ADDUCI MASTRIANI & SCHAUMBERG LLP

DEANNA TANNER OKUN
Tel: (202) 407-8615 ▪ okun@adduci.com

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VIA ELECTRONIC FILING AND HAND DELIVERY

Honorable Rhonda K. Schmidtlein
Chairman
U.S. International Trade Commission
500 E Street, S.W., Suite 112
Washington, DC 20436

Re: Non-institution of Investigation Based on *Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form*, Docket No. 3247

Dear Chairman Schmidtlein:

We write on behalf of our client, the Council for Responsible Nutrition ("CRN"), to demonstrate why the Commission should not institute the investigation requested in the complaint filed by Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively, "Amarin") on August 30, 2017, *Certain Synthetically Produced, Predominantly EPA Omega-3 Products in Ethyl Ester or Re-esterified Triglyceride Form,* Docket No. 3247. CRN is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers.[1] CRN members produce a large portion of the dietary supplements marketed in the United States and globally,[2] including some the Omega-3 dietary supplements identified in Amarin's complaint. CRN submits that significant legal deficiencies in Amarin's complaint preclude institution of an investigation under Section 337, 19 U.S.C. § 1337, and the Commission Rules, 19 C.F.R. § 210 et seq.

Amarin's complaint is missing a critical factual allegation that is indispensable to its claims: Amarin has not alleged, because it cannot, that the Food and Drug Administration ("FDA") has determined that the Proposed Respondents' products are not "dietary supplements." Without this factual allegation, Amarin's two "unlawful and unfair acts of proposed respondents," as pled, are not cognizable under Section 337(a)(1)(A). Amarin's first claim is that the Proposed Respondents violate the Lanham Act through false or misleading representations of their products as "dietary supplements" under the Food, Drug and Cosmetic Act, 21 U.S.C. §

[1] https://www.crnusa.org/about-crn (last accessed Sept. 14, 2017).

[2] *Id.*

321(ff).[3] Compl., § VI.A, ¶ 53. Amarin's second claim is that the Proposed Respondents violate Section 337 "based on the standards set forth in the FDCA." Compl. § VI.B, ¶¶ 106-113. As both of Amarin's claims are tethered to an interpretation of the FDCA, finding a Section 337 violation will require a showing that it has been determined, as a matter of law, that the Proposed Respondents' representation of their products as "dietary supplements" violates the FDCA. Amarin's complaint concedes that such a determination, which can be made only by the FDA, has not been made. *See e.g.*, FDCA § 337(a) (reserving FDCA enforcement to the United States); *POM Wonderful LLC v. Coca-Cola Co.*, 134 S.Ct. 2228, 2231 (2014) ("The FDCA's enforcement is largely committed to the FDA . . ."); Compl. ¶¶ 19-20, 81-82. Absent an FDA determination establishing this critical fact, both of Amarin's claims are deficient and, consequently, its complaint is deficient.

CRN, therefore, requests that the Commission exercise its authority to reject Amarin's complaint for failing to comply with the Commission Rules and determine not to institute the requested investigation.

I. The FDA's Has Not Determined That the Proposed Respondents' Products are Not Dietary Supplements

The Proposed Respondents' products are concentrated Omega-3 fish oil products created from oil extracted from fish, i.e., common fish oil. These products are made by distilling and concentrating common fish oil, using ethanol through a process called esterification, to achieve a combined percentage of naturally-occurring eicosapentaenoic acid ("EPA") and docosahexaenoic acid ("DHA") exceeding 30% of the weight of the oil. Concentrated Omega-3 fish oil products, like those of the Proposed Respondents, are frequently used by healthy people to maintain and promote health, not to treat disease. The Global Organization for EPA and DHA Omega-3s ("GOED"), an organization Amarin cites as authoritative on the subject of Omega-3 products, provides a summary of the Global Recommendations for EPA and DHA Intake. Compl. ¶ 2; *see* Exhibit A, GOED Global Recommendations for EPA and DHA Intake (April 16, 2014). Those recommendations, provided by U.S. and other national and international organizations, suggest Omega-3 intake for "pregnant/lactating women," children and adults, and the "[g]eneral population." *Id.* at 1, 8-12 (listing the Institute of Medicine, the March of Dimes, the U.S. Departments of Agriculture and Health and Human Services, the Executive Office of the President, and the American Academy of Pediatrics as organizations recommending Omega-3 intake without a disease indication). Based on composition and use, among other things, the Proposed Respondents' concentrated Omega-3 fish oil products are properly classified as "dietary supplements" under FDCA § 321(ff).

Although Amarin concedes that the FDA has not determined that the Proposed Respondents' products are not "dietary supplements," Amarin suggests that this inaction is due

[3] Hereinafter, the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., is cited as the "FDCA."

to "limited resources" or a failure to "act[] to the full extent of [FDA's] authority." Compl. ¶¶ 19-20. Contrary to Amarin's allegations about FDA inaction (Compl. ¶¶ 19, 89), documents issued by the FDA indicate that it has evaluated whether concentrated Omega-3 products such as those of the Proposed Respondents are "dietary supplements" within the meaning of FDCA § 321(ff), and concluded that the Proposed Respondents' products meet its definition. In particular, the FDA's Revised Draft 2016 "Guidance for Industry" document (Compl. Ex. 31) indicates that the FDA considers esterification and the use of ethanol to be accepted chemical reactions that are commonly used in the production of dietary ingredients for use in dietary supplements. Compl. Ex. 31 at 25, 27, 100. And Amarin concedes that Respondents' products are created by "react[ion] with ethanol through a process known as esterification." Compl. ¶ 46. Accordingly, despite Amarin's claims that the Proposed Respondents' products are "synthetic" or produced by "chemical reaction," Amarin can point to no FDA determination that these products are something other than "dietary supplements" under FDCA § 321(ff). Compl. ¶¶ 45-46.

In addition, while pre-market approval is not required to advertise or sell "dietary supplements" under FDCA § 321(ff), Amarin acknowledges that the FDA has been aware of concentrated Omega-3 products being marketed as "dietary supplements" since the "late 1980s." Compl. ¶ 81. Amarin details enforcement efforts that confirm the FDA's knowledge of, and authority to proceed against, products masquerading as "dietary supplements" and Omega-3 products making unlawful drug claims. Compl. ¶¶ 67, 70, 81. Each of these instances demonstrates a case-by-case determination by the FDA. Moreover, the FDA asserted no objection in response to Unilever Marinol's and Twin Rivers' generally recognized as safe (GRAS) dietary ingredient petitions for use in concentrated Omega-3 supplement products.[4]

Amarin further acknowledges that, despite the FDA's awareness and authority to enforce the FDCA, the FDA has not excluded the Proposed Respondents' products from its definition of "dietary supplement," or determined that these products violate the standards of the FDCA. Compl. ¶¶ 81-82. Where approval is not required, but may be implied by inaction, the lack of FDA enforcement against the Proposed Respondents' for representing their products as "dietary supplements" suggests that the FDA disagrees with Amarin's proffered interpretation of the FDCA. *See infra*, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 926 (9th Cir. 2010) ("The issue was presented to the FDA, but it does not appear that the agency ever reached the conclusion sought by PhotoMedex.").

[4] See Twin Rivers GRAS Notice 200 (May 30, 2006), available at www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm263924.pdf (last accessed Sept. 14, 2017); Agency Response to Twin Rivers GRAS notice 200 (Nov. 24, 2006), available at www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154679.htm (last accessed Sept. 14, 2017); Unilever GRAS Notice 105 (Apr. 13, 2002), available at https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM260971 (last accessed Sept. 14, 2017); Agency Response to Unilever GRAS Notice 105 (Oct. 15, 2002), available at https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153913.htm (last accessed Sept. 14, 2017).

II. The Commission Should Not Institute an Investigation because Amarin's Complaint Does Not Comply with Commission Rule 210.12(a)(2)

The Commission has, where appropriate, declined to institute investigations where complaints, like Amarin's, fail to set forth factual allegations sufficient to state a cause of action under Section 337. *See Syntex Agribusiness, Inc. v. Int'l Trade Comm'n*, 659 F.2d 1038, 1044-1045 (C.C.P.A. 1981) (upholding Commission's determination not to institute an investigation based on a complaint that "disclose[d] no facts which show the alleged [unfair] acts"); *see also, Hydroxyprogesterone Caproate & Prods. Containing Same* ("*Hydroxyprogesterone Caproate*"), Docket No. 2919, Comm'n Correspondence (Dec. 21, 2012) (determining not to institute an investigation where the complaint did "not allege an unfair method of competition or an unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A)"). As set forth in more detail below, Amarin's complaint is deficient because it attempts to bootstrap alleged violations of the FDCA to create a cause of action under the Lanham Act and, in turn, Section 337. Amarin's request that the Commission institute the requested investigation fails to meet the Commission's requirements for a properly pled complaint and should, therefore, be rejected.

A. The Commission Is Not Required to Institute a Deficient Complaint

The Commission has the authority and discretion not to institute an investigation upon receiving a complaint, if that complaint fails to comply with its requirements. *See Dunlop v. Bachowski*, 95 S.Ct. 1851, 1860 (1975) (concluding Secretary of Labor had authority and discretion to determine if the prerequisites for taking statutorily mandated action were met, but lacked discretion not to act if those prerequisites were met); *Syntex Agribusiness*, 659 F.2d 1038 (C.C.P.A. 1981) (upholding determination not to institute deficiently pled claims). Although Section 337 provides that the Commission "shall investigate any alleged violation of this section on complaint," the Commission is authorized to adopt procedures, rules, and regulations for fulfilling that statutory mandate. *See* 19 U.S.C. §§ 1337(b)(1), 1335. The Commission has done so through Commission Rules 210.10(a)(1) and 210.12, which, respectively, require determination of "whether the complaint is properly filed and whether an investigation should be instituted," and define the contents required in a "complaint." Thus, Section 337 requires the Commission to institute an investigation ***only*** if a complaint includes each of the elements required by Commission Rule 210.12.

Commission Rule 210.12(a)(2) requires a complaint to "[i]Include a statement of the facts constituting the alleged unfair methods of competition and unfair acts." "Where the facts are insufficient or fail to constitute an unfair act, there is no reason to conduct an investigation." *Anhydrous Ammonia from Mexico* ("*Anhydrous Ammonia*"), Docket No. 891, GC-G-022, Mem., 1983 WL 207055, at *4 (Jan. 21, 1983) ("After examining 'facts constituting the alleged unfair methods of competition and unfair acts,' the Commission must ascertain whether the complaint states a claim under section 337. If it does not, the Commission should dismiss the complaint."). The Commission's decision not to institute an investigation based on a complaint that defectively pled an unfair method of competition or unfair act has been upheld on appellate review, by the

predecessor court to the Court of Appeals for the Federal Circuit. *Syntex Agribusiness,* 659 F.2d at 1044-1045 (denying petition for writ of mandamus to compel institution because the complaint "disclose[d] no facts which show the alleged [unfair] acts," rendering it "no more than a theory built on suppositions").

B. Amarin's Lanham Act Claim Is Deficient because Amarin Concedes There Has Been No Determination That the Proposed Respondents' Products Are Not "Dietary Supplements"

Amarin's Lanham Act claim of false advertising is not cognizable under Section 337 because Amarin has not alleged the critical fact underlying the Complaint—that the FDA has determined that proposed Respondents' products are not "dietary supplements" under the FDCA. *See PhotoMedex*, 601 F.3d at 928 ("PhotoMedex is not permitted to circumvent the FDA's exclusive enforcement authority by seeking to prove that Defendants violated the FDCA, when the FDA did not reach that conclusion."). Consequently, the Complaint does not allege an actionable Lanham Act claim and should be rejected.

1. Lanham Act Claims Like Amarin's Have Been Rejected

As Amarin recognizes, the first element of false advertising under the Lanham Act is "a false or misleading statement of fact is being made by the defendant about a product." Compl. ¶ 55. There can be no "false or misleading statement of fact" in the advertisement of the Proposed Respondents' products as "dietary supplements" until it is determined by the FDA that their products are not "dietary supplements" under FDCA § 321(ff)(1). In similar circumstances, multiple circuit courts have held that a court cannot adjudicate a Lanham Act claim based on an FDCA violation absent a legal determination by the FDA that the underlying violation exists. *See PhotoMedex, Inc.*, 601 F.3d at 930 ("To permit PhotoMedex to proceed with a claim that Defendants violated [the FDCA] when the FDA did not so determine would, in effect, permit PhotoMedex to assume enforcement power which the statute does not allow and require the finder of fact to make a decision that the FDA itself did not make."); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 510, 513 (7th Cir. 2009) ("Schering jumped the gun by suing before the FDA addressed the misbranding issue;" "Schering cannot just intone "literal falsity" and by doing so prove a violation of the Lanham Act."); *Cottrell, Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1254-1255 (10th Cir. 1999) (adopting district court's framework for dismissing a Lanham Act claim, where "the issue of whether the defendants' product's claim to be a 'dietary supplement' was false or misleading involved interpretation and application of the FDA definition of 'dietary supplement,'" to reject a claim based on violation of Environmental Protection Agency standards); *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231, 232 (3rd Cir. 1990) (declining "to find, either 'as a matter of common sense' or 'normal English,' that which the FDA, with all of its scientific expertise, has yet to determine;" "[T]he issue of whether an ingredient is properly labeled . . . under FDA standards is not properly decided as an original matter by a district court in a Lanham Act case.").

The most recent of these circuit court cases, *PhotoMedex*, is directly on point. Though an affirmative statement of FDA approval was not required, PhotoMedex, like Amarin, alleged that failure to obtain approval amounted to a misrepresentation that the "product had received FDA clearance, when the FDA declined to make a finding that there was no valid clearance or to bring an enforcement action itself." *PhotoMedex*, 601 F.3d at 922. The Ninth Circuit explained that while a Lanham Act claim can be brought based on an FDCA violation, it "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. Here, Amarin's request that the Commission make a legal determination under the FDCA is precluded by statute and case law, and does not amount to a properly pled fact, as required by Commission Rule 210.12(a)(2). *See id.* Even more recently, a district court found a Lanham Act claim nearly identical to Amarin's was precluded by the FDCA because "to determine the falsity or misleading nature of the representation" of the products at issue as 'dietary supplements,' instead of as 'new drugs,' the court would be required to interpret and apply FDCA statutory regulatory provisions." *Hi-Tech Pharm., Inc. v. Hodges Consulting, Inc.*, 230 F.Supp.3d 1323, 1330 (N.D. Ga. 2016) (citing *POM Wonderful*, 134 S.Ct. at 2238 and concluding that where the FDA had not had "an opportunity to determine whether [a product] is a new drug or a prescription drug, [ ] it is inappropriate for the Court to make those determinations in place of the FDA").

In addition to failing to allege any facts showing conflict between the FDA's enforcement of the definition of "dietary supplement" and the Proposed Respondents' advertisements, Amarin's convoluted legal arguments conflict with the FDA's regulations, guidance, and actions. *See supra* at Sec. I. Amarin's allegations as to the first element of its false advertising claim, therefore, amount to mere statements of law or opinion, "no more than a theory built on suppositions" about how the FDA and the Commission should interpret the FDCA. *Syntex Agribusiness*, 659 F.2d at 1044. In circumstances such as these, where the information available to the Commission suggests facts contrary to claims made in a complaint, the Commission has refused to institute an investigation. *See Anhydrous Ammonia*, 1983 WL 207055, at *5 (citing data showing respondents small market share as establishing that "there is no meaningful factual basis" for the complaint's monopoly claim, and providing a recommendation against institution). The Commission should, similarly, refuse to institute the requested investigation because the complaint lacks the factual allegations necessary to support a false advertising claim and alleges no "legally cognizable 'unfairness'" nor any "unfair method of competition or an unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A)." *Certain Bearings & Packaging Thereof*, Inv. No. 337-TA-469, Comm'n Order at 3 (Sept. 23, 2002).

2. *POM Wonderful* and Recent Investigations Do Not Support Institution Here

Amarin argues that the Supreme Court's decision in *POM Wonderful* supports instituting the requested investigation. *See* Compl. Ex. 30. It does not. The Court's holding in *POM*

Wonderful confirms that the regulatory framework of the FDCA and the Lanham Act are complementary, and that a judiciable Lanham Act claim for unfair competition can co-exist with FDA regulations allowing the conduct alleged to be unfair. *POM Wonderful*, 134 S.Ct. at 2238-2239. But *POM Wonderful* was not based on any legal interpretation of the FDCA; to the contrary, in *POM*, the parties conceded that the label in question was appropriate under the FDA's food labeling regulations. *Id.* at 2234-35. Here, in direct contrast, Amarin's claims turn entirely on interpretation of the FDCA.

Thus, while the Commission can exercise jurisdiction over a properly pled Lanham Act claim, despite FDA regulations that allow the alleged unfair act, nothing in *POM Wonderful* changed the pleading requirements to state a claim under the Lanham Act (or Section 337). *POM Wonderful* therefore fails to create a pathway to institution for Amarin. Rather, *POM Wonderful* emphasizes the deficiency in Amarin's complaint because POM's claim included the factual allegations necessary to state its false advertising claim. The Supreme Court specifically noted that POM's false advertising claim was based on the established and undisputed fact that Coca-Cola's product contained only 0.3% pomegranate juice and 0.2% blueberry juice. *POM Wonderful*, 134 S.Ct. at 2235. Based on this factual allegation, "POM alleged that the name, label, marketing, and advertising of Coca–Cola's juice blend mislead consumers into believing the product consists predominantly of pomegranate and blueberry juice ***when it in fact*** consists predominantly of less expensive apple and grape juices." *Id.* (emphasis added). Contrary to Amarin's pleas, *POM Wonderful* supports rejection of Amarin's Lanham Act claim.

Amarin may also argue that the Commission's institution of the requested investigations in *Certain Potassium Chloride Powder Products*, Inv. No. 337-TA-1013, and *Certain Periodontal Laser Devices*, Inv. No. 337-TA-1070 supports institution here. That argument, too, fails because those investigations were instituted based on complaints that included factual allegations supporting each element of the Lanham Act claims alleged therein. In *Potassium Chloride Powder Products*, the complaint alleged false advertising because the complaint alleged that respondents packaged their products to look like drugs and advertised them as comparable to complainants' drugs, as generic versions of approved drugs, and as "follow[ing] strict FDA guidelines and operating procedures." *Potassium Chloride Powder Prods.*, Inv. No. 337-TA-1013, Compl. ¶¶ 2, 4-6, 30-33, 35, 51 (June 15, 2016). To support its Lanham Act allegation, the complaint alleged that Respondents' products were not listed as FDA approved drugs or FDA approved generic drugs, thereby alleging facts necessary to determine whether respondents' advertisements were false or misleading. *See e.g.*, *id.* at 16-21, 31, 33, 35. Similarly, in *Periodontal Laser Devices*, the complaint alleged that respondents advertised their products as comparable to complainants' FDA approved devices and included factual allegations showing that respondents' products were not affirmatively FDA approved like complainants', thus establishing a factual basis for determining whether respondents' advertisements were false or misleading. *Periodontal Laser Devices*, Inv. No. 337-TA-1070, Compl. at ¶¶ 3-6, 22-23, 26-28 (Aug. 10, 2017). Here, Amarin's complaint fails to allege the necessary factual basis for determining whether the Proposed Respondents' advertisements are false or misleading: Amarin's complaint does not, because it cannot, include factual allegations that the FDA has

determined that the Proposed Respondents' products are not "dietary supplements" under the FDCA.

Instead of properly pleading the requisite facts, Amarin's complaint requests that the Commission make a conclusion of law—one that is the FDA's conclusion to make—to create a factual basis for its Lanham Act claim. Amarin then accuses the Proposed Respondents of making statements that are false or misleading because they conflict with Amarin's preferred (and erroneous) interpretation of the FDCA. That improper request for a legal determination under the FDCA does not properly allege a Lanham Act violation and, therefore, Amarin's complaint fails to meet the requirements in Commission Rule 210.12(a)(2).

C. Amarin's Claim Based on "Standards Set Forth in the FDCA" Is Not Actionable under Section 337

Amarin's second claim, which is based on violation of "standards set forth in the FDCA[,]"does not allege an unfair method of competition or an unfair act cognizable under Section 337 and should, therefore, be rejected. This claim is not based on a private cause of action available to Amarin, an unfair curtailment of Amarin's rights, or any law of unfair competition. *See e.g., Certain Bearings & Packaging Thereof*, Comm'n Order at 4 ("The cases do not establish a cause of action based on free riding. Moreover, the courts have not extended the law of unfair competition to encompass free riding generally"). Instead, Amarin's second claim is nearly identical to the claim in the *Hydroxyprogesterone Caproate*, which alleged a Section 337 violation based on the complainant's belief, without factual support from an FDA determination, that respondents were violating FDCA drug compounding laws. *Hydroxyprogesterone Caproate*, Comm'n Correspondence. As the Commission correctly determined the FDCA violation in *Hydroxyprogesterone Caproate* was not actionable under Section 337, Amarin's second claim also fails to allege sufficient factual or legal bases for finding an FDCA violation remediable as unfair competition, and the Commission should again determine not to institute an investigation.

First and foremost, Amarin's allegations under its second count fail to state a claim upon which relief can be granted because the FDCA authorizes no private cause of action. *See* FDCA § 337(a) (reserving proceedings to "enforce[], or to restrain violations," of the FDCA to the United States). Amarin appears to recognize that the appropriate recourse for a violation of the FDCA is enforcement by the FDA and that, in certain circumstances, a district court may compel FDA enforcement. *See e.g.*, Compl. ¶ 67 ("[W]hen purported 'dietary supplements' have contained a synthetic ingredient that is not common in conventional foods, FDA has taken action."), ¶ 113 ("If FDA finds an apparent FDCA violation . . . , it must refuse the drug admission to the United States;" citing *Cook v. FDA*, 733 F.3d 1, 10 (D.C. Cir. 2013)). Despite recognizing the available procedures for remedying an FDCA violation, Amarin's complaint nonetheless makes conclusory assertions that the Commission has jurisdiction to enforce standards in the FDCA. *See* Compl. ¶¶ 19- 20; Compl. Ex. 30 at 11-24.

In addition, Amarin's claim based on the Proposed Respondents' purported violation of standards in the FDCA fails to allege a legally cognizable violation and fails to even make appropriate allegations that such a violation is encompassed by the law of unfair competition. While Section 337 is broad, "for the Commission to find that conduct involves an unfair method of competition or unfair act, it must be able to identify some sort of *legally cognizable* 'unfairness' in that conduct." *Certain Bearings & Packaging Thereof*, Comm'n Order at 3 ("[Complainant's] unfair pecuniary benefits claim does not allege the requisite legally cognizable unfairness."); *Causes of Action under Section 337*, GC-G-243, Mem., 1983 WL 206913, at *1 (Sept. 30, 1983) (advising that "the Commission cannot deviate too far from what the courts have found actionable [as 'unfair'] under statutory or common law" due to treaty obligations). The Commission has therefore declined to institute an investigation where a complaint failed to allege a legally cognizable unfair method of competition or unfair act. *See Hydroxyprogesterone Caproate*Comm'n Correspondence (finding complaint based on violation of the FDCA drug compounding laws did "not allege an unfair method of competition or an unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A)," and declining to institute investigation); *Syntex Agribusiness*, 659 F.2d at 1042 (quoting the Commission's reasoning against instituting an investigation where the complaint "'did not provide an adequate factual basis for its conspiracy and monopoly claims, and therefore was not properly filed within the meaning of the applicable rules'"); *Anhydrous Ammonia*, 1983 WL 207055, at ** 4-5, 12-13 (recommending the Commission decline to institute an investigation because the facts alleged in the complaint failed to establish claims of "cost-price squeeze" or "illegal price discrimination").

Amarin's position that Section 337 authorizes the Commission to investigate and remedy any conduct a complainant perceives as unfair would lead to an unbounded expansion of Section 337 and disregard for the statutory authority reserved to other agencies. Under Amarin's interpretation of "unfair method of competition or unfair acts," the Commission would have to investigate allegations that a respondent benefitted from violating, for example, consumer safety laws, traffic laws, environmental emissions standards, or international treaties, even if the governing law does not allow private enforcement and the alleged violation does not result in unfairness to the complainant. Such a broad construction of "unfairness" would lead to an unreasonable exercise of Commission authority, and render the Commission's pre-institution gatekeeping authority meaningless.

As in *Hydroxyprogesterone Caproate*, Amarin's claim based on violation of FDCA standards does not allege an actionable unfair act under Section 337 and does not comply with Commission Rule 210.12(a)(2). The Commission should therefore exercise its authority and determine not to institute an investigation based on a defective complaint.

III. The Commission Cannot Enforce the FDCA to Create a Factual Basis for Amarin's Claims

Amarin may argue that the Commission has the authority to interpret the FDCA to establish the necessary "facts" needed to support its complaint. This argument fails. Without

express statutory authority permitting such a broad exercise of jurisdiction, the Commission cannot step into its sister agencies' shoes and adjudicate those agencies' regulations. *See Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1355 (Fed. Cir. 2008) ("The ITC is a creature of statute, and must find authority for its actions in its enabling statute.")

Here, only the FDA is authorized to "enforce[], or restrain violations," of the FDCA, and the FDA has provided no indication that it considers the Proposed Respondents' products to violate its laws. *See e.g.*, FDCA §§ 337(a), 372 (authorizing the FDA to coordinate with other agencies through a memorandum of understanding)[5], 393(a) (establishing the FDA to enforce the FDCA); Compl. Exhibit 28 at 1 ("[T]he [FDA] will exercise primary jurisdiction over all matters regulating the labeling of foods, drugs, devices, and cosmetics."); Compl. ¶ 20 ("FDA has primary responsibility for policing the 'labeling' of 'dietary supplements' . . . "). The FDA's guidance documents suggest that the FDA *has* considered whether products like those of the Proposed Respondents are "dietary supplements" within the meaning of FDCA § 321(ff)(1), but has yet to reach a final legal determination on this issue. *See supra* at Sec. I (discussing Compl. Ex. 31, 2016 FDA Guidance). In similar circumstances, the district court in *Schering-Plough* dismissed a plaintiff's Lanham Act claim, and was affirmed by the Seventh Circuit, "because the FDA has not yet made a final determination regarding these marketing and labeling issues, and because Schering-Plough's Lanham Act claim would require this court to 'determine preemptively how a federal agency will interpret and enforce its own regulations' . . ." *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 547 F.Supp.2d 939, 947 (E.D. Wis. 2009), *aff'd*, 586 F.3d 500 (7th Cir. 2009). To reach a contrary result, as Amarin requests, the Commission would not only exceed its mandate and encroach on the FDA's, but it would create the potential for inconsistent results that would adversely impact other Federal and state agencies, law enforcement, and consumers. And this is particularly true here, where FDA guidance suggests a determination that the Proposed Respondents' products are "dietary supplements" under the FDCA. *See supra* at Sec. I. If Amarin believes the FDA is not following its mandate, its recourse is with the FDA or with a district court empowered to compel the FDA to act. *See e.g., Weinberger v. Bentex Pharm., Inc.*, 93 S.Ct. 2488, 2494 (1973) (approving district court's referral of the determination of whether products were a "new drug" under the FDCA to the FDA); *Cook*, 733 F.3d at 12 (affirming district court's injunction and notification order to the FDA); *Schering-Plough*, 547 F.Supp.2d at 947 ("Schering-Plough is free to petition the FDA to resolve the alleged labeling violations.").

The Commission and several other jurisdictions have previously declined to adjudicate claims that would force them to encroach on the FDA's, or other agencies', administration of their laws. *See Hydroxyprogesterone Caproate*, Comm'n Correspondence ("[T]he [FDA] is charged with the administration of the [FDCA]."); *Syntex Agribusiness*, 659 F.2d at 1040 (summarizing the Commission's referral claims within the purview of the Treasury Department

[5] While the Complaint references the Memorandum of Understanding between the FDA and the Federal Trade Commission, it does not allege that there is a similar memorandum of understanding between the FDA and the Commission. Compl. ¶ 20, Compl. Ex. 28.

and defending its determination not institute an investigation); *Certain Bearings & Packaging Thereof*, Comm'n Order at 4 (concluding complaint's claim concerned application of antidumping duty deposit rates and assessment rates and fell "within Commerce's jurisdiction"); *see also, supra* at Sec. II.B. The Commission's practice of deference when a legal determination, within the jurisdiction of another agency, stands between a complaint's inadequate allegations and conduct actionable under Section 337 has been upheld. *See Syntex Agribusiness, Inc.*, 659 F.2d at 1045.

The Commission should, therefore, defer to the FDA to determine whether the Proposed Respondents' products violate the FDCA. If the FDA, in its proper role, determines as a legal matter that Amarin's interpretation of the FDCA and its regulations is correct, Amarin may at that point have a viable claim under Section 337. Absent that determination, however, Amarin's complaint fails to state a claim under Section 337 and institution of an investigation would be inappropriate.

IV. If an Investigation is Instituted, the Commission Should First Resolve Whether Amarin Can Prove a Section 337 Violation Absent an FDA Determination

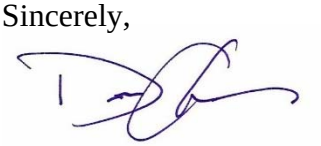
If the Commission determines to institute the requested investigation, it should direct the presiding Administrative Law Judge to first resolve the legal question of whether the Proposed Respondents can be found in violation of Section 337 based on FDCA violations, where the FDA has found no such violation. *See Certain Audio Processing Hardware & Software & Prods. Containing Same*, Inv. No. 337-TA-949, Comm'n Not. at 2 (Mar. 12, 2015) (ordering the ALJ to "hold an early evidentiary hearing, find facts, and issue an early decision, as to whether the complainant has standing to assert each of the asserted patent . . . in the form of an initial determination"); *Certain Incremental Dental Positioning Adjustment Appliances & Methods of Producing Same*, Inv. No. 337-TA-562 (Enforcement), Comm'n Not. at 2 (Apr. 25, 2012) ("[T]he presiding administrative law judge may wish to consider [whether digital datasets are within the scope of the consent order] at an early date. Any such decision should be issued in the form of an initial determination . . ."); *Certain Sucralose, Sweeteners Containing Sucralose, & Related Intermediate Compounds Thereof*, Inv. No. 337-TA-604, Comm'n Not. at 2 (May 7, 2007) ("[T]he presiding administrative law judge may wish to consider these fundamental issues at an early date. Any such decision should be issued in the form of an initial determination . . ."). Resolution of this issue is potentially case dispositive: if an FDA determination that the Proposed Respondents' products are not "dietary supplements" is indispensable to Amarin's claims, then the absence of such a determination mandates finding no violation of Section 337(a)(1)(A). Resolving this issue early in the investigation, if it is instituted, would preserve public and private party resources, and provide certainty to the public and potential litigants regarding the viability of claims like Amarin's.

V. Conclusion

The factual allegations contained in Amarin's complaint fail to allege an unfair method of competition or unfair act as required by Section 337(a)(1)(A) and Commission Rule 210.12(a)(2). Without factual allegations that the FDA has determined that the Proposed Respondents' products are not "dietary supplements" under the FDCA, there can be no "fact" that the Proposed Respondents could have falsely or misleadingly stated, and there can be no violation of FDCA standards. Consequently, Amarin's complaint does not satisfy the Commission's requirements, and the Commission should determine not to institute an investigation.

If, however, the Commission determines to institute an investigation, it should order an early determination of whether the Proposed Respondents can be found in violation of Section 337 based on FDCA violations where the FDA has found no such violation.

Sincerely,



Deanna Tanner Okun

Enclosure: As stated

EXHIBIT A

Global Recommendations for EPA and DHA Intake (Rev 16 April 2014)

Country/Region	Organization	Org. Type	Target Population	Recommendation
Global	World Health Organization (WHO)[1]	Authoritative Body	General adult population	▪ n-3 PUFAs: 1-2% of energy/day
	Food and Agriculture Organization of the United Nations (FAO)[2]	Authoritative Body	0-6 months	▪ DHA: 0.1-.018%E
			6-24 months	▪ DHA: 10-12 mg/kg bw
			2-4 years	▪ EPA + DHA: 100-150 mg
			4-6 years	▪ EPA + DHA: 150-200 mg
			6-10 years	▪ EPA + DHA: 200-250 mg
			Pregnant/Lactating Women	▪ EPA + DHA: 0.3 g/d of which at least should be 0.2 g/d
	International Society for the Study of Fatty Acids and Lipids (ISSFAL)	Expert Scientific Organization	General adult population for cardiovascular health[3]	▪ at least 500 mg/day of EPA+DHA
			Pregnant/Lactating Women[4]	▪ DHA: 200 mg/day
	NATO Workshop on ω-3 and ω-6 Fatty Acids[5]	Workshop	General Adult Population	▪ 300-400 mg EPA+DHA/day
	World Association of Perinatal Medicine[6]	Working Group	Pregnant and Lactating Women	▪ 200 mg DHA/ day
			Infants, when breastfeeding is not possible	▪ 0.2-0.5% wt total fat
	World Gastroenterology Organisation[7]	Expert Scientific Organization	General Adult Population	▪ 3-5 servings/wk of fish
Australia	National Heart Foundation of Australia[8]	Expert Scientific Organization	General adult population to lower risk of CHD	▪ 500 mg EPA + DHA per day, obtained through fish, fish oil capsules, or enriched foods & drinks
			Patients with documented CHD	▪ 1000 mg EPA + DHA per day, obtained through fish, fish oil capsules, or enriched foods & drinks
			Patients with hypertriglyceridemia	▪ 1200mg of EPA + DHA per day, obtained through fish, fish oil

Country/Region	Organization	Org. Type	Target Population	Recommendation
				capsules or enriched foods & drinks as first-line therapy ▪ Increase to 4000 mg of EPA +DHA per day, as needed.
	Australian & New Zealand Health Authorities (Department of Health & Ageing, National Health & Medical Research Council)[9]	Authoritative Bodies	Infants (0-12 mo)	▪ 0.5 g n-3 polyunsaturated fats/day adequate intake
			Boys & Girls (1-3 yrs)	▪ 40 mg total LC n-3 (DHA+EPA+DPA) / day adequate intake
			Boys & Girls (4-8 yrs)	▪ 55 mg total LC n-3 (DHA+EPA+DPA) / day adequate intake
			Boys & Girls (9-13 yrs)	▪ 70 mg total LC n-3 (DHA+EPA+DPA) / day adequate intake
			Boys (14-18 yrs)	▪ 125 mg total LC n-3 (DHA+EPA+DPA) / day adequate intake
			Girls (14-18 yrs)	▪ 85 mg total LC n-3 (DHA+EPA+DPA) / day adequate intake
			Men (19+ yrs)	▪ 160 mg total LC n-3 (DHA+EPA+DPA) per day adequate intake
			Women (19+ yrs)	▪ 90 mg total LC n-3 (DHA+EPA+DPA) / day adequate intake
			Pregnancy (14 -18 yrs)	▪ 110 mg total LC n-3 (DHA+EPA+DPA) / day
			Pregnancy (19-50 yrs)	▪ 115 mg total LC n-3 (DHA+EPA+DPA) / day
			Lactating (14-18 yrs)	▪ 140 mg LC n-3 (DHA+EPA+DPA) / day

Country/Region	Organization	Org. Type	Target Population	Recommendation
			Lactating (19-50 yrs)	▪ 145 mg LC n-3 (DHA+EPA+DPA) / day
			Men-Suggested dietary target to reduce chronic disease risk	▪ 610mg LC n-3 (DHA+EPA+DPA) / day
			Women-Suggested dietary target to reduce chronic disease risk	▪ 430mg LC n-3 (DHA+EPA+DPA) / day
	Defence Science and Technology Organisation, Australian Government Department of Defence[10]	Authoritative Body	Male soldiers	▪ 610mg EPA+DPA+DHA/ day
			Female soldiers	▪ 430mg EPA+DPA+DHA / day
Europe	Expert Workshop of the European Academy of Nutritional Sciences[11]	Expert Scientific Organization	General Adult Population	▪ People who do not eat fish should consider obtaining 200 mg EPA + DHA from other sources
	European Food Safety Authority[12]	Authoritative Body	General Adult Population	▪ 250mg EPA+DHA /day
			Pregnant & Lactating Women	▪ 100-200 mg DHA / day in addition to general adult requirements
			Children 7-24 months	▪ 100 mg DHA / day
			Children 2-18 years	▪ 250mg EPA+DHA /day
	The PeriLip and EARNEST projects of the European Commission[4]	Expert Scientific Organization	Pregnant & Lactating Women	▪ 200mg DHA/day
	Fifth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice (constituted by representatives of nine societies and by invited experts)[13]	Expert Scientific Organization	General Adult Population for Cardiovascular Disease Risk Reduction	▪ Fish at least twice a week, one of which to be oily fish.
	Task Force on	Expert		• Increase consumption of omega-

Country/Region	Organization	Org. Type	Target Population	Recommendation
	the Management of ST-Segment Elevation Acute Myocardial Infarction of the European Society of Cardiology[14]	Scientific Organization		3 fatty acid (oily fish) • Supplementation with 1 g of fish oil in patients with a low intake of oily fish ▪ omega-3 supplements should be considered in patients who do not tolerate statins, especially if TG >150 mg/dL (1.7 mmol/L)
	Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS)[15]	Expert Scientific Organization	General Adult Population for Cardiovascular Disease Risk Reduction	▪ At least two or three portions of fish per week
			Secondary prevention of CVD	▪ 1 g/day n-3 unsaturated fats, which is not easy to derive exclusively from natural food sources, and use of nutraceutical and/or pharmacological supplements may be considered
France	AFFSA[16]	Authoritative Body	General Adult Population	▪ 500 mg EPA + DHA / day ▪ 250 mg EPA / day ▪ 250 mg DHA / day
			Metabolic Syndrome-Diabetes-Obesity Risk Reduction	▪ 500 mg EPA + DHA / day
			Cardiovascular Risk Reduction	▪ 500-750 mg EPA + DHA / day
			Breast & Colon Cancer Risk Reduction	▪ 500 mg EPA + DHA / day
			Neuropsychiatric Risk Reduction	▪ >200-300 mg EPA + DHA / day
			Age-Related Macular Degeneration Risk Reduction	▪ 500 mg EPA + DHA / day
			Infants (0-6 months)	▪ 0.32% of fats from DHA ▪ EPA < DHA

Country/Region	Organization	Org. Type	Target Population	Recommendation
			Infants & Toddlers (6 months to 3 years)	▪ 70mg DHA /day
			Children (3-9 years)	▪ 125mg DHA /day ▪ 250mg EPA+DHA /day
			Adolescents (9 to 18 years)	▪ 250mg DHA /day ▪ 250mg EPA+DHA /day
			Pregnant & Lactating Women	▪ 250mg DHA /day ▪ 250mg EPA+DHA day
Austria	Austrian Society for Nutrition[17]	Expert Scientific Organization	General adult population	▪ 250mg LCPUFA / day for primary prevention of CVD
			General adult population	▪ 0.5% of energy total n-3 PUFA intake
			CHD Patients	▪ 1g LCPUFA / day for secondary prevention of CVD
			Pregnant & nursing women	▪ At least 200mg DHA / day
Germany	German Society for Nutrition[17]	Expert Scientific Organization	General adult population	▪ 250mg LCPUFA / day for primary prevention of CVD
			General adult population	▪ 0.5% of energy total n-3 PUFA intake
			CHD Patients	▪ 1g LCPUFA / day for secondary prevention of CVD
			Pregnant & nursing women	▪ At least 200mg DHA / day
	Healthy Start - Young Family Network[25, 45, 57]	Expert Scientific Organization	Pregnant women	• to supply the recommended 200mg/day of DHA, consume 2 servings/wk of marine fish, including at least one serving of fatty sea fish (such as mackerel, Herring, sardines, salmon) ▪ pregnant women who do not regularly consume fish, the use of supplements with the Omega-3 fatty acid DHA is recommended
Switzerland	Swiss Society for Nutrition Research	Expert	General adult population	▪ 250mg LCPUFA / day for primary

Country/Region	Organization	Org. Type	Target Population	Recommendation
	/ Swiss Nutrition Association[17]	Scientific Organization		prevention of CVD
			General adult population	▪ 0.5% of energy total n-3 PUFA intake
			CHD Patients	▪ 1g LCPUFA / day for secondary prevention of CVD
			Pregnant & nursing women	▪ At least 200mg DHA / day
Belgium	Superior Health Council of Belgium[18]	Authoritative Body	Pregnant & nursing women	▪ 250mg DHA / day
			General adult population (primary cardioprevention)	▪ Two servings of fatty fish/wk
			secondary cardioprevention	▪ 1g EPA+DHA per day
Netherlands	Health Council of the Netherlands	Authoritative Body	0-5 months[19]	▪ ▪ DHA: 20 mg/kg/day
			6-11 months[19]	▪ N-3 fatty acids from fish: 15-20 mg/kg/day
			1-18 years old[19]	▪ N-3 fatty acids from fish: 15-20 mg/kg/day
			19 years +[19]	▪ N-3 fatty acids from fish: 20 mg/kg/day
			Pregnant women[19]	▪ N-3 fatty acids from fish: 20 mg/kg/day
			Lactating women[19]	▪ N-3 fatty acids form fish: 20 mg/kg/day
			Adults[20]	• n-3 fatty acids from fish: 450 mg/day
Scandinavia	Nordic Council of Ministers[21]	Authoritative Body	6-11 months	▪ n-3 fatty acids should contribute at least 1 E%
			12-23 months	▪ n-3 fatty acids should contribute at least 0.5 E%
			Adults and children from 2 yrs of age	▪ n-3 fatty acids should contribute at least 1.0 E%
			Pregnant & Lactating Women	▪ 1 E% from n-3 fatty acids of which 200 mg/d should be DHA
United Kingdom	British Nutrition Foundation[22]	Expert	Adults, 19-50 yrs	▪ one to two portions of oil-rich

Country/Region	Organization	Org. Type	Target Population	Recommendation
		Scientific Organization		fish per week, which will provide around 2-3g of the very long chain *n-3* fatty acids ▪ weekly intake of 1.5g of EPA + DHA
	Committee on Medical Aspects of Food Policy (COMA)[23]	Authoritative Body	Adults	▪ at least two portions of fish, of which one should be oily, weekly ▪ n-3 PUFA intake: 0.2 g/day
	Scientific Advisory Committee on Nutrition (SACN)[24]	Authoritative Body	Adults	▪ at least two portions of fish, of which one should be oily, weekly ▪ n-3 PUFA intake: 0.45 g/day
	National Institute for Health and Clinical Excellence (May 2008)[26]	Authoritative Body	People at high risk of or with CVD	▪ consume at least two portions of fish per week, including a portion of oily fish
	Joint British Societies[27]	Expert Scientific Organization	General Adult Population	▪ Regular intake of fish and other sources of omega 3 fatty acids (at least two servings of fish per week)
	Irish Heart Foundation[54]	Expert Scientific Organization	General Adult Population	▪ 200 mg/day long-chain fatty acids
	National Collaborating Center for Primary Care[28]	Expert Scientific Organization	General Adult Population	▪ At least two servings of omega-3 fatty acid containing fish per week
			People with Established CVD	▪ At least two servings of omega-3 fatty acid containing fish per week week)
Italy	Italian Ministry of Health[52]	Authoritative Body	Pregnant and Nursing Women	▪ Vegan women should consume foods rich in DHA
Spain	Spanish Society of Intensive Care Medicine and Coronary Units and Spanish Society of Parenteral and Enteral Nutrition[29]	Expert Scientific Organization	Individuals with acute coronary syndrome and patients with chronic heart failure	▪ Administration of 1 g/day of omega-3 (EPA+DHA) in the form of fish oil can prevent sudden death in the treatment of acute

Country/Region	Organization	Org. Type	Target Population	Recommendation
				coronary syndrome and can also help to reduce hospital admission for cardiovascular events in patients with chronic heart failure
	Spanish Society of Intensive Care Medicine and Coronary Units and Spanish Society of Parenteral and Enteral Nutrition[30]	Expert Scientific Organization	patients with acute lung injury (ALI) or acute respiratory distress syndrome (ARDS)	▪ An enteral diet enriched with ω-3 diet fatty acids may have a beneficial effects
Brazil	Brazilian Society of Cardiology[31]	Expert Scientific Organization	Patients with coronary artery disease	▪ supplementation of 1 g / day of omega-3 (EPA + DHA) capsules
United States	Institute of Medicine[32]	Authoritative Body	Boys & Girls 1-3 yrs	▪ ALA: 0.7 g/day of which ~ 10% EPA+DHA
			Boys & Girls 4-8 yrs	▪ ALA: 0.9 g/day of which ~ 10% EPA+DHA
			Boys 9-13 yrs	▪ ALA: 1.2 g/day of which ~ 10% EPA+DHA
			Boys 14-18 yrs	▪ ALA: 1.6 g/day of which ~ 10% EPA+DHA
			Girls 9-13 yrs	▪ ALA: 1.0 g/day of which ~ 10% EPA+DHA
			Girls 14-18 yrs	▪ ALA: 1.1 g/day of which ~ 10% EPA+DHA
			Adult men ≥ 19 yrs	▪ ALA: 1.6 g/day of which ~ 10% EPA+DHA
			Adult women ≥ 19 yrs	▪ ALA: 1.1 g/day of which ~ 10% EPA+DHA
	American Diabetes Association[55]	Expert Scientific Organization	Individuals with diabetes	Eat fish (particularly fatty fish) at least two times (two servings) per week.

Country/Region	Organization	Org. Type	Target Population	Recommendation
	Academy of Nutrition and Dietetics (formerly American Dietetics Association)	Expert Scientific Organization	General Adult Population[56]	▪ 500 mg EPA+DHA per day
			Varied[53]	Those with increased requirements (e.g., pregnant and lactating women or those with diseases associated with poor essential fatty acid status) or those at risk for poor conversion (e.g., people with diabetes) may benefit from direct sources of long-chain n-3 fatty acids, such as DHA-rich microalgae
	March of Dimes[34]	Expert Scientific Organization	Pregnant and Nursing Women	▪ 200 mg DHA/day
	National Heart, Lung, and Blood Institute, National Cholesterol Education Program[35]	Authoritative Body	Persons with CHD or multiple risk factors for CHD	▪ Supported AHA recommendation to include fish as part of a CHD risk reduction diet. Higher dietary intakes of n-3 PUFAs are an option for reducing CHD risk
	Omega-3 Fatty Acids Subcommittee, assembled by the Committee on Research on Psychiatric Treatments of the American Psychiatric Association (APA)[36]	Expert Scientific Organization	Adults	▪ Eat fish >/= 2X/wk
			Patients with mood, impulse control, or psychotic disorders	▪ 1 g EPA + DHA / day
	American Heart Association	Expert Scientific Organization	All adults without CHD[37]	▪ Eat fish (particularly fatty fish) at least two times a week; include oils and foods rich in ALA
			General adult population[58]	▪ Fish with 500 mg or more of EPA+DHA per 85 g (3 oz cooked) can apply for the AHA Heart-Check food certification program at heartcheckmark.org.
			Patients with CHD[37]	▪ Consume approximately 1 g/day of EPA+DHA preferably from oily

Country/Region	Organization	Org. Type	Target Population	Recommendation
				fish. EPA+DHA supplements could be considered in consultation with the physician
			Patients with high triglycerides[37]	▪ 2-4 g/day EPA+DHA as capsules under a physician's care
			Patients with high triglycerides[51]	• …increasing consumption of marine-based omega-3 products,…, will further optimize triglyceride-lowering efforts.
			Cardiovascular Disease Risk Reduction in Women[38]	▪ Consume fish, especially oily fish, at least twice a week ▪ Consumption of omega-3 fatty acids in the form of fish or in capsule form may be considered in women with hypercholesterolemia and/or hypertriglyceridemia for primary and secondary prevention
			Patients with Coronary and Other Atherosclerotic Vascular Disease[39]	• For all patients, it may be reasonable to recommend omega-3 fatty acids from fish or fish oil capsules (1 g/d) for CVD risk reduction

Country/Region	Organization	Org. Type	Target Population	Recommendation
	U.S. Dept of Agriculture and U.S. Department of Health and Human Services[40]	Authoritative Body	General adult population	▪ Increase the amount and variety of seafood consumed by choosing seafood in place of some meat and poultry
			Pregnant or breastfeeding women	▪ consume at least 8 and up to 12 ounces of a variety of seafood per week
	Executive Office of the President[50]	Authoritative Body	General population	• Dietary Guidelines and Food Guide Pyramid should be revised to emphasize the benefits of…increasing consumption of foods rich in omega-3 fatty acids
	Agency for Healthcare Research and Quality[49]	Authoritative Body	General population	• Fish and fish oil supplements reduce the risk of cardiovascular disease
	American Academy of Pediatrics[41]	Expert Scientific Organization	Nursing Women	• The mother's diet should include an average daily intake of 200 to 300 mg of the ω-3 long-chain PUFAs (DHA) to guarantee a sufficient concentration of

Country/Region	Organization	Org. Type	Target Population	Recommendation
				preformed DHA in the milk. Consumption of 1 to 2 portions of fish (e.g., herring, canned light tuna, salmon) per week will meet this need. The concern regarding the possible risk from intake of excessive mercury or other contaminants is offset by the neurobehavioral benefits of an adequate DHA intake and can be minimized by avoiding the intake of predatory fish (e.g., pike, marlin, mackerel, tile fish, swordfish). Poorly nourished mothers or those on selective vegan diets may require a supplement of DHA as well as multivitamins
Canada	Minister of National Health and Welfare, Canada[42]	Authoritative Body	General adult population	• 1.2-1.6 g/day total n-3 PUFAs (ALA, EPA, DHA)
	Dietitians of Canada[33]	Expert Scientific Organization	General adult population	• 500 mg n-3 long-chain PUFAs/day
India	Cardiology Society of India[59]	Expert Scientific Organization	For patients with high triglycerides and patients after MI for secondary prevention	• Omega-3 acid ethyl esters (2-4g/day)
Japan	Ministry of Health, Labour and Welfare[43]	Authoritative Body	General adult population	• >1g EPA+DHA per day
			0-5 months – boys and girls	• 0.9g total omega-3 per day
			6-11 months- boys and girls	• 0.9g total omega-3 per day
			1-2 years – Boys and Girls	• 0.9g total omega-3 per day

Country/Region	Organization	Org. Type	Target Population	Recommendation
			3-5 years – Boys and Girls	• 1.2g total omega-3 per day
			6-7 years – Boys	• 1.6g total omega-3 per day
			(6-7 years) –Girls	• 1.3g total omega-3 per day
			8-9 years – Boys	• 1.7g total omega-3 per day
			8-9 years – Girls	• 1.5g total omega-3 per day
			10-11 years – Boys	• 1.8g total omega-3 per day
			10-11 years – Girls	• 1.7g total omega-3 per day
			12-14 years – Boys and Girls	• 2.1g total omega-3 per day
			15-17 years – Boys	• 2.5g total omega-3 per day
			15-17 years – Girls	• 2.1g total omega-3 per day
			Adults (18-29 years) – Men	• 2.1g total omega-3 per day
			18-29 years – Women	• 1.8g total omega-3 per day
			30-49 years – Men	• 2.2g total omega-3 per day
			30-49 years – Women	• 1.8g total omega-3 per day
			50-69 years – Men	• 2.4g total omega-3 per day
			50-69 years – Women	• 2.1g total omega-3 per day
			Over 70 years – Men	• 2.2g total omega-3 per day
			Over 70 years – Women	• 1.8g total omega-3 per day
			Pregnant Women	• 1.9g total omega-3 per day
			Nursing Women	• 1.7g total omega-3 per day
Malaysia	Ministry of Health	Authoritative Body	Acute ST Segment Elevation Myocardial Infarction[46]	• Increased intake of omega 3 – fatty acids (1g daily) is beneficial. • Eat fish at least twice a week.
			Women with CHD[47]	• omega-3-fatty-acids (>1gm/day) have been found to be beneficial
			Management of Dyslipidemia[48]	• A dose of 3-9 gm/day to lower TG levels

Country/Region	Organization	Org. Type	Target Population	Recommendation
				• A dose of 0.75-1 gm/day as secondary prevention to prevent sudden death
Israel	Israel Heart Society[44]	Expert Scientific Organization	For people with high risk or secondary prevention	• 1000 mg EPA + DHA/day as supplement for people who don't eat fish
			For the general public or primary prevention	• 500-1000 mg EPA + DHA/day as fish

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the **COUNCIL FOR RESPONSIBLE NUTRITION'S LETTER IN SUPPORT OF NON-INSTITUTION** was served to the parties, in the manner indicated below, this 14th day of September 2017:

The Honorable Rhonda K. Schmidtlein
Chairman
U.S. INTERNATIONAL TRADE COMMISSION
500 E Street, SW, Room 112-A
Washington, DC 20436

☒ **VIA ELECTRONIC FILING**
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COUNSEL FOR COMPLAINANTS AMARIN PHARMA, INC. AND AMARIN PHARMACEUTICALS IRELAND LTD

Jeffrey M. Telep, Esq.
KING & SPALDING, LLC
1700 Pennsylvania Avenue, NW, Suite 200
Washington, D.C. 20006-4706

☒ **VIA U.S. FIRST CLASS MAIL**

/s/ Nicole Robinson, Paralegal
ADDUCI, MASTRIANI & SCHAUMBERG LLP