 (g)(1)(A)-(D) of the FDCA – including if they are intended to affect the

structure or function of the body. *See* 21 U.S.C. § 321(g)(1)(A)-(D).

86. FDA need not deem products to be "drugs," for them to be "drugs." Products are "drugs" if they meet any of the four prongs of the definition of "drug" in the FDCA. 21 U.S.C. § 321(g)(1). Drug sponsors often take steps toward drug approval before any FDA involvement at all. Typically, basic scientists collect data from animal studies. If the data look promising, the drug company develops a prototype drug, and it seeks permission from FDA to begin clinical testing in humans by way of an IND application. *See id.* § 355(i). Once the clinical trials are conducted, the sponsor may submit an NDA, and if FDA believes that the drug is safe and effective, that the proposed labeling is appropriate, and that manufacturing methods assure that the drug's identity, strength, quality, and purity, then the agency will approve the drug. *See id.* § 355(d). At that point, the drug may be legally marketed. In other words, it is incumbent upon the sponsor of a "drug" to recognize that a product is a "drug" pursuant to the definition in the FDCA, and to comply with FDA's regulatory requirements for "drugs" accordingly. *See generally,* Susan Thaul, How FDA Approves Drugs and Regulates Their Safety and Effectiveness, Congressional Research Service, June 25, 2012, **Exhibit 53**.

87. Sponsors of products that meet the definition of "drug," that fail to comply with FDA's *drug approval process* are engaging in a prohibited act. The FDCA expressly prohibits the introduction or delivery for introduction of an *unapproved "new drug"* into

interstate commerce. 21 U.S.C. §§ 355(a), 331(d); *see also* 21 U.S.C. §§ 352(f), 331(a)-(c). And, as a practical matter, all unapproved "drugs" are also unapproved "new drugs." Products that meet the definition of "drug" are "new drugs" under Section 201(p) of the FDCA if they are not generally recognized by qualified experts as safe and effective for their intended uses. 21 U.S.C. § 321(p). To be so "generally recognized," the Supreme Court has found that, among other things, there must be a consensus of expert opinion that a drug is safe and effective based on "substantial evidence," as that term is defined in Section 505(d) of the FDCA. *See Weinberger v. Hynson, Wescott & Dunning Inc.,* 412 U.S. 609, 632 (1973) (citing 21 U.S.C. 355(d)). Notably, the *Hynson* decision effectively incorporates FDA's "new drug" approval standard for efficacy into the "new drug" definition. *See id.* Since 1975, FDA has opposed virtually every attempt to deem a "new drug" as generally recognized by qualified experts as safe for the uses mentioned in the labeling by any mechanism other than FDA approval. *See* David G. Adams, *et al.,* Food and Drug Law and Regulation (3d. 2015), at p. 298, **Exhibit 54**. In other words, practically speaking, to avoid designation as a "new drug," a product that meets the definition of "drug," must be approved by FDA.

88. Some sponsors of products that are "drugs," pursuant to the "drug" definition, may attempt to illegally evade the drug approval requirements by hiding the identity of these products with false labels, such as "dietary supplement," or even "medical food" – because products that actually meet those definitions are exempt from certain "drug" requirements, including

premarket review. *See id.* §§ 321(g), (ff), 360ee(b)(3). But if the products do not actually meet the definitions of those terms in the statute, and they meet the definition of the term "drug," then they are unapproved "new drugs." Because "dietary supplements" and "medical foods" are not subject to premarket review, FDA would not review the labeling of those products before the products are marketed or have the occasion to consider whether the products are actually unapproved "new drugs." And, once the products are on the market, FDA still may not be aware of the statements made in the labeling or have the occasion to consider whether the products are actually unapproved "new drugs." Accordingly, the sponsors' false statements may go undetected.

89. When FDA detects such false labeling and has the requisite resources to pursue the violation, it may send a warning letter to the violator. For example, in late May and early June of this year, FDA sent three separate warning letters to different companies that cited them for selling products containing synthetic steroids as "dietary supplements" when in fact (1) the products did not meet the definition of "dietary supplement," and (2) the products were actually unapproved "new drugs." *See* FDA Warning Letter to Flex Fitness Products and Big Dan's Fitness, dated May 25, 2017, **Exhibit 55**; FDA Warning Letter to Hardcore Formulations, dated June 5, 2017, **Exhibit 56**; FDA Warning Letter to AndroPharm LLC, dated June 5, 2017, **Exhibit 57**.

90. FDA has taken similar actions against approved "new drugs" falsely labeled as "medical

foods." For example, FDA took action in May 2017 against Enzymotec Ltd. (and one of its suppliers) for falsely positioning three *omega-3 fatty acid products* – Vayarol®, Varyarin®, and Vayacog® – as "medical foods," when they were actually unapproved "new drugs." *See* BRIEF-Enzymotec Ltd- FDA issued import alert that included vayarol, vayarin and vayacog products, Reuters.com, May 10, 2017, **Exhibit 58**; Import Alert 66-41, Detention Without Physical Examination of Unapproved New Drugs Promoted in the U.S., dated June 19, 2017, **Exhibit 59**; Enzymotec Ltd., SEC Form 6-K, dated May 2017, **Exhibit 60**; FDA Warning Letter to Rainbow Gold Products, Inc. dated May 4, 2017, **Exhibit 61** (citing Vayarin® as an unapproved "new drug").

91. The Synthetically Produced Omega-3 Products come in several molecular forms (*e.g.,* E-EPA, rTG-EPA, E-OM3, and rTG-OM3) and, typically, in two different physical forms (*i.e.,* in liquid form, as an oil for use in or as a "dietary supplement," or in an encapsulated form, for use as a "dietary supplement"). Each Synthetically Produced Omega-3 Product is a "drug" because it triggers one or more elements of the "drug" definition, and the elements in the "drug" definition triggered by each product depend on the molecular and physical form of the product.

i. All of the Synthetically Produced Omega-3 Products meet the definition of "drug" in the FDCA

a) Encapsulated E-OM3

92. The encapsulated E-OM3 products subject to this complaint are "drugs" because they meet at least one of the four prongs of the "drug" definition. *See id.* With regard to the first prong, subsection 201(g)(1)(A) of the FDCA, "Omega-3-Acid Ethyl Ester Capsules" are named in the drug USP/NF, *see* USP/NF (USP40-NF35), Vol. 2 (2017), at 5430-5433. **Exhibit 62**. Notably, to be "recognized" in the USP, products need only meet the definition of a product named in the USP; they need not comply with compendial identity standards. *See* 21 U.S.C. §§ 351(b), 352(e)(3)(B); *see also* USP/NF (USP40-NF35), at xiii,§ 2.30. **Exhibit 63**. (Recognized products that do not meet the compendial identity standards are "drugs" that are adulterated, misbranded or both. *See* 21 U.S.C. §§ 351(b), 352(e)(3)(B)). According to the USP, "Omega-3-Acid Ethyl Ester Capsules" are capsules that include E-EPA and E-DHA as well as five other omega-3 fatty acids in ethyl ester form (e.g., alpha-linolenic acid in ethyl ester form). *See* USP/NF (USP40-NF35), Vol. 2 (2017), **Exhibit 62**, at 5430-5433. Upon information and belief, all of the encapsulated E-OM3 products identified in this complaint (and attachments hereto) meet that definition. Accordingly, they are all "recognized" in the USP, and therefore, are "drugs."

93. With regard to the second and third prongs of the "drug" definition, subsections 201(g)(1)(B) and

201(g)(1)(C) of the FDCA, all of the Proposed Respondents' E-OM3 capsules named in this complaint (except those sold by Ultimate) are clearly intended to affect disease and/or the structure/function of the body. Under FDA's regulations, evidence that a product is intended to be used as "drug" includes advertising, labeling, or "other oral or written statements" by the entities that are legally responsible for the labeling of the drug, as well as the circumstances surrounding the distribution of the product. 21 C.F.R. § 201.128. As set forth in Section VII below, the Promotional Materials associated with each of these products (except those sold by Ultimate) indicate that the products are intended to affect disease and/or the structure function of the body. Moreover, upon information and belief, the circumstances of sale corroborate that intent.

94. With regard to the fourth prong of the "drug" definition, subsection 201(g)(1)(D) of the FDCA, upon information and belief, the encapsulated E-OM3 products sold by Ultimate are intended for use as a component of a "drug."

b) E-OM3 in Oil Form

95. The E-OM3 products in oil form are "drugs" because they meet at least one of the four prongs of the "drug" definition. With regard to the first prong, subsection 201(g)(1)(A) of the FDCA, "Omega-3-Acid Ethyl Esters" (in oil form) are named in the drug USP/NF, *see* USP/NF (USP40-NF35), Vol. 2 (2017), at 5428-5430, **Exhibit 64**. According to the USP/NF, "Omega-3 Acid Ethyl Esters" are mixtures of ethyl esters, principally E-EPA and E-DHA, that may also contain one of five other omega-3 fatty acids. *See id.*

Upon information and belief, all E-OM3 sold by the Proposed Respondents in oil form meet this definition. Therefore, they are recognized in the USP/NF, and as such are "drugs."

96. With regard to the second and third prongs of the "drug" definition, subsections 201(g)(1)(B) and 201(g)(1)(C) of the FDCA, all of the Proposed Respondents' E-OM3 oil named in this complaint (except that sold by Ultimate) is clearly intended to affect disease and/or the structure/function of the body. As set forth in Section VII below, the Promotional Materials associated with each of these products (except those sold by Ultimate) indicate that the products are intended to affect disease and/or the structure function of the body. Moreover, upon information and belief, the circumstances of sale corroborate that intent.

97. With regard to the fourth prong of the "drug" definition, subsection 201(g)(1)(D) of the FDCA, upon information and belief, the E-OM3 oil sold by Ultimate is intended for use as a component of a "drug."

c) E-EPA, rTG-EPA, and rTG-OM3, as well as other forms of E-OM3

98. E-EPA, rTG-EPA, and rTG-OM3, as well as other forms of E-OM3, are "drugs" because they meet one or more of the prongs of the definition of "drug" in the FDCA. With regard to the second and third prong, namely subsections 201(g)(1)(B) and 201(g)(1)(C), most of these products are intended to affect disease and/or the structure/function of the body. As set forth in

Section VII below, the Promotional Materials associated with each of these products (except those sold by Ultimate and Nordic Pharma) indicate that the products are intended to affect disease and/or the structure function of the body. Moreover, upon information and belief, the circumstances of sale corroborate that intent.

99. With regard to the fourth prong, subsection 201(g)(1)(D) of the FDCA, upon information and belief, when these substances are sold by Ultimate and Nordic Pharma, they are intended for use as a component of a "drug."

ii. All of the Synthetically Produced Omega-3 Products are unapproved "new drugs"

100. All of the Synthetically Produced Omega-3 Products are also "new drugs" under Section 201(p) of the FDCA because they are not generally recognized by qualified experts as safe and effective for their intended uses. 21 U.S.C. § 321(p).

101. As mentioned above, as a practical matter, for a drug to be generally recognized by qualified experts as safe and effective for its intended uses, it has to be FDA-approved. None of the Synthetically Produced Omega-3 Products is an FDA-approved drug. *See* List of FDA Approved Icosapent Ethyl Drugs (E-EPA) in Orange Book, **Exhibit 16** (listing none of the Synthetically Produced Omega-3 Products); List of FDA-Approved Omega-3 Ethyl Ester Drugs in the Orange Book, **Exhibit 17** (same). Thus, they are all "new drugs" – and indeed, *unapproved* "new drugs."

2. The other elements for false advertising and contributory false advertising under the Lanham Act are met

102. The Promotional Materials associated with all of the Synthetically Produced Omega-3 Products (except for those sold by Ultimate) indicate that the products are for use in, or as "dietary supplements," **Exhibits 1-B – 7-B, 8-A-ii. – 12-M-ii.** As explained above, falsely labeling or promoting these products as "dietary supplements" is literally false for two reasons: (1) the products do not meet the definition of "dietary supplement" in 21 U.S.C. § 321(ff), and (2) calling the products "dietary supplements" hides the material fact that the products are actually unapproved "new drugs."

103. Because these statements are literally false, they have the capacity to deceive a substantial segment of potential consumers, and this deception is presumed to be material to consumer purchasing decisions. Indeed, the express use of a false moniker and the failure to disclose the unapproved "new drug" status of the products is undoubtedly material. If consumers knew that the products were illegally marketed unapproved "new drugs" and that, as such, it was unclear whether the products were safe and effective, it would influence the consumers' purchasing decisions.

104. All of the Proposed Respondents (except Ultimate) are causing the literally false statements to enter interstate commerce, **Exhibit 1-B – 7-B and 8-A-ii – 12-M-ii**. Finally, the false statements of the Proposed Respondents (except Ultimate) about their

products have injured, or are likely to injure, Amarin, as discussed in paragraphs 217-238.

105. Further, upon information and belief, as set forth in Section VII, Ultimate and Nordic Pharma Inc. are contributorily liable under the Lanham Act for knowingly inducing or causing the entities distributing their products, respectively, Nature's Bounty and Nordic Naturals, to falsely advertise their products as "dietary supplements," or for materially participating in that illegal conduct.

B. Proposed Respondents' Importation And Sale Of The Synthetically Produced Omega-3 Products Violate Section 337 Based On The Standards Set Forth In The FDCA

106. The importation and sale of the Proposed Respondents' Synthetically Produced Omega-3 Products constitute unfair acts or unfair methods of competition under Section 337 based upon the standards set forth in the FDCA. As discussed in paragraphs 61-83, none of Proposed Respondents' Synthetically Produced Omega-3 Products meets the definition of "dietary supplement" in the FDCA, 21 U.S.C. § 321(ff). In addition, as discussed in paragraphs 84-101, all of the products are actually unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a); *see also* 21 U.S.C. § 352(f). The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" violates the standards set forth in Section 505(a) of the FDCA, *id.* § 355(a); *see also* 21 U.S.C. §§ 352(f), 331(a)-(c)

107. As explained in paragraphs 86-87, products that meet the definition of "drug" in the FDCA, *id.* § 321(g), must follow the requirements in the FDCA and its implementing regulations that apply to "drugs," regardless of whether FDA has acknowledged that the products are "drugs." As explained below, none of the Synthetically Produced Omega-3 Products follows a number of these requirements, and as such, they are misbranded drugs in violation of the standards set forth in Section 502 of the FDCA, *id.* § 352, and adulterated drugs, in violation of Section 501 of the FDCA, *id.* § 351.

108. Section 502(a) of the FDCA prohibits "labeling" that is "false or misleading in any particular." *Id.* § 352(a); *see also* 21 U.S.C. § 321(m) (defining the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article"). In addition, Section 502(n) of the FDCA similarly prohibits promotional material other than labeling from being false or misleading. 21 U.S.C. § 352(n); 21 C.F.R.§ 202.1(e)(6). The labeling for all of the Distributors' Synthetically Produced Omega-3 Products is false, at minimum, because it falsely asserts that the products are "dietary supplements," or it falsely implies that they are "dietary supplements" by using some modification of that term. **Exhibits 8-A-ii – 12-M-ii**. Similarly, the Promotional Materials associated with the Manufacturer's products (except for Ultimate's products) are false because they provide that the products at issue are for use in, or as "dietary supplements." **Exhibits 1-B – 7-B**.

109. Further, Section 502(f) of the FDCA provides that drugs are misbranded if their labeling fails to bear "adequate directions for use." 21 U.S.C. § 352(f). "Adequate directions for use" means "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. According to FDA,

> Prescription drugs can only be used safely at the direction, and under the supervision, of a licensed practitioner. Therefore, it is impossible to write "adequate directions for use" for prescription drugs. FDA-approved drugs which bear their FDA-approved labeling are exempt from the requirement that they bear adequate directions for use by a layperson. But otherwise, all prescription drugs by definition lack adequate directions for use by a layperson.

See, e.g., FDA Warning Letter to Flex Fitness Products and Big Dan's Fitness, dated May 25, 2017, **Exhibit 55** (citing 21 U.S.C. §§ 352(f)(1), 353(b)(2)). All of the Distributors' Synthetically Produced Omega-3 Products are "prescription drugs" as defined by the FDCA, 21 U.S.C. § 353(b)(1)(A), because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary for their use. *See id.* Indeed, all products containing synthetically produced omega-3 that have been approved by FDA are prescription drugs. *See* List of FDA-Approved Icosapent Ethyl (E-EPA) Drugs in Orange Book, **Exhibit 16**; List of FDA-Approved Omega-3 Ethyl Ester Drugs in the

Orange Book, **Exhibit 17**. As explained in paragraphs 84-101, all of the Distributors' Synthetically Produced Omega-3 Products are intended for "drug" uses (*i.e.,* to affect the structure/function of the body and/or to affect disease), **Exhibits 8-A-iii – 12-M-iii, 8-A-iv - 12-M-iv**; **Table 1**. Those uses have not been approved by FDA, and therefore, the labeling for the products at issue does not, and cannot, contain adequate directions for those uses. Accordingly, those products are misbranded in violation of Section 502(f).

110. Further, upon information and belief, all of the Synthetically Produced Omega-3 Products are misbranded drugs under Section 502(o) of the FDCA because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or the products at issue were not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j). *Id.* § 352(o).

111. In addition, upon information and belief, all of the Synthetically Produced Omega-3 Products are adulterated for failure to comply with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

112. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 30l(d) and (a) of the FDCA. *Id.* § 331(a), (d).

113. Finally, the FDCA prohibits unapproved "new drugs," and adulterated and misbranded "drugs," from entering the United States under Section 801(a) of the FDCA, 21 U.S.C. § 381(a), when the "drugs" have been manufactured, prepared, propagated, compounded, or processed in a foreign establishment that is not registered in accordance with Section 510(i) of the FDCA. Upon information and belief all of the products sold by the Manufacturers were manufactured, prepared, propagated, compounded, or processed in such a foreign establishment. Section 801(a) requires FDA to (1) sample any drugs that have been manufactured in an unregistered establishment, and (2) examine samples to determine whether any appear to be misbranded, adulterated, or unapproved new drugs. *See Cook v. FDA,* 733 F.3d 1, 10 (D.C. Cir. 2013). If FDA finds an apparent FDCA violation (*e.g.,* that a product is an unapproved, misbranded, and adulterated "new drug"), it must refuse the drug admission to the United States. *See id.*

VII. INSTANCES OF UNFAIR IMPORTATION AND SALE

A. Manufacturers

DSM

114. Proposed Respondent Royal DSM NV ("DSM NV") and its corporate affiliates, DSM Marine Lipids Peru S.A.C. ("DSM-Peru"), DSM Nutritional Products Canada Inc., ("DSM-Canada") and "DSM Nutritional Products LLC" in the United States ("DSM-US") manufacture, import, and/or sell Synthetically Produced Omega-3 Products. Royal DSM NV acquired

a fish oil concentration facility in Nova Scotia, Canada in 2012, to "strengthen its position in the North American dietary supplement market." Koninklijke DSM NV to Acquire Ocean Nutrition Canada to Expand Its Nutritional Lipids Growth Platform Conference Call – Final, May 18, 2012 FDA (Fair Disclosure) Wire, **Exhibit 65**. Upon information and belief, this facility is now DSM-Canada. At the time of acquisition, the facility manufactured fish oil concentrates of up to 70% EPA/DHA levels, and those supplements were sold in "Walmart, GNC, and Sam's Club." *Id.* Since that time, DSM has begun to use 3C technology, a new concentrating technology, to make "[u]ltra-pure, high potency EPA and DHA up to 85%," and it continues to manufacture those oils at the Nova Scotia facility. *See* The Modern Movement Forward In Omega-3, DSM Brochure, **Exhibit 66**; Meg-3, Business Opportunities, Accessed Aug. 8, 2017 ("DSM's flagship fish oil production facility is located in Mulgrave, Nova Scotia. In 2015, DSM invested $40 million to expand the facility, which refines and concentrates Omega-3 fish oil"), **Exhibit 67**. In April 2017, World Fishing & Aquaculture announced that DSM's Meg-3 ingredients "processed in DSM's facilities in Peru and Canada (DSM Marine Lipids Peru SAC and DSM Nutritional Products Canada Ltd [sic])," received a Friend of the Sea seal of approval, and the article noted that Meg-3 is a "leading global brand containing omega-3 EPA and DHA. The ingredients are used in dietary supplement, pharmaceutical and food & beverage applications worldwide." World Fishing & Aquaculture, April 20, 2017, **Exhibit 68**. DSM also advertises Meg-3 as conforming to the quality and purity standards established for dietary supplements by the U.S. FDA.

Meg-3, Business Opportunities, **Exhibit 67**. The Meg-3 product line sold by DSM includes E-OM3 concentrates and concentrates in the triglyceride form (upon information and belief, these concentrates are rTG-OM3 and rTG-EPA). *See* DSM in Food, Beverages & Dietary Supplements, **Exhibit 1-A-i**. Upon information and belief, DSM-Peru and DSM-Canada are manufacturing Meg-3 products that are Synthetically Produced Omega-3 Products, including E-OM3 oil and rTG-OM3 oil comprised predominantly of E-EPA or rTG-EPA.

115. Complainants have obtained data from Datamyne, Inc.[2] showing that DSM-Peru shipped to the United States, to DSM-US, "240 drums containing 45.60 MT of omega3T1000 [and] Meg-3 refined fish oil." **Exhibits 1-F-i.** Upon information and belief, DSM-Peru is supplying DSM-US with E-OM3 oil and/or rTG-OM3 oil comprised predominantly of E-EPA or rTG-EPA. In addition, DSM-Peru imported 191 MT of purified fish oil into the United States in bond for immediate export to consignee DSM-Canada. **Exhibit 1-F-i.** Based on the commercial relationships described above, DSM-Canada's concentrated production facility in Nova Scotia, and DSM-Canada's "focus on the North American Market" described in paragraph 114 above, and upon information and belief, DSM-Canada is supplying those products to DSM-US.

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[2] Datamyne, Inc. obtains trade data gathered from U.S. Customs and Border Protection's Automated Manifest System, customs declarations, and import-export Customs statistics. U.S. shipment data are updated daily upon receipt from U.S. Customs and Border Protection.

116. DSM violates Section 337 of the Tariff Act, because it violates the standards established in the FDCA. Specifically, the E-OM3 sold by DSM cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-70, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. As further explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF, **Exhibit 64**. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by DSM. For example, DSM makes the following structure/function claims: "Omega-3 fatty acids play a critical role in supporting human health across different stages. DHA . . . provides important brain and eye benefits, while DHA and EPA . . . together promote cardiovascular health." **Exhibit 1-C-i; Table 2**. In addition, DSM makes the following disease claims:

> The omega-3s EPA and DHA have been the focus of cardiovascular research for several decades. Numerous observational and randomized clinical trials have shown EPA/DHA intake reduces cardiovascular risk via reduction in blood triglycerides (TGs), resting heart rate, blood pressure and inflammation and improved vascular function. The strongest evidence for EPA/DHA is for reduction of coronary heart disease (CHD) death and sudden

> cardiac death (SCD), with the latter being attributed to the antiarrhythmic effects of omega-3s.

Exhibit 1-D-i; Table 2. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

117. Similarly, the rTG-OM3 oil sold by DSM cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-83. As further explained in paragraphs 98-99, it is a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the structure/function and disease claims identified in paragraph 116, above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

118. In addition, DSM's E-OM3 and rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose, and they are actually unapproved "new drugs," in violation of Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 1-B-i – 1-B-iii**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, adulterated drugs because they were

not manufactured in compliance with current good manufacturing practices for drugs, in violation of Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

119. DSM also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

120. In addition, DSM violates Section 337 of the Tariff Act, based upon violations of the Lanham Act. Specifically, DSM is falsely stating that its E-OM3 oil and its rTG-OM3 oil can be used in "dietary supplements" when these products are actually unapproved "new drugs," **Exhibits 1-B-i – 1-B-iii**; these literally false statements have the capacity to deceive customers and are likely to influence purchasing decisions; DSM caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Ultimate BioPharma

121. Proposed Respondent Ultimate Biopharma (Zhongshan) Corporation ("Ultimate") is a Chinese company that manufactures softgel capsules containing E-OM3 and OM3 in triglyceride form, **Exhibit 2-A**. Upon information and belief, some, if not all, of the OM3 in triglyceride form is rTG-OM3 comprised predominantly of rTG-EPA.

122. **Exhibit 2-F** contains 30 Datamyne documents showing 29 shipments of fish oil (labeled, 2100 Fish Oil, 2340 Fish Oil, 2099 Fish Oil, 2370 Fish Oil, and 2333 Fish Oil), and one shipment of 2340 Fish Oil Softgels, from Ultimate to Nature's Bounty between September 15, 2016 – February 11, 2017. Upon information and belief, Ultimate is shipping E-OM3 comprised predominantly of E-EPA and rTG-OM3 comprised predominantly of rTG-EPA in oil and softgel form to Nature's Bounty.

123. As discussed m paragraphs 163-173 below, Proposed Respondent Nature's Bounty is a U.S. importer and distributor of Synthetically Produced Omega-3 Products under brand names Nature's Bounty®, Puritan's Pride®, and Solgar®, **Exhibit 2-E-i**. Nature's Bounty was the consignee on the import shipments described in paragraph 122 above. **Exhibit 2-F**. Ultimate is a subsidiary or affiliate of Nature's Bounty. **Exhibit 2-E-ii**.

124. Ultimate violates Section 337 of the Tariff Act, because it violates the standards set forth in the FDCA. Specifically, the E-OM3 oil and capsules sold by Ultimate cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321 (ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. As further explained in paragraphs 92 and 95, both the E-OM3 oil and capsules are "drugs" because, upon information and belief, they are drugs recognized in the USP/NF. **Exhibits 62 and 64**. Ultimate's E-OM3

capsules and oil are also drugs because, upon information and belief, as explained in paragraphs 94 and 97, they are intended for use in, or as, a final product that is a "drug" (*e.g.,* Nature's Bounty purported "dietary supplements," which are actually unapproved "new drugs"). **Exhibits 8-A-ii – 8-N-ii**; **Table 4**. As explained in paragraphs 100-101, these products are also unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

125. Similarly, the rTG-OM3 oil and capsules sold by Ultimate cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather, Ultimate's rTG-OM3 oil and capsules are drugs because, upon information and belief, the rTG oil and capsules are intended for use in (or as) a final product that is a "drug" (*e.g.,* Nature's Bounty purported "dietary supplements," which are actually unapproved "new drugs"). **Exhibits 8-A-ii – 8-N-ii**; **Table 4**. As explained in paragraphs 100-101, these products are also unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

126. In addition, upon information and belief, Ultimate's E-OM3 oil and capsules are (1) as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (2) upon information and belief, as explained in paragraph 111, adulterated drugs

because they were not manufactured in compliance with current good manufacturing practices for drugs, as required by Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

127. Ultimate also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

128. In addition, Ultimate violates Section 337 of the Tariff Act, predicated upon violations of the provisions of the Lanham Act. Specifically, Ultimate is liable for contributory false advertising because Nature's Bounty is engaged in false advertising, as explained in paragraphs 163-173, and upon information and belief, Ultimate knowingly induced or caused that false advertising or otherwise materially participated in it.

Marine Ingredients

129. Marine Ingredients is a KD Pharma Group Company. **Exhibit 69**. Proposed Respondent Marine Ingredients AS is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that Marine Ingredients AS, in Norway, shipped to Marine Ingredients LLC, in the United States: 17.06 metric tons of oil, including "Omevital 400200 EE Mix" and "Omevital 3322 EE," around July 23, 2017; in two separate shipments, 17.06 metric tons of oil (in each

shipment), including "Omevital 400200 EE Mix," "Omevital 3322 EE," "4510 TG Ultra," and "Omevital 3322 TG," around July 17, 2017; 17.06 metric tons of oil, including "Omevital 4510 TG Ultra" and "Omevital 3322EE" in June 2017; and 22 Drums of "Omevital 3322 EE," in December 2016, **Exhibit 3-F-i**. Omevital 3322EE and Omevital 400200 EE are E-OM3, **Exhibit 3-F-i**, and upon information and belief, Omevital 4510 TG Ultra is rTG-OM3. *See id.* Thus, E-OM3 oils comprised predominantly of E-EPA and rTG-OM3 oils comprised predominantly of rTG-EPA are being imported into the United States from Marine Ingredients AS to Marine Ingredients LLC.

130. Proposed Respondent Marine Ingredients LLC is a U.S. importer of Synthetically Produced Omega-3 Products. Marine Ingredients LLC was the consignee on the import shipment described in paragraph 129 above. **Exhibit 3-F-i**. Marine Ingredients LLC markets its Synthetically Produced Omega-3 Products under the brand "Omevital." **Exhibit 3-A-i**. These products include E-OM3 oil comprised predominantly of E-EPA, and upon information and belief, they include rTG-OM3 oil comprised predominantly rTG-EPA as well. *See id.* Marine Ingredients LLC acquired BASF's concentrated fish oil production facility in 2014, which produces "Omevital" brand Synthetically Produced Omega-3 Products, and it merged with KD Pharma in 2016. **Exhibit 3-E-i**. Marine Ingredients AS is a subsidiary of Marine Ingredients LLC. **Exhibit 3-E-ii**.

131. Marine Ingredients violates Section 337 of the Tariff Act, because it violates certain standards in

the FDCA. Specifically, the E-OM3 oil sold by Marine Ingredients cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF, **Exhibit 64**. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Marine Ingredients. Marine Ingredients' structure/function claims include the following:

> Together EPA & DHA play a critical role in our cell development, growth, and maintenance . . . [they] are necessary for several important body functions, such as • Essential building blocks for our brain, eyes, and nerves . . . • Building cell membrane [sic] in our brain . . . • Maintenance of normal brain function . . . . More than 20,000 clinical studies showing positive health benefits have been conducted on Omega-3 EPA & DHA.

Exhibit 3-C-ii; Table 2. In addition, Marine Ingredients' disease claims include:

> More than 20,000 clinical studies showing positive health benefits have been conducted on Omega-3 EPA & DHA.

> Many of these studies indicate that these vital nutrients may be of importance by themselves or in combination with other drugs for the management of the following disorders: • Cardiovascular Disease, • Inflammation and Rheumatoid Arthritis, • Developmental Disorders, • Psychiatric Disorders, • Cognitive Aging, • Coronary Heart Disease, • Lupus, • Cancer.

Exhibit 3-D-ii, Table 2. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

132. Similarly, the rTG-OM3 oil sold by Marine Ingredients cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the same structure/function and disease claims cited above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

133. In addition, Marine Ingredients' E-OM3 oil and rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose and they are actually unapproved "new drugs," in violation of the standards set forth in Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 3-B-i – 3-B-iv**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section

502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 3600); and (3) upon information and belief, as explained in paragraph 110, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, as required by Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

134. Marine Ingredients also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

135. In addition, Marine Ingredients violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Marine Ingredients is falsely stating that its E-OM3 oil and rTG-OM3 oil can be used in "dietary supplements" when these products are actually unapproved "new drugs" **Exhibits 3-B-i – 3-B-iv**. These literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Marine Ingredients caused these false statements to enter interstate commerce; and as discussed in paragraphs 216-237, Amarin is likely to be injured as a result.

Golden Omega

136. Proposed Respondent Golden Omega S.A. is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that Golden Omega S.A. shipped to the United States. 6.84 metric tons of "Fish Oil Omega-3 Concentrate Ethyl Ester (EE3322)," 6.84 metric tons of Fish Oil Omega-3 Concentrate Ethyl Ester (EE4020)," and 1.52 metric tons of "Fish Oil Omega-3 Concentrate Triglyceride (TG3624)" in October 2016. **Exhibit 4-F-i**. Proposed Respondent Golden Omega USA LLC is a U.S. importer of Synthetically Produced Omega-3 Products. In particular, it was the consignee on the import shipments described above. **Exhibit 4-F-i**. Golden Omega S.A. and Golden Omega USA LLC are affiliated entities. **Exhibit 4-E**.

137. Golden Omega identifies "EE3322" as a "balanced EPA+DHA EE concentrate" **Exhibit 4-A-iii**, "TG3624 as a balanced EPA+DHA TG concentrate," **Exhibit 4-A-iii**, and "EE4020" as a "high EPA EE concentrate" **Exhibit 4-A-iv**. The "EE," or E-OM3, products are Synthetically Produced Omega-3 Products, and upon information and belief the concentrated TG product is rTG-OM3.

138. Golden Omega violates Section 337 of the Tariff Act, because it violates certain standards of the FDCA. Specifically, the E-OM3 oil sold by Golden Omega cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary

supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF, **Exhibit 64**. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Golden Omega. For example, Golden Omega's structure/function claims include:

> Omega 3s and specifically EPA and DHA, are involved in the structure and function of cells in your body – from your head to your toes. There are more than 30,000 published studies on EPA and DHA Omega 3s, focused on the positive impact that the high consumption of Omega 3s has for the health of the heart, brain, and eye.

Exhibit 4-C-i; **Table 2.** In addition, disease claims include the following: "High EPA Omega-3 concentrates are commonly used in products to support . . . anti-inflammatory health." **Exhibit 4-D**; **Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

139. Similarly, rTG-OM3 oil sold by Golden Omega cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. It also is a "drug" because it is intended to affect the structure/function of the body and to affect disease, as

evidenced by, among other things, the same structure/function and disease claims cited in the paragraph above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

140. In addition, Golden Omega's E-OM3 oil and its rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose, and they are actually unapproved "new drugs," in violation of Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 4-B-i – 4-B-iv**; (2) upon information and belief, as explained in paragraph 1109, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, as required by Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

141. Golden Omega also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

142. In addition, Golden Omega violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Golden Omega is falsely stating that its E-OM3 oil and its rTG-OM3 oil can be used in "dietary supplements" when these products are actually unapproved "new drugs" **Exhibits 4-B-i – 4-B-iv**; these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Golden Omega caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Nordic Pharma

143. Proposed Respondent Nordic Pharma, Inc. ("Nordic Pharma") is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc., that show that Nordic Pharma imported into the United States: "Fish Oil, TG90 2050" on or about July 30, 2017; "Fish Oil TG90 3525" also on or about July 30, 2017; "Fish Oil TG90 3525" on or about May 19, 2017; "Fish Oil TG90 3525" and "Fish Oil TG 2050" on or about May 7, 2017; and "Fish Oil TG90 4020 80 drums" and "Fish Oil TG90 3525 37 Drums" in December 2016. **Exhibit 5-F**. Nordic Pharma is "exclusively dedicated to manufacturing Nordic Naturals omega oils" and the company is "privately owned by Nordic Naturals." **Exhibit 5-E**. Nordic Naturals, as explained in paragraphs 174-181, sells a large number of concentrated omega-3 products in triglyceride form. Upon information and belief, the products sold by Nordic Naturals and the products referenced in

Datamyne, Inc. are rTG-OM3 oil comprised predominantly of rTG-EPA.

144. Nordic Pharma violates Section 337 of the Tariff Act, because it violates certain standards of the FDCA. The rTG-OM3 oil sold by Nordic Pharma cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather Nordic Pharma's rTG-OM3 oil is a drug because, as explained in paragraph 99, upon information and belief, the rTG-OM3 oil is intended for use in a final product that is a "drug" (*e.g.,* the purported "dietary supplements" sold by Nordic Naturals that are actually unapproved "new drugs"). **Exhibits 9-A-ii – 9-UU-ii**. As explained in paragraphs 100-101, these products are also unapproved "new drugs" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

145. In addition, Nordic Pharma's rTG-OM3 oil is (1) falsely promoted for use in "dietary supplements" when it cannot legally be used for that purpose and it is actually an unapproved "new drug," in violation of the standards set forth in Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 9-A-ii – 9-UU-ii**; (2) upon information and belief, as explained in paragraph 110 a misbranded drug under Section 502(o) of the FDCA, *id.* § 352(o), because it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, an adulterated drug because it was not

manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

146. Nordic Pharma also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

147. In addition, Nordic Pharma violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Nordic Pharma is liable for contributory false advertising because Nordic Naturals is engaged in false advertising, as explained in paragraphs 174-181, and upon information and belief, Nordic Pharma knowingly induced or caused that false advertising or otherwise materially participated in it.

Croda

148. Proposed Respondent Croda Europe Ltd. is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that Croda Europe Ltd. shipped to the United States: 13.6 metric tons of oil, including TG 3322, in March 2017; 17.29 metric tons of "Crodamol/Incromega" in January 2017; 16.08 metric tons of Incromega E3322-LQ in August 2016; and 16.07 metric tons of oil including Incromega E3322-LQ in May 2016. **Exhibit 6-F.**

149. Proposed Respondent Croda Inc. is a U.S. importer of Synthetically Produced Omega-3 Products. In particular, it was the consignee on the import shipment described in paragraph 148 above. **Exhibit 6-F**. Croda Europe Ltd. and Croda Inc. are affiliated entities, namely "[r]elated undertakings" of Croda International Plc. **Exhibit 6-E-i**.

150. Croda's Promotional Materials identify "Incromega" as the name for a number of fish oils, including fish oil concentrates that are produced using PureMax™ technology. **Exhibit 6-A-i**. Incromega products include a number of E-OM3 products and concentrated OM3 products in triglyceride form. **Exhibit 6-A-ii**. Upon information and belief, these E-OM3 products and concentrated OM3 products in triglyceride form are among the Incromega products imported into the United States.

151. Croda violates Section 337 of the Tariff Act, because it violates certain standards in the FDCA. Specifically, the E-OM3 oil sold by Croda cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF. **Exhibit 64**. It is also a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims

made by Croda. For example, structure/function claims include "Croda's Incromega™ range offers many possibilities for consumer health trends having clear benefits in numerous condition specific areas such as heart health, joint health, cognitive function, and eye health." **Exhibit 6-C-i; Table 2**. In addition, disease claims include "EPA can be beneficial for • Depression, • Inflammatory and autoimmune conditions," "Studies reveal that essential Omega 3 fats help reduce the brain inflammation associated with cognitive decline, which can harm brain cells," "Accumulating evidence suggests that diets that include Omega 3 fatty acids, specifically . . . [EPA and DHA] also protect against the development of dementia and Alzheimer's." **Exhibits 6-D-i and 6-D-iii; Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

152. Similarly, the rTG-OM3 oil sold by Croda cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather, it is a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the same promotional claims cited above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

153. In addition, Croda's E-OM3 oil and its rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements" when they cannot legally be used for that purpose and they are actually unapproved "new drugs," in violation of the standards set forth in Section 502(n)

of the FDCA, *id.* § 352(n), **Exhibits 6-B-i – 6-B-iv**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 111, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).).

154. Croda also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

155. In addition, Croda violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, Croda is falsely stating that its E-OM3 oil and its rTG-OM3 oil can be used in "dietary supplements," **Exhibits 6-B-i – 6-B-iv**, when these products are actually unapproved "new drugs"; these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Croda caused these false statements to enter interstate commerce; and as

discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

TASA

156. Proposed Respondent Tecnologica de Alimentos S.A. ("TASA") is a manufacturer of Synthetically Produced Omega-3 Products. Complainants have obtained data from Datamyne, Inc. showing that TASA shipped to the United States 16.61 metric tons of oil, including "Concentrate Omega 3 EE 33/22" on or about July 17, 2017; 32.37 metric tons of oil, including "Omega 3 Fish Oil EE 33-22," on or about July 6, 2017; 17.10 metric tons of oil, including "Omega 3 Fish Oil EE 33-22" on or about June 7, 2017; 16.23 metric tons of oil, including "Fish Oil EE 33-22" on or about May 15, 2017; and 80 drums of "Peruvian Refined Anchovy Omega 3 Fish Oil EE 33-22" in March 2017. **Exhibits 7-F-i**.

157. According to Promotional Materials on TASA's website, TASA "offer[s] . . . Omega-3 concentrates according to the needs of our customers with different concentration levels of EE and TG." **Exhibits 7-A-i**. "EE" stands for""ethyl esters," or E-OM3, **Exhibit 7-A-i**, and, upon information and belief "TG" stands for rTG-OM3. *See id.*

158. TASA violates Section 337 of the Tariff Act, because it violates certain standards in the FDCA. Specifically, the E-OM3 oil sold by TASA cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the

exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 95, it is a "drug" because, upon information and belief, it is a drug recognized in the USP/NF. **Exhibit 64**. It is also a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by TASA. For example, TASA's structure/function claims include the following: "HIGH Omega levels are related to speed improvements IN TEENS . . . . The study indicates that the 1% increase in the Omega-3 Index I related to an increase of 1.23 in the substitution test (LDST)." **Exhibit 7-C**; **Table 2**. In addition, TASA's disease claims include:

> Low Omega-3 consumption CONTRIBUTES to increased death rate . . . . The risk-of-morbidity study (GBD 2013), which quantifies threats to the health of the population and opportunities for prevention, concludes that low levels of omega-3 intake may increase the risk of disease . . .

Exhibit 7-D-i; **Table 2**. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

159. Similarly, rTG-OM3 oil sold by TASA cannot meet the definition of "dietary supplement" because it is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. Rather, it is a drug because it is intended to affect the structure/function of the body and to affect disease, as evidenced by, among

other things, the same structure/function and disease promotional claims made by TASA cited above. As explained in paragraphs 100-101, this product is also an unapproved "new drug" under the FDCA. *Id.* §§ 321(g), (p), 355(a).

160. In addition, TASA's E-OM3 oil and its rTG-OM3 oil are (1) falsely promoted for use in "dietary supplements," by TASA, when they cannot legally be used for that purpose and they are actually unapproved "new drugs," in violation of the standards set forth in Section 502(n) of the FDCA, *id.* § 352(n), **Exhibits 7-B-i – 7-B-ii**; (2) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (3) upon information and belief, as explained in paragraph 110, adulterated drugs because they were nor manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).).

161. TASA also violates the standard set forth in Section 301 of the FDCA. Section 301 of the FDCA prohibits the introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA. *Id.* § 331(a), (d).

162. In addition, TASA violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, TASA is falsely stating that its E-OM3 oil and its rTG-OM3 oil can be used in "dietary supplements," **Exhibits 7-B-i – 7-B-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; TASA caused these false statements to enter interstate commerce; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

B. Distributor Respondents

Nature's Bounty

163. Proposed Respondent The Nature's Bounty Company ("Nature's Bounty") is a U.S. importer and distributor of Synthetically Produced Omega-3 Products under brand names Nature's Bounty®, Puritan's Pride®, Solgar®, and Sundown Naturals®. Nature's Bounty was the consignee on the import shipments from its affiliate, Ultimate, described in paragraph 122 above. **Exhibit 2-F**.

164. Nature's Bounty sells the following E-OM3 products comprised predominantly of E-EPA in the United States under the brand name Nature's Bounty: Fish Oil 1400 mg (E-OM3), **Exhibit 8-A**, and Mini-Fish Oil 1290 mg (E-OM3), **Exhibit 8-B**. The Promotional Materials accompanying Mini-Fish Oil 1290 mg state that Nature's Bounty sources its fish oil "directly from Peru." **Exhibit 8-B-vi-b**. Although the Fish Oil 1400 mg product does not contain country of origin markings

visible on the Nature's Bounty website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70.** In addition, at least one unit of Nature's Bounty Fish Oil 1400 mg has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Fish Oil 1400 mg product containing concentrated fish oil is imported.

165. The following Nature's Bounty E-OM3 products comprised predominantly of E-EPA and rTG-OM3 products comprised predominantly of rTG-EPA are offered for sale in the United States under the brand name Puritan's Pride®: Double Strength Omega-3 Fish Oil 1200 mg (E-OM3), **Exhibit 8-C**; Omega-3 Fish Oil 645 mg Mini Gels (upon information and belief, rTG-OM3), **Exhibit 8-D**; Krill Oil+ High Omega-3 Concentrate 1085 mg (E-OM3), **Exhibit 8-**E; Lutigold™ Nutra-Vision with Lutein, Zeaxanthin & Omega-3 (E-OM3), **Exhibit 8-F**; One Per Day Omega-3 Fish Oil 1360 mg (upon information and belief, rTG-OM3), **Exhibit 8-G**; Specific Care™ Vision (E-OM3), **Exhibit 8-H**; Triple Strength Omega-3 Fish Oil 1360 mg (E-OM3), **Exhibit 8-I**; Ubiquinol 100 mg & Omega Fish Oil 400 mg (E-OM3), **Exhibit 8-J**. Upon information and belief, the Puritan's Pride® Synthetically Produced Omega-3 Products are imported into the United States. Although the Puritan's Pride® Synthetically Produced Omega-3 Products do not contain country of origin markings visible on the Puritan's Pride® website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70**. In addition, at least one unit of Puritan's Pride®

Omega-3 Fish Oil 645 mg Mini Gels has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Puritan's Pride® Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

166. The following Nature's Bounty E-OM3 Products comprised predominantly of E-EPA are sold in the United States under the brand name Solgar®: Triple Strength Omega 3 950 MG (E-OM3), **Exhibit 8-K**; Double-Strength Omega-3 700 MG (E-OM3), **Exhibit 8-L**; and EFA 1300 MG Omega 3-6-9 (E-OM3), **Exhibit 8-M**. Upon information and belief, the Solgar® Synthetically Produced Omega-3 Products are imported into the United States. Although the Solgar® Synthetically Produced Omega-3 Products do not contain country of origin markings visible on the Solgar® website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70**. In addition, at least one unit each of Solgar's Triple Strength Omega 3 950 MG and Double-Strength Omega-3 700 MG has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Solgar® Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

167. The following Nature's Bounty E-OM3 Product comprised predominantly of EEPA is sold in the United States under the brand name Sundown Naturals®: Odorless Fish Oil 1290mg/900mg (E-OM3), **Exhibit 8-N**. The Promotional Materials accompanying the Sundown Naturals® Odorless Fish Oil 1290mg/900mg product state that Sundown

Naturals®' "fish oil is sourced in Peru." **Exhibit 8-N-vi-b**. In addition, at least one unit of Sundown Naturals® Fish Oil Omega 3-1290 MG has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Sundown Naturals® Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

168. Nature's Bounty violates Section 337 of the Tariff Act, because it violates standards established in the FDCA. Specifically, the E-OM3 capsules sold by Nature's Bounty cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraph 92, the capsules are "drugs" because, upon information and belief, they are recognized in the USP/NF. **Exhibit 62**. The capsules are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Nature's Bounty (**Table 1** (listing structure/function claims and disease claims for all of Distributors' products)).

169. Similarly, the rTG-OM3 capsules sold by Nature's Bounty cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. The capsules are also "drugs" because they are intended to affect the

structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Nature's Bounty for those products (**Table 1** (listing structure/function claims and disease claims for all of Distributors' products)).

170. For example, Nature's Bounty's website provides the following structure/function claim, which applies to all of the Nature's Bounty brand products: "Nature's Bounty® Fish Oil contains Omega-3 fatty acids including EPA and DHA which help support and maintain the health of your cardiovascular and circulatory system." **Exhibits 8-A-iii-b, 8-B-iii-b.** The Puritan's Pride® website contains many structure/function claims, including "Omega-3 fatty acids are important for heart health," "Omega-3 fatty acids are important for the body's immune system," and "Omega-3's can support bone health." **Exhibits 8-C-iii-b – 8-J-iii-b.** The same website also contains disease claims, including "Omega 3 fatty acids are important for heart health . . . Cardiovascular disease is the number one cause of death in the United States [implied claim for the prevention or treatment of cardiovascular disease and for the prevention of death]," and "In a study of women over 65 with osteoporosis, those who took EPA and GLA supplements saw a reduced rate of bone loss. In fact, many of the women experienced an increase in bone density [implied prevention/treatment of osteoporosis claim]." **Exhibits 8-C-iv-b, 8-D-iv – 8-I-iv, 8-J-iv-b.** Further, a Solgar brochure for all of its essential fatty acid products contains structure/function claims, such as "EPA and DHA leapfrog several metabolic steps, so

they quickly yield health benefits.* EPA forms the hormone-like prostaglandin 3 series of compounds, which have circulatory and other heart-healthy benefits." **Exhibits -K-iii-b – 8-M-iii-b**. In addition, Sundown Naturals®' Odorless Fish Oil 1290mg/900mg is marketed with a number of structure/function claims, including "Sundown Naturals® Odor-less Fish Oil 1290 mg supplies omegas that are important for your heart health.* Omega-3s are 'good fats' that support cardiovascular health, and cellular/joint/skin health.*" **Exhibit 8-N-iii**. Other structure/function and disease claims for these products are listed in **Table 2**.

171. In addition, Nature's Bounty's E-OM3 and rTG-OM3 products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibits 8-A-ii – 8-N-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, as explained in paragraph 110, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, as explained in paragraph 111, adulterated drugs

because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

172. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

173. Nature's Bounty also violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, Nature's Bounty is falsely stating on the product labels for all of its E-OM3 and rTG-OM3 products that they are "dietary supplements," **Exhibits 8-A-ii – 8-N-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Nature's Bounty caused these false statements to enter interstate commerce, **Exhibits 8-A-ii – 8-N-ii**; and as discussed in paragraphs 216-237, Amarin is likely to be injured as a result.

Nordic Naturals

174. Proposed Respondent Nordic Naturals is a U.S. distributor of Synthetically Produced Omega-3 Products. As described in paragraph 143 above, Complainants have obtained data from Datamyne, Inc. that show that Respondent Nordic Pharma imported "Fish Oil TG90 4020 80 drums" and "Fish Oil TG90 3525 37 Drums into the United States in December

2016. **Exhibit 5-F.** Nordic Pharma is "exclusively dedicated to manufacturing Nordic Naturals omega oils" and is "privately owned by Nordic Naturals." **Exhibit 5-E**. Nordic Naturals' Promotional Materials state that 100% of Nordic Naturals fish oil is manufactured in Norway" and its "soft gel products are bottled and encapsulated at [its] plant in Southern California." **Exhibit 71.**

175. Nordic Naturals distributes the following Synthetically Produced Omega-3 Products for direct sale to consumers or health care professionals: Ultimate Omega-D3, **Exhibit 9-A**; Ultimate Omega Xtra (Soft Gel), **Exhibit 9-B**; Ultimate Omega Xtra (Liquid), **Exhibit 9-C**; Ultimate Omega Liquid 2840 mg, **Exhibit 9-D**; Ultimate Omega Junior, **Exhibit 9-E**; Ultimate Omega in Fish Gelatin 1280 mg, **Exhibit 9-F**; Ultimate Omega D3 Sport (Professional Product), **Exhibit 9-G**; Ultimate Omega D3 Sport (Liquid) (Professional Product, **Exhibit 9-H**; Ultimate Omega 1280 mg, **Exhibit 9-I**; Ultimate Omega 2X, **Exhibit 9-J**; Ultimate Omega 2X with Vitamin D3, **Exhibit 9-K**; Ultimate Omega 2X Mini, **Exhibit 9-L**; Ultimate Omega 2X Mini with Vitamin D3, **Exhibit 9-M**; Ultimate Omega+ CoQ10, **Exhibit 9-N**; ProEPA, **Exhibit 9-O**; Complete Omega + D3 Junior, **Exhibit 9-P**; Complete Omega Junior, **Exhibit 9-Q**; Complete Omega XTRA, **Exhibit 9-R**; Daily Omega Kids, **Exhibit 9-S**; EPA Xtra, **Exhibit 9-T;** Omega ONE, **Exhibit 9-U**; EPA, **Exhibit 9-V**; Omega LDL, **Exhibit 9-W**; Omega Joint XTRA, **Exhibit 9-X**; Omega Curcumin, **Exhibit 9-Y**; Omega Blood Sugar, **Exhibit 9-Z**; ProOmega 2000 (Professional Product), **Exhibit 9-AA**; ProOmega (Professional Product), **Exhibit 9-BB**;

ProOmega in Fish Gelatin (Professional Product), **Exhibit 9-CC**; Pro-Omega Liquid (Professional Product), **Exhibit 9-DD**; ProOmega-D (Professional Product), **Exhibit 9-EE**; ProOmega-D Xtra (Professional Product), **Exhibit 9-FF**; ProOmega-D Xtra Liquid (Professional Product), **Exhibit 9-GG**; ProOmega 2000-D (Professional Product), **Exhibit 9-HH**; Nordic Omega-3 Gummy Fish (Professional Product), **Exhibit 9-II**; Omega Boost Junior (Professional Product), **Exhibit 9-JJ**; Omega-3 Fishies (Professional Product), **Exhibit 9-KK**; Nordic Omega-3 Gummy Worms (Professional Product), **Exhibit 9-LL**; Nordic Omega-3 Gummies (Professional Product), **Exhibit 9-MM**; ProOmega 2000 Jr. (Professional Product), **Exhibit 9-NN**; ProOmega Junior (Professional Product), **Exhibit 9-OO**; ProOmega 3-6-9 (Professional Product), **Exhibit 9-PP**; ProOmega CRP (Professional Product), **Exhibit 9-QQ**; ProOmega Blood Sugar (Professional Product), **Exhibit 9-RR**; ProOmega LDL (Professional Product), **Exhibit 9-SS**; ProOmega Joint Xtra (Professional Product), **Exhibit 9-TT**; ProOmega CoQ10 (Professional Product), **Exhibit 9-UU**. In addition, at least one unit each of Nordic Naturals Complete Omega XTRA and Nordic Naturals ProOmega Blood Sugar has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Nordic Naturals Synthetically Produced Omega-3 Products containing concentrated fish oil are imported.

176. Notably, many of these products (*i.e.,* those designated as "Professional Product") are marketed directly to health care professionals (*see, e.g.,* **Exhibits 9-AA-i-a, 9-UU-i-a**). But, at least as a general matter, the purported "Professional Products" also are

available to the general public on Amazon.com, *see, e.g.,* **Exhibits, 9-O:-vi, 9-II-vi-a, 9-AA-vi-a, 9-GG-vi-a**.

177. The Nordic Naturals website states that "all Nordic Naturals formulas are produced in true triglyceride form," **Exhibit 72**. Upon information and belief, given that all of the products listed above contain EPA in concentrations above, or in ratios different from, common fish oil, *see id.,* all of these products contain rTG-OM3.

178. Nordic Naturals violates Section 337 of the Tariff Act, because it violates the standards established in the FDCA. Specifically, the products containing rTG-OM3 sold by Nordic Naturals cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. These products are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Nordic Naturals for those products. For example, the Nordic Naturals website contains structure/function claims that apply to all of the products, such as "Extensive research has documented the health benefits of EPA and DHA, which include not only a healthy heart, but brain and cognitive function, joint mobility, eye health, pregnancy and lactation, healthy skin and hair, and a normally functioning immune response." **Exhibits 9-A-iii, 9-B-iii-b – 9-DD-iii-b, 9-EE-iii, 9-FF-iii-b – 9-HH-iii-b, 9-II-iii, 9-JJ-iii-b – 9-KK-iii-b, 9-LL-iii – 9-MM-iii, 9-NN-iii-b – 9-QQ-iii-b, 9-RR-iii, 9-SS-iii-b – 9-UU-iii-b.** Similarly, the website contains disease

claims that apply to all of the products such as "Protects against age-related oxidative damage," "Can help alleviate [eye] dryness and redness," "May help slow the progression of age-related memory loss," "Supports internal repair systems that operate in response to physical stress," "Omega-3 consumption may reduce the risk of allergies in children," and "Omega-3 consumption may reduce the risk of colds in infants." **Exhibits 9-A-iv – 9-U-iv, 9-V-iv-b – 9-W-iv, 9-X-iv-b – 9-Y-iv-b, 9-Z-iv – 9-QQ-iv, 9-RR-iv-b, 9-SS-iv, 9-TT-iv-b – 9-UU-iv-b**. Other structure/function and disease claims for these products are listed in **Table 1.**

179. In addition, the Nordic Naturals rTG-OM3 products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibit 9-A-ii – 9-UU-ii**; (2) misbranded as a matter of law, in violation of Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured

in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

180. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

181. Nordic Naturals also violates Section 337 of the Tariff Act, because it violates the provisions of the Lanham Act. Specifically, Nordic Naturals is falsely stating on the product labels for all of its products that they are "dietary supplements," **Exhibits 9-A-ii – 9-UU-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Nordic Naturals caused these false statements to enter interstate commerce, **Exhibits 9-A-ii – 9-UU-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Pharmavite LLC/Nature Made

182. Proposed Respondent Pharmavite LLC is a U.S. distributor of Nature Made-branded imported Synthetically Produced Omega-3 Products. In particular, Pharmavite sells at least the following Synthetically Produced Omega-3 Products in the United States under the Nature Made brand: Fish-Oil One Per Day Burpless (E-OM3), **Exhibit 10-A**; Fish

Oil One Per Day (E-OM3), **Exhibit 10-B**; Fish Oil Pearls (E-OM3), **Exhibit 10-C**; Full Strength Mini Omega-3 (E-OM3), **Exhibit 10-D**; Omega-3 with Xtra Absorb (E-OM3), **Exhibit 10-E**; Triple Omega (E-OM3), **Exhibit 10-F;** and Ultra Omega-3 (E-OM3), **Exhibit 10-G**.

183. According to the applicable country of origin markings on the Nature Made Synthetically Produced Omega-3 Products, Norway is the country of origin of the fish oil used in Full Strength Mini Omega-3 product, **Exhibit 10-D-vi-b,** and the Omega-3 with Xtra Absorb product, **Exhibit 10-E-vi-b**. Colombia is the country of origin of the fish oil used in the Fish Oil Pearls product, **Exhibit 10-C-vi-b**. Canada is the country of origin of the fish oil used in the Fish Oil One Per Day, Burpless product, **Exhibit 10-A-vi-b** and the Fish Oil One Per Day product, **Exhibit 10-B-vi-b**. The Triple Omega product also is imported into the United States. Although the Triple Omega product does not contain country of origin markings visible on the Nature Made website, there are no known commercial-grade fish oil concentration production facilities in the United States. **Confidential Exhibit 70**. In addition, at least one unit of Nature Made Fish Oil Pearls has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Nature Made Synthetically Produced Omega-3 Products are imported.

184. Pharmavite violates Section 337 of the Tariff Act, because it violates the standards established in the FDCA. Specifically, the E-OM3 capsules sold by Pharmavite cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary

ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83.. In addition, as explained in paragraph 92, the capsules are "drugs" because, upon information and belief, they are recognized in the USP/NF. **Exhibit 62.** The capsules are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, the structure/function and disease promotional claims made by Pharmavite. *See* **Table 1** (listing structure/function claims and disease claims for all of Distributors' products).

185. For example, structure/function claims on Pharmavite's website for Nature Made's fish oil products include the following: "A regular intake of EPA and DHA can play a positive role in your health. When made available to the body, EPA and DHA are incorporated into cell membranes (such as heart cells) and help support flexible cell membranes," and "EPA and DHA . . . help support a healthy heart." **Exhibits 10-A-iii-b – 10-G-iii-b**; **Table 1**. Pharmavite's website for all of Nature Made's fish oil products also includes, for example, the disease claim, "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease." **Exhibits 10-A-iv-b – 10-G-iv-b**; **Table 1.** Notably, FDA has exercised enforcement discretion over this claim when it is used to promote dietary supplements and conventional foods. **Exhibit 73**. As explained in paragraph 184, however, Pharmavite's E-OM3 products are not "dietary

supplements," and clearly, they are not conventional foods. Accordingly, they are not subject to FDA's enforcement discretion policy for this claim. Other structure/function and disease claims for these products are listed in **Table 1**.

186. In addition, Pharmavite's E-OM3 products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibits 10-A-ii – 10-G-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

187. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any

adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

188. Pharmavite violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Pharmavite is falsely stating on the product labels for all of its E-OM3 products that they are "dietary supplements," **Exhibits 10-A-ii – 10-G-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Pharmavite caused these false statements to enter interstate commerce, **Exhibits 10-A-ii – 10-G-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Innovix Pharma Inc./Omega Via

189. Proposed Respondent Innovix Pharma Inc. ("Innovix Pharma") is a U.S. distributor of Omega Via-branded imported Synthetically Produced Omega-3 Products. In particular, Innovix Pharma sells at least the following Synthetically Produced Omega-3 Products in the United States: OmegaVia EPA 500 (rTG-EPA), **Exhibit 11-A**, and OmegaVia Fish Oil (rTG-OM3), **Exhibit 11-B**. Both of these products contain omega-3 in the rTG form. **Exhibits 11-A-i and 11-B-i.**

190. According to the Omega Via Promotional Materials, the concentrated fish oil used in the Omega Via Synthetically Produced Omega-3 Products is sourced from Peru, Chile and the United States, and is concentrated in Europe before being imported into the United States for encapsulation. **Exhibits 11-A-vi** –

11-B-vi. The labels for OmegaVia EPA 500 and for Omega Via Fish Oil state that the "source" of the fish oil is Peru and Chile, and the product is "[c]oncentrated and purified in Europe." *See id.* In addition, at least one unit of Omega Via's EPA 500 has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Omega Via Synthetically Produced Omega-3 Products are imported.

191. Innovix Pharma violates Section 337 of the Tariff Act, because it violates certain standards established in the FDCA. Specifically, the rTG-OM3 and rTG-EPA products sold by Innovix Pharma cannot meet the definition of "dietary supplement" because rTG-OM3 and rTG-EPA are not "dietary ingredients," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. These products are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Innovix Pharma for those products. For example, the Innovix Pharma website contains structure/function claims that apply to all of the products, such as: "Comfort your joints," "Keep Your Mind Sharp," and "maintaining mood health." **Exhibits 11-A-iii-c and 11-B-iii-c**. Similarly, the website contains disease claims that apply to all of the products such as: "Reduces enzymes that destroy cartilage," "reduces joint discomfort," "Moderate growth of atherosclerosis plaque," "EPA has been found to be as effective as prescription anti-depressants," "Manage age-related brain decline," "bring your triglyceride levels down naturally," "moderate blood pressure," "reducing redness and scaling," "That's 20% More

Omega-3 Than Prescription Lovaza" (comparison claims to drugs are disease claims, 21 C.F.R. § 101.93(g)((vi)), "Clinically effective dose for triglycerides," "Pharmaceutical Grade," "EPA is more effective than DHA at lowering triglycerides," "improve mood and depression," "powerful anti-inflammatory for soothing arthritis." **Exhibits 11-A-iv-b – 11-A-iv-c, 11-B-iv-b – 11-B-iv-c**. Other structure/function and disease claims for these products are listed in **Table 1**.

192. In addition, Innovix Pharma's rTG-OM3 and rTG-EPA products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibit 11-A-ii – 11-B-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

193. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections 501 and/or 502 of the FDCA, is prohibited by Section 301(d) and (a) of the FDCA. *Id.* § 331(a), (d).

194. Innovix Pharma also violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Innovix Pharma is falsely stating on the product labels for all of its rTG-OM3 and rTG-EPA products that they are "dietary supplements," **Exhibits 11-A-ii – 1-B-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Innovix Pharma caused these false statements to enter interstate commerce, **Exhibits 11-A-ii – 11-B-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

Carlson

195. Proposed Respondent J.R. Carlson Laboratories, Inc. ("Carlson") is a U.S. distributor of imported Synthetically Produced Omega-3 Products. In particular, Carlson sells at least the following Synthetically Produced Omega-3 products in the United States: Women's Omega Multi (upon information and belief, rTG-OM3), **Exhibit 12-A**; Very Finest Fish Oil Liquid (upon information and belief, rTG-OM3), **Exhibit 12-B**; Super Omega-3 Gems (E-OM3), **Exhibit 12-C**; Elite EPA Gems (E-EPA), **Exhibit 12-D**; Elite Omega-3 Gems (E-OM3), **Exhibit 12-E**; Fish Oil Q 100 mg (E-OM3), **Exhibit 12-F**;

Inflammation Balance (upon information and belief, rTG-OM3), **Exhibit 12-G**; Maximum Omega 2000 (upon information and belief, rTG-OM3), **Exhibit 12-H**; MCT & Omega-3 (upon information and belief, rTG-OM3), **Exhibit 12-I**; Men's Omega Multi (E-OM3), **Exhibit 12-J**; Super Omega-3 Gems, Fish Gelatin (E-OM3), **Exhibit 12-K**; Omega 3-6-9 (upon information and belief, rTG-OM3), **Exhibit 12-L**; Super 2 Daily (upon information and belief, rTG-OM3), **Exhibit 12-M**. Notably, Carlson's omega-3 product brochure expressly states that its omega-3 products are comprised of (1) non-concentrated 100% natural triglycerides, (2) concentrated ethyl esters, (3) concentrated re-esterified triglycerides (rTG), and (4) a mixture of both the natural triglyceride form and the more potent ethyl ester form. **Exhibits 12-A-i-c, 12-B-i-c, 12-G-i-c, 12-H-i-c, 12-I-i-c, 12-L-i-c, 12-M-i-c**.

196. According to the Carlson Promotional Materials, the concentrated fish oil used in the Carlson Omega-3 Products is sourced from Norway. **Exhibits 12-A-vi – 12-M-vi**. In addition, at least one unit each of Carlson's Elite EPA Gems and Elite Omega-3 Gems has been sold in the United States. **Confidential Exhibit 70.** Accordingly, the Carlson Synthetically Produced Omega-3 Products are imported.

197. Carlson violates Section 337 of the Tariff Act, because it violates certain standards established by the FDCA. Specifically, the E-OM3 capsules and oils sold by Carlson cannot meet the definition of "dietary supplement" because E-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in

paragraphs 61-71, and it is excluded from the definition of "dietary supplement" by the exclusionary clause, *id.* § 321(ff)(3), as explained in paragraphs 71-83. In addition, as explained in paragraphs 92 and 95, the E-OM3 capsules and the oil are "drugs" because, upon information and belief, they are recognized in the USP/NF. **Exhibits 62 and 64**. The E-OM3 products are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function and disease promotional claims made by Carlson. *See* **Table 1** (listing structure/function claims and disease claims for all of Distributors' products).

198. Similarly, the rTG-OM3 products sold by Carlson cannot meet the definition of "dietary supplement" because rTG-OM3 is not a "dietary ingredient," 21 U.S.C. § 321(ff)(1), as explained in paragraphs 61-71. The products are also "drugs" because they are intended to affect the structure/function of the body and to affect disease, as evidenced by, among other things, structure/function promotional claims made by Carlson for those products. *See* **Table 1** (listing structure/function claims and disease claims for all of Distributors' products).

199. For example, a Carlson brochure accessible from Carlson's website provides the following structure/function claims, which apply to all of the Carlson Synthetically Produced Omega-3 Products: "EPA and DHA are required by our bodies and aid in our well-being by promoting and supporting:* Cardiovascular health . . . Brain and nerve health . . . Vision heath . . . Immune system health . . . Joint

health . . . Skin health." **Exhibits 12-A-iii-c – 12-B-iii-c, 12-C-iii-b, 12-D-iii-c – 12-M-iii-c**. Other structure/function claims for these products are listed in **Table 1**.

200. In addition, Carlson's products are (1) falsely labeled as "dietary supplements," in violation of the standards set forth in Section 502(a) and/or (n) of the FDCA, 21 U.S.C. § 352(a), (n), when they cannot legally be used for that purpose and they are actually unapproved "new drugs," **Exhibits 12-A-ii – 12-M-ii**; (2) misbranded as a matter of law, in violation of the standards set forth in Section 502(f), as explained in paragraph 109, because they are "prescription drugs" that have not been approved by FDA, and therefore, the labeling fails to contain adequate directions for use, 21 U.S.C. § 352(f)(1), 353(b)(2); (3) upon information and belief, misbranded drugs under Section 502(o) of the FDCA, *id.* § 352(o), because they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of the FDCA, *id.* § 360; and/or not included in a list as required by Section 510(j) of the FDCA, *id.* § 360(j); and (4) upon information and belief, adulterated drugs because they were not manufactured in compliance with current good manufacturing practices for drugs, in violation of the standards set forth in Section 501(a)(2)(B) of the FDCA, 21 U.S.C. § 351(a)(2)(B).

201. The introduction, or delivery for introduction, into interstate commerce of any unapproved "new drug" that violates Section 505(a) of the FDCA, and/or any adulterated or misbranded drug that violates Sections

501 and/or 502 of the FDCA, is prohibited by Section 30l(d) and (a) of the FDCA. *Id.* § 331(a), (d).

202. Carlson also violates Section 337 of the Tariff Act, because it violates the Lanham Act. Specifically, Carlson is falsely stating on the product labels for all of its Synthetically Produced Omega-3 Products that they are "dietary supplements," **Exhibits 12-A-ii – 12-M-ii**, when these products are actually unapproved "new drugs;" these literally false statements have the capacity to deceive consumers and are likely to influence purchasing decisions; Carlson caused these false statements to enter interstate commerce, **Exhibits 12-A-ii – 12-M-ii**; and as discussed in paragraphs 217-238, Amarin is likely to be injured as a result.

VIII. CLASSIFICATION OF THE RESPONDENTS' PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE

203. The Proposed Respondents' products are imported under the following HTS classifications: HTS Nos. 0306.19.0030; 1504.20.6040; 1517.90.2080; 1605.40.1090; 2106.90.99; 106.90.9998; 2916.19.5000; 3003.90.0000; 3004.90.9120; 3504.00.5000; 3824.90.4020; and 3824.90.4090.

IX. RELATED LITIGATION

204. Complainants are not aware of any related litigation.

X. DOMESTIC INDUSTRY

205. Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Two of Amarin Corporation's wholly owned subsidiaries are Complainants in this action: Amarin Pharma and Amarin Ireland. Amarin Pharma is a Delaware corporation and is located in Bedminster, New Jersey. Amarin Ireland is organized under the laws of the Republic of Ireland and is headquartered in Dublin, Ireland. Amarin has made significant expenditures in the United States. The details of these expenditures are set forth below and in the Confidential Declaration of Michael W. Kalb, Senior Vice President and Chief Financial Officer of Amarin Pharma, attached as **Confidential Exhibit 23**.

206. Amarin Pharma has full time employees and leases property located at 1430 Route 206, Bedminster, New Jersey. Amarin's administrative, commercial, research and development, supply chain, and regulatory activities, among other business services, take place in its Bedminster, NJ location. The details of Amarin's U.S.-based employment and physical facilities at its Bedminster, NJ location are contained in **Confidential Exhibit 23, at ¶ 4.**

207. Amarin has entered into agreements with three commercial API encapsulators for the encapsulation of Vascepa®. These companies have qualified and validated their manufacturing processes and are capable of manufacturing Vascepa® in each case consistent with the stringent requirements

applicable to manufacturing of drugs sold in the United States. The details of Amarin's U.S.-based encapsulation expenditures in 2016 and the first and second quarters of 2017 are contained in **Confidential Exhibit 23, at ¶ 5.**

208. Amarin also has entered into packaging arrangements with two commercial API packagers for the packaging of Vascepa®. These companies have qualified and validated their manufacturing processes and are capable of packaging Vascepa® in each case consistent with the stringent requirements applicable to manufacturing of drugs sold in the United States. The details of Amarin's U.S.-based portion of these packaging expenditures in 2016 and the first and second quarters of 2017 are contained in **Confidential Exhibit 23, at ¶ 6**.

209. Amarin also has entered into a Logistics Service Agreement with a U.S.-based company. This agreement provides for inbound receipt of product, warehousing, order acceptance, order fulfillment and shipment of orders, among other services. The details of the U.S.-based portion of Amarin's logistics expenditures in 2016 and the first quarter 2017 are contained in **Confidential Exhibit 23, at ¶ 7.**

210. Amarin markets Vascepa® in the United States through its direct sales force of approximately 150 sales professionals, including sales representatives and their managers. Amarin also employs various marketing and medical affairs personnel to support Amarin' s commercialization of Vascepa®. In addition to Vascepa® promotion by Amarin sales representatives, Amarin has a co-promotion agreement

with Kowa Pharmaceuticals America, Inc. ("Kowa") that provides for no fewer than 250 sales representatives to promote Vascepa® in the United States. Total sales and marketing expenses for Vascepa, including the Kowa co-promotion fee, are contained in **Confidential Exhibit 23, at ¶ 8**.

211. To comply with the stringent regulatory requirements for the sale of a drug in the United States, Amarin undertook substantial risk and has made substantial investments in labor dedicated to research and develop Vascepa® to its current state. Amarin' s program for developing Vascepa has lasted over a decade, and the details of the total U.S.-based labor expenses dedicated to research and development during 2016 and the first and second quarters of 2017 are contained in **Confidential Exhibit 23 at ¶ ¶ 9-11.**

212. Significantly, the Vascepa® development programs include three key human clinical trials entitled MARINE, ANCHOR, and REDUCE-IT. Each clinical trial was undertaken under a special protocol assessment ("SPA") agreement with FDA involving years of costly regulatory interactions and SPA amendments. Such agreements reflect FDA's concurrence on the vigorous testing the company had to successfully complete even to be considered for FDA approval of Vascepa®.

213. The MARINE clinical trial demonstrated that Vascepa® was safe and effective for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TGs ≥500 mg/dL) hypertriglyceridemia, commonly known as very triglyceride levels, and it

supported FDA's July 26, 2012 approval of the drug for that indication.

214. Likewise, the ANCHOR clinical trial demonstrated that the product was safe and effective for use as an adjunct to diet to reduce triglyceride levels in adult patients with persistent high (TGs 200-499 mg/dL) triglyceride levels in addition to statin therapy.

215. The REDUCE-IT cardiovascular outcomes trial is an 8,175-patient clinical trial evaluating whether treatment with Vascepa® will reduce major cardiovascular events in patients who, despite stabilized statin therapy, have elevated triglyceride levels and other cardiovascular risk factors. The results of this important trial could help healthcare professionals save millions of lives and lead to improved medical care for tens of millions of patients. If successful, the REDUCE-IT study has the potential to significantly change the treatment paradigm for cardiovascular risk reduction, the leading cause of death in the United States. In a 2014 letter to Amarin, John Jenkins, M.D., then FDA's Director, Office of New Drugs, Center for Drug Evaluation and Research (now retired) stated that completed REDUCE-IT study "data would be of significant public health value." Dr. Jenkins went on to state, "I strongly urge Amarin to complete the trial and I know [FDA's clinical data review division for cardiovascular-focused drugs], is ready and willing to work with Amarin to address any issues that may arise as you work to that end." *See* FDA Letter to Amarin Pharma, dated September 11, 2014. **Exhibit 74.**

216. Amarin manages the REDUCE-IT study through a Contract Research Organization with the exception of costs for clinical trials management and costs for internal management. Amarin expects to report results from the REDUCE IT study in the second or third quarter of 2018. Amarin's total historical and expected costs of conducting the REDUCE-IT study are more than $200 million, most of it in the United States, and are set forth in **Confidential Exhibit 23 at ¶¶ 9-11.** Amarin's total R&D expenses since 2007, including expenses for all three studies, are contained in **Confidential Exhibit 23 at ¶¶ 9-11.**

XI. SUBSTANTIAL INJURY

217. The Proposed Respondents have engaged in unfair acts and unfair methods of competition, the threat or effect of which is to substantially injure Amarin's domestic industry in manufacturing, selling, and distributing its Vascepa® capsules. The importation and sale of Proposed Respondents' Synthetic Omega-3 Products by means of their unfair acts and unfair methods of competition have injured Amarin's domestic industry or threatened it with injury by (i) damaging the Vascepa® brand by exploiting Vascepa®'s status as an FDA-approved drug, (ii) causing lost sales and market share to Vascepa®, and (iii) diminishing Amarin's profitability and Vascepa®'s eroding prices.

A. Damage To The Vascepa® Brand

218. Amarin has spent considerable time, money, effort, and resources developing the Vascepa® brand.

As described in paragraphs 205-216 above, it developed Vascepa® in compliance with the FDCA and obtained FDA approval of its drug. It conducted the successful ANCHOR and MARINE trials, and is conducting REDUCE-IT trial as part of its development of Vascepa®. To expand marketing claims for its drug by demonstrating its effect on cardiovascular risk reduction, Amarin has invested and expects to invest more than $200 million since 2011 on its REDUCE-IT study alone. **Confidential Exhibit 23 at ¶¶ 9-11.** Through this substantial pharmacological development risk, effort and investment, Amarin has built and is continuing to build a successful, branded FDA-approved pharmaceutical product that helps patients who have been diagnosed with persistent high or very high triglyceride levels.

219. By contrast, Proposed Respondents market their Synthetic Omega-3 Products as non-prescription "dietary supplements," which exploits the Vascepa® brand and creates non-prescription competition and product substitution by the Synthetically Produced Omega-3 Products marketed illegally as "dietary supplements." These products are largely untested and much less stringently regulated, despite the fact that they are accompanied by claims by the Proposed Respondents that such products reduce triglyceride levels. By labeling and promoting Synthetically Produced Omega-3 Products as "dietary supplements" when, in fact, they are unapproved "new drugs," Proposed Respondents are diluting the Vascepa® brand and its status and notoriety as an FDA-approved drug and profiting from Amarin's substantial efforts and investments – all without using their own resources,

investing their own time or money, or exerting similar efforts of their own.

220. For example, a 2015 article on the NutraceuticalsWorld website entitled *Omega-3s: Turning the Tide & Watching the Current,* explained how Omega-3 manufacturers exploit the presence of Vascepa® and other prescription drugs in the market at the expense of Amarin and the Vascepa® brand. The article explains that "[t]he presence in the market of prescriptions forms of omega-3 esters such as Lovaza, Vascepa and Epanova gives an extra level of confidence even in the absence of [a Reference Daily Intake] or unqualified health claim." **Exhibit 75.**

221. In another article entitled *Lovaza: A Wolf in Sheep's Clothing,* a Nordic Naturals sales manager was quoted as saying that the presence of FDA-approved pharmaceuticals in the market is "very positive" because "it validates the use of omega 3s in a clinical application." **Exhibit 76.** Another market participant agreed, noting that if pharmaceutical companies "want[] to spend millions of dollars advertising the health benefits of fish oil on TV, it can do nothing but benefit all of us. I'm in." **Exhibit 76.**

222. The Proposed Respondents' conflation of Amarin's FDA-approved Vascepa® product with their Synthetically Produced Omega-3 Products has caused confusion in the marketplace about the distinction between "drugs" and "dietary supplements" to the detriment of the Vascepa® brand. A survey conducted by Fairleigh Dickenson University's Public Mind Poll entitled, *"What's In Your Supplements? Even The Experts Are Stumped,"* reported that "[a]mong those

physicians and pharmacists who had recommended a non-prescription omega-3 product to patients, more than four in five (85%) believed incorrectly that they had recommended an FDA-approved OTC product . . . ." **Exhibit 77.** Notably, there are no legally marketed OTC drugs containing omega-3 fatty acids.

223. Companies like Proposed Respondent Innovix Pharma intentionally add to the confusion by promoting their products with claims that make direct comparisons to FDA-approved drugs (*e.g.,* "Most fish oils are not the same as Lovaza. But some Are! A few over-the counter pharmaceutical grade fish oils [sic] are just as potent, pure and effective at reducing triglycerides as Lovaza," *see* OmegaVia Website, **Exhibit 44**; *see also* OmegaVia Website 2, **Exhibit 45** (making implicit comparisons of OmegaVia's so-called "pharmaceutical grade fish oil" products to both Vascepa® and Lovaza®)).

224. These and other statements made by the Proposed Respondents in conjunction with the importation and sale of the Synthetically Produced Omega-3 Products have damaged or diluted the Vascepa® brand causing injury and threatened injury to Amarin.

B. Lost Sales And Market Share

225. Amarin has lost sales and market share as a result of Proposed Respondents' unfair acts and unfair methods of competition in multiple channels of distribution. The Synthetically Produced Omega-3 Products can be purchased off the shelf at retail establishments, such as grocery stores, pharmacies, big

box stores, and over the Internet, without restriction. In addition, the Synthetically Produced Omega-3 Products can be purchased through doctor prescriptions. By contrast, Vascepa® can only be distributed pursuant to a prescription.

226. The ubiquitous presence of the Proposed Respondents' products in retail and consumer distribution channels has injured or threatened Amarin with injury. For example, in 2012, Amarin commissioned Hall & Partners, a New York City-based market research firm to conduct a consumer direct-to-consumer market research program for Vascepa®. The sample included a total of 810 individuals with high triglycerides (200-499 mg/dL) and very high triglycerides (500+ mg/dL). When asked "[w]hich of the following medications are you currently taking to treat high triglycerides, whether treated alone or with another condition?," 41% responded that they took a prescription omega-3 product and 54% responded that they took a fish oil dietary supplement. **Confidential Exhibit 78.**

227. Proposed Respondents' unfair acts and unfair methods of competition also have resulted in lost sales and lost market share for Amarin's Vascepa® product in the physician prescription channel of distribution. In particular, a TVG Marketing Research & Consulting Study conducted in late 2015 indicates that physicians are more than three times more likely (28 percent to 8 percent) to recommend "Omega-3 Fish Oil Dietary Supplements" instead of prescribing Vascepa® when treating patients with elevated triglycerides. **Confidential Exhibit 79.** Moreover, certain

Distributors, like Nordic Naturals, have an entire line of purported "Professional Products," that are specifically marketed to healthcare professionals. **Exhibits 80.** Proposed Respondents have induced doctors to recommend and patients to purchase Respondents' products in the mistaken belief that they are equivalent to FDA-approved products, with the threat or effect of lost sales and lost market share to Vascepa®.

228. Proposed Respondents' sales of Synthetically Produced Omega-3 Products resulting from unfair acts and unfair methods of competition have injured or threatened Amarin with injury. In the absence of Proposed Respondents' unfair acts and unfair methods of competition, sales of Vascepa® would displace a significant percentage of Proposed Respondents' sales of Synthetically Produced Omega-3 Products in the direct-to-consumer channel of distribution, as consumers would seek prescriptions for Vascepa and other FDA-approved triglyceride-lowering drugs. And in the absence of Proposed Respondents' unfair acts and unfair methods of competition, sales of Vascepa® or other FDA-approved prescription triglyceride-lowering drugs would displace all of Proposed Respondents' sales of Synthetically Produced Omega-3 Products in the physician prescription channel of distribution.

229. Amarin has the capacity and/or inventory to supply the entire U.S. market demand for the Synthetically Produced Omega-3 Products (and similarly situated products), and Proposed

Respondents' unfair acts prevent Amarin from making these sales. **Confidential Exhibit 70 at ¶ 23.**

C. Lost Profits And Price Erosion

230. Proposed Respondents' unfair acts and unfair methods of competition have contributed to Amarin's lost profits and to the price erosion of Vascepa®. FDA regulates "drugs" more stringently than "dietary supplements": drugs are subject to FDA approval, 21 U.S.C. § 505; and drug approval triggers the need for complying with the FDCA's drug registration and listing requirements, 21 U.S.C. § 360, the FDCA's drug manufacturing requirements, 21 U.S.C. § 351, and certain user fees. 21 U.S.C. § 379h. Moreover, FDA regulates drug labeling, promotional materials, and advertising stringently. FDA reviews drug labeling and approves claims that can be made regarding the product's use and conditions of use. 21 U.S.C. §§ 321(p), 505; 21 C.F.R. § 314.81. And promotional materials and advertising are submitted to FDA at the time of dissemination. Further, prescription drugs, such as Vascepa® can only be distributed pursuant to a prescription. 21 U.S.C. § 353(b).

231. By illegally importing and selling Synthetically Produced Omega-3 Products, the Proposed Respondents are able to avoid the substantial costs of obtaining FDA approval, maintaining FDA approval (*i.e.,* certain user fees), and complying with FDA's drug registration, listing, labeling/advertising, and manufacturing requirements. By contrast, Amarin has had to incur substantial costs in obtaining and maintaining. FDA approval for Vascepa®, and for complying with FDA's various requirements.

232. All of Amarin's product revenue is derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa®, net of allowances, discounts, incentives, rebates, chargebacks and returns. Amarin sells product to a limited number of major wholesalers and selected regional wholesalers and specialty pharmacy providers (collectively "Vascepa® Distributors") who resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions that are issued by authorized medical professionals. The commercial launch of 1-gram size Vascepa® capsules in the United States occurred in January 2013 and a smaller 0.5-gram size capsule was introduced in October 2016. Since 2014, Amarin has recognized revenue based on sales to its Vascepa® Distributors. Net product revenues based on sales of Vascepa® to distributors totaled $79.3 million and $58.1 million during the six months ended June 30, 2017 and 2016, respectively. Amarin's revenues would have been higher but for the Proposed Respondents' unfair acts and unfair methods of competition.

233. Amarin has not yet reached profitability on sales of Vascepa®, and anticipates incurring losses for an indefinite period of time. For the fiscal years ended December 31, 2016, 2015, and 2014, Amarin reported losses of approximately $86.4 million, $49.1 million, and $56.4 million, respectively, and the company has an accumulated deficit as of December 31, 2016 of $1.2 billion. For the three months ended March 31, 2017 and 2016, Amarin reported losses of approximately $20.9 million and $29.8 million, respectively.

234. This cumulated deficit in operating losses is typical of pharmaceutical companies that introduce a new drug into the market. They reflect the fact that to legally enter the pharmaceutical market with a drug like Vascepa® involves years of development, hundreds of millions of dollars in research and development costs, and several years of operating losses, as well as the risk of development failure. Pharmaceutical companies like Amarin typically recover their development costs over time through increasing volumes of sales. Amarin's losses, however, are exacerbated by Proposed Respondents' conduct. Put differently, Amarin's operating losses would have been smaller, or Amarin would have become profitable more quickly, but for the Proposed Respondents' unfair acts or unfair methods of competition.

235. The details of Amarin's production volumes and inventories of Vascepa® are contained in **Confidential Exhibit 70,** at **¶¶ 121-23**. Amarin has entered into long-term supply agreements with multiple FDA-approved API suppliers and encapsulators, which include the potential for capacity expansion aimed at creating sufficient volumes to meet future demand for Vascepa®. Amarin's ability to meet those growth projections (and to achieve profitability) is inhibited by Proposed Respondents' unfair acts and unfair methods of competition.

236. Proposed Respondents' sales of the Synthetically Produced Omega-3 Products resulting from unfair acts and unfair methods of competition also have had a substantial adverse impact on Vascepa® pricing. While Vascepa® pricing may be affected by

insurance coverage and offered discounts, the fact that Vascepa® and Proposed Respondents' products are sold in the same or similar channels of distribution also has adverse impacts on Vascepa® pricing. Amarin Corporation plc 2016 10K Statement at 41, attached as **Exhibit 81.**

237. The adverse price effects of the Synthetically Produced Omega-3 Products also is evident from Amarin's coupon discount sales program. According to that program, a consumer with commercial insurance can pay as little as $9.00 for a 90-day supply prescription of Vascepa®. **Exhibit 25.** The percentage of Vascepa® prescriptions covered by Amarin's coupon program is set forth in the attached **Confidential Exhibit 23.** Amarin's coupon program was designed to make Vascepa price competitive with Synthetically Produced Omega-3 Products and to discourage physicians and pharmacists from directing consumers to purchase Synthetically Produced Omega-3 Products based on price. As a result, Amarin has suffered price erosion from the unfairly traded Synthetically Produced Omega-3 Products with respect to at least the sales covered by Amarin's coupon program.

238. In sum, the Proposed Respondents' importation and sale of Synthetically Produced Omega-3 Products has injured and/or threatened Amarin with substantial injury by (i) damaging the Vascepa® brand by exploiting Vascepa®'s status as an FDA-approved drug, (ii) causing lost sales and market share to Vascepa, and (iii) diminishing Amarin's profitability and eroding Vascepa®'s prices.

XII. RELIEF

WHEREFORE, by reason of the foregoing, Complainants request that the Commission:

A. Institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to the Proposed Respondents' violations of Section 337 based on the importation and sale in the United States of the Synthetically Produced Omega-3 Products;

B. Schedule and conduct a hearing on permanent relief pursuant to 19 U.S.C. § 1337(d) and (f) of the Tariff Act of 1930, as amended;

C. Find that Synthetically Produced Omega-3 Products are violating Section 337 of the Tariff Act because they violate the Lanham Act and the standards set forth in the FDCA in that they are sold as "dietary supplements" in the United States, without meeting the definition of "dietary supplement" in the FDCA. Further find that the Synthetically Produced Omega-3 Products are violating Section 337 of the Tariff Act because they meet the definition of "drugs," under the FDCA, by virtue of the fact that they are articles: (i) recognized in the USP/NF, (ii) intended to affect disease (*e.g.,* they are marketed with drug comparison claims, as well as other "disease" claims), *see* **Tables 1 and 2,** (iii) intended to affect the structure or function of the body (*e.g.,* they are marketed with claims that they support healthy heart, brain, and joint function, among other structure/function claims), *see* **Tables 1 and 2,** and/or

(D) intended for use as a component of any articles specified in clauses (i)-(iii). 21 U.S.C. § 321(g)(1).

D. Issue a permanent General Exclusion Order excluding from entry into the United States all Synthetically Produced Omega-3 Products pursuant to 19 U.S.C. § 1337(d);

E. Issue a permanent Limited Exclusion Order specifically directed to each named Proposed Respondent and its subsidiaries and affiliates, pursuant to 19 U.S.C. § 1337(d), excluding from entry into the United States the Synthetically Produced Omega-3 Products through direct or indirect means;

F. Issue a permanent cease-and-desist order pursuant to 19 U.S.C. § 1337(f), prohibiting each Proposed Respondent and its subsidiaries and affiliates from directly or indirectly engaging in the importation, the use, the offering for sale, the sale after importation, or otherwise transferring within the United States, the Synthetically Produced Omega-3 Products;

G. Require Respondents to post a bond to secure Complainants' interests during any Presidential review of a Commission exclusion order; and

H. Issue such other and further relief as the Commission deems just and proper under the law, based upon the facts determined by the investigation and the authority of the Commission.

Respectfully submitted,

/s/Jeffrey M. Telep
Jeffrey M. Telep

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Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

Date: August 30, 2017

31013996.v6

UNITED STATES INTERNATIONAL TRADE COMMISSION

Investigation No. 337-TA- ___

In The Matter of	)
	)
Certain Synthetically Produced,	)
Predominantly EPA Omega-3	)
Products In Ethyl Ester Or	)
Re-esterified Triglyceride Form	)
	)

VERIFICATION OF COMPLAINT

I, Steven Ketchum, am Senior Vice President, President of Research and Development, and Chief Scientific Officer for Amarin Pharma, Inc., and am authorized to execute this verification on behalf of Complainants, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. I have read the Complaint and am aware of its contents. To the best of my knowledge, information, and belief and based upon reasonable inquiry under the circumstances, I hereby certify that

1. The allegations contained in the Complaint are well grounded in fact and have evidentiary support, or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery;

2. The claims and other legal contentions set forth in the Complaint are warranted by existing laws or by a good faith, non-frivolous argument for

extension, modification, or reversal of existing law, or by the establishment of new law; and

3. The Complaint is not being filed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

Dated: August 25, 2017

/s/Steven Ketchum
Steven Ketchum, Ph.D.
Senior Vice President, President of Research and Development, and Chief Scientific Officer Amarin Pharma, Inc.

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APPENDIX E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

OCT 06 2017

Hon. Lisa R. Barton
Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, DC 20436

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

[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

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.

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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.

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, 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

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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).

product must, among other things, contain one or more "dietary ingredients." 21 U.S.C. § 32l(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

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

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 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

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

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.

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]

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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.

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

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Cir. 2012) (finding that FDA Warning Letter was not final agency action).

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)].").

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

[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.

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) 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.

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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).

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.

Sincerely,

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

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[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.

/s/Rebecca K. Wood
Rebecca K. Wood
Chief Counsel
U.S. Food and Drug Administration

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[*Certificate of Service Omitted in the Printing of this Appendix*]