UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of	)	
	)	
Certain Synthetically Produced, Predominantly EPA Omega-3 Products In Ethyl Ester Or Re-esterified Triglyceride Form	)	**Investigation No. 337-TA- ___**

COMPLAINANTS' STATEMENT ON THE PUBLIC INTEREST

Respectfully submitted,

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Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd.

August 30, 2017

Pursuant to Commission Rule 210.8(b), Complainants, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively "Amarin"), submit this Statement on the Public Interest regarding the remedial orders they seek against the Proposed Respondents' importing and selling certain synthetically produced, predominantly EPA omega-3 products in ethyl ester or re-esterified triglyceride form that are falsely labeled and/or promoted for use in, or as "dietary supplements," when they are actually illegal unapproved "new drugs" under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 321 *et seq.* This false labeling and/or promotion constitutes an unfair method of competition or an unfair act under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337") because it violates the Lanham Act, 15 U.S.C. § 1125(a), and the standards established by the FDCA.

The 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 and are not subject to this investigation. Common fish oil typically includes a mixture of saturated and unsaturated fats, including a variety of omega fatty acids in their natural triglyceride ("nTG-OM3") form. The products at issue here contain purified eicosapentaenoic acid ("EPA") or omega-3 fatty acid mixtures (that are predominantly EPA) in the ethyl ester form (respectively, "E-EPA" and "E-OM3") or in the re-esterified form (respectively, "rTG-EPA" and "rTG-OM3") (collectively, "Synthetically Produced Omega-3 Products"). Chemical synthesis enables higher EPA concentration and potency and removal of unwanted components, like saturated fat.

Amarin developed Vascepa®, a prescription drug that lists purified E-EPA as its active ingredient – legally – by investing the necessary resources to conduct clinical trials to show that the drug is safe and effective. Vascepa® is approved by the Food and Drug Administration ("FDA") for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe

hypertriglyceridemia. Although Vascepa® is the only FDA-approved drug that contains purified E-EPA, FDA has approved branded and generic drugs that contain E-OM3, for the same use.

As explained in the Complaint, since the launch of these FDA-approved drugs, products that contain E-EPA or E-OM3, or chemically modified versions of those active ingredients, rTG-EPA or rTG-OM3, have increasingly been falsely labeled or promoted for use in, or as "dietary supplements" – even though they are illegal unapproved "new drugs." This constitutes an unfair trade practice or unfair method of competition because such false statements 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 in violation of the standards set forth in Section 502 of the FDCA. 21 U.S.C. § 352(f), (n).

In addition, the false labeling and/or promotion of Synthetically Produced Omega-3 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, *see* 21 U.S.C. § 355. And, by flouting the drug approval process, the Proposed Respondents are able to promote their products for a broader array of uses, *see id.*, and skirt prescription requirements as well, *see id.* § 353(b). This is unfair to pharmaceutical companies who have invested the necessary resources to bring drugs to market – legally – and it disincentivizes future investment in drug development.

Investment in drug development in this area is critical to advance the public health. Amarin, for example, is currently conducting the REDUCE-IT cardiovascular outcomes trial, an 8,175-patient clinical trial, to evaluate 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. If successful, the trial has the potential to significantly change the treatment paradigm for cardiovascular risk reduction, the leading cause of death in the United States. Indeed, as John Jenkins, M.D., the former Director of the Office of New Drugs, at FDA has observed, the data from REDUCE-IT will be of "significant public health value." *See* **Complaint, ¶ 215.**

I. Use Of The Synthetically Produced Omega-3 Products In The United States

The Synthetically Produced Omega-3 Products are intended to be used for the purposes in which they are promoted, namely to affect the structure or function of the body and/or to affect disease. *See* **Complaint, § VI.A.1**. Presumably, they are purchased and used for those purposes. Structure/function claims that have been made for these products include, for example: support cardiovascular health; promote healthy immune responses; provide mood support; promote joint flexibility; and support healthy brain function. ***Id.* § VII.** Further, many are intended to affect disease, as evidenced by claims comparing the products to FDA-approved drugs (21 C.F.R. § 101.93(g)(vi) (disease claims include comparison claims)), and statements such as, "bring your triglyceride levels down naturally," and "anti-inflammatory for soothing arthritis." *Id.*

The Synthetically Produced Omega-3 Products are sold through multiple channels of distribution, including at retail establishments, such as grocery stores, pharmacies, and big box stores, as well as over the Internet. Moreover, unlike Vascepa® and other E-EPA and E-OM3 drug products that have been proven to be safe and effective for their intended uses, the Synthetically Produced Omega-3 Products can be accessed without a prescription.

II. Public Health, Safety, Or Welfare Concerns Relating To The Requested Order

An exclusion order in this case will not raise any public health, safety, or welfare concerns. Rather, removal of the purported "dietary supplements" will further the public interest because

those products are actually drugs that evade FDA regulation. Absent such an exclusion order, Proposed Respondents will continue to operate outside of the FDCA's drug regime, which was established by Congress to protect and promote the public health. 21 U.S.C. § 393(b). These activities will undermine incentives to invest in drug development, as explained above, and they may more immediately affect the public health. As mentioned in the complaint, former-Attorney General Loretta Lynch has observed that "dietary supplements" are not reviewed by FDA "before they reach the store shelves," and those that are illegally marketed can – not only abuse consumer trust by promising "results that they can't deliver" – but also "endanger public health" by leading consumers to use them as a substitute of proven therapies they may need," among other things. *See* **Complaint, ¶ 18.**

III. Directly Competitive Articles That Could Replace The Products At Issue

As mentioned, FDA has approved Vascepa® for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Although Vascepa® is the only FDA-approved purified E-EPA product on the United States market, FDA has approved one branded drug and several generic drugs containing E-OM3 for the same use. If the purported "dietary supplements" are removed from the market, consumers who took those products could consult a healthcare professional to determine whether prescription drugs are appropriate. Fish oil would also remain available to supplement diet and support body structures or functions.

IV. Amarin And Third-Parties Have The Capacity To Replace The Volume Of Articles At Issue In A Commercially Reasonable Period Of Time

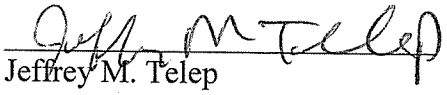
As mentioned in the complaint, Amarin has the capacity and/or inventory to supply through prescription the entire U.S. market demand for the purported "dietary supplements," in a commercially reasonable period of time, if necessary. *See* **Complaint, ¶ 229.** The demand for these products, however, also may shift to: (1) FDA-approved prescription drugs containing E-

OM3, and (2) legally marketed "dietary supplements" that contain common fish oil, where prescription drugs are not appropriate. We have no reason to believe that the manufacturers of these products could not increase production as necessary, in a commercially reasonable time.

V. Impact of the Requested Remedial Orders on Consumers

Amarin does not believe that the issuance of the requested remedial orders will adversely affect patient access to omega-3 products. Vascepa® is a low-cost drug from a consumer perspective. *See* **Complaint, ¶¶ 16, 237.** The monthly cost of Vascepa® is typically less than $200, and this cost is mostly covered by insurance plans. *Id.* 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. *Id.* In fact, a consumer with commercial insurance can pay as little as $9.00 for a 90-day supply prescription of Vascepa®. *Id.* Therefore, patients who need drugs to reduce triglyceride levels will still be able to access Vascepa®, or drugs containing E-OM3, including generics. Common fish oil would also remain available to supplement the diet or support certain structures or functions of the body.

Respectfully submitted,



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