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September 14, 2017

VIA ELECTRONIC FILING AND OVERNIGHT MAIL

The Honorable Lisa R. Barton
Secretary to the Commission
United States International Trade Commission
500 E Street, SW
Washington, DC 20436

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

Dear Secretary Barton:

We write on behalf of our client, the Council for Responsible Nutrition ("CRN"), in response to the Commission's solicitation of comments concerning the public interest issues raised by the Complaint and Rule 210.8(b) Statement filed by Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (collectively, "Amarin"). For the reasons detailed below, CRN requests that the Commission, should it determine to institute the investigation requested in the above-referenced complaint,[1] authorize the Administrative Law Judge ("ALJ") to take evidence and make a recommended determination relating to the public interest factors set forth in 19 U.S.C. § 1337(d)(1). *See* 19 C.F.R. § 210.50(b)(1). The relief requested by Amarin raises significant public interest concerns that warrant taking evidence to determine the extent of the harm the requested relief would cause to consumers and the public.

A. Concentrated Omega-3 Dietary Supplements Provide Recognized Health Benefits

"Dietary supplements," such as Respondents' concentrated Omega-3 products, have long been a part of United States consumers' diets, and were expressly recognized as a unique category of food when the Dietary Supplements Health and Education Act of 1994 ("DSHEA") amended the Federal Food, Drug, and Cosmetic Act ("FDCA").[2] In enacting DSHEA, Congress memorialized the importance of dietary supplements to U.S. consumers and set forth a

[1] The Commission should decline to institute the requested investigation for the reasons detailed in CRN's letter relating to institution, filed concurrently. Docket No. 3247, Correspondence from D. Okun to Chairman Schmidtlein Re: Non-institution of Investigation (Sept. 14, 2014).

[2] *Dietary Supplement Health and Education Act* of 1994 (Public Law 103-417, 103rd Congress).

distinctive regulatory framework to ensure convenient and affordable access to these products.[3] The Congressional findings supporting DSHEA also recognize that almost 50% of Americans consumed a dietary supplement as a means of improving their nutrition and reducing long-term healthcare costs. Importantly, from its original passage, DSHEA was intended to ensure that healthy individuals would have access to nutritional products that promote good health and fill nutrition gaps in their diets.

The products at issue are concentrated Omega-3 fish oil products derived from oil extracted from fish, i.e., common fish oil. These products provide consumers 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 taken by healthy people to maintain and promote health, and not to treat disease. Clinical evidence demonstrates that Omega-3 intake is associated with numerous several health benefits, such as supporting cardiovascular health, reducing the risk of cardiovascular disease, supporting brain development in children, helping to maintain cognitive function, improving mood, maintaining elasticity in skin, and supporting immunity. Thus, organizations in the United States and worldwide, such as NATO, the Departments of Agriculture and Health and Human Services, and the American Academy of Pediatrics recommend Omega-3 intake for healthy people—pregnant/lactating women, children, adults, and the general population—often at levels of 200-400 mg per day, which are generally achieved through Concentrated Omega-3 dietary supplements.[4] It is estimated that Omega-3 supplements increase the dietary intake of EPA and DHA in United States consumers by approximately 30%.

The FDA has been aware of Concentrated Omega-3 products being marketed as "dietary supplements" since the "late 1980s." Compl. ¶ 81. While pre-market approval by the FDA is not required for supplements, the FDA has, at times, affirmatively approved or acknowledged Concentrated Omega-3 products as supplements.[5]

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[3] *See* CRN Fact Sheet: Dietary Supplements: Safe, Regulated and Beneficial (2017), *available at* www.crnusa.org/sites/default/files/DOH-2017/DSSafeRegulatedBeneficial_2017.pdf (last accessed Sept. 14, 2017).

[4] *See* Global Org. for EPA & DHA Omega-3 (GOED), Global Recommendations for EPA and DHA Intake at 1, 8-12 (Apr. 14, 2016), *available at* www.goedomega3.com/index.php/files/download/304 (last accessed Sept. 14, 2017); *see also* Compl. ¶ 77 (explaining that one capsule of common fish oil contains about 50 mg of EPA).

[5] See e.g., FDA Correspondence to J. Barnett (June 13, 2006), available at www.fda.gov/ohrms/dockets/dockets/95s0316/95s-0316-rpt000343-002-vol268.pdf, Twin Rivers Generally Recognized As Safe (GRAS) Notice 200 (May 30, 2006), available at www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm263924.pdf, FDA Resp. to Twin Rivers GRAS notice 200 (Nov. 24, 2006), available at www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154679.htm, Unilever GRAS Notice 105 (Apr. 13, 2002), available at www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/UCM260971, FDA Resp. to Unilever GRAS Notice 105 (Oct. 15, 2002), available at

B. The Relief Requested Will Negatively Affect Public Health and Harm Consumers

Due to the recognized health benefits associated with consumption of the Respondents' products, the requested remedial orders would have significant, negative effects on public health. In particular, preventing the importation and sale of these supplements would dramatically affect consumers' access by making it more difficult and expensive, if not impossible, to obtain the health benefits associated with those products. This is especially true with respect to consumers who do not seek to increase levels of EPA and DHA to treat a disease or condition, but rather, they consume these products to *maintain* their health and/or achieve recommended levels of EPA and DHA. Healthy consumers seeking to achieve the levels of EPA and DHA provided by Respondents' products would, as Amarin concedes, likely find it intolerable to consume a comparable amount of common fish oil or krill oil to reach recommended levels. *See* Compl. ¶ 77.

The requested remedial orders would also have the effect of dramatically increasing the cost to achieve the health benefits associated with concentrated Omega-3 products. Indeed, Amarin acknowledges that the typical monthly cost of obtaining their product Vascepa® is $200, excluding the cost of a doctor's visit to obtain a prescription. While some of this cost may be offset by insurance, the healthy consumers who take concentrated Omega-3 products for a condition other than lowering triglyceride levels would no longer have access to these products over-the-counter, or at all. Concentrated Omega-3 dietary supplements can be purchased, without a prescription, from retailers for as little as $10-20 per month.

Taken together, the decreased availability, accessibility, and affordability of concentrated Omega-3 products present a near certainty that the requested relief would harm U.S. consumers.

C. There Are No Like or Directly Competitive Articles to Respondents' Products

Because of the breadth of the relief requested, which covers all concentrated Omega-3 products sold as dietary supplements, the requested relief would leave *no* "like or directly competitive" articles in the U.S. market. Although there are Omega-3 products with "natural triglycerides" (Compl. ¶ 2), these products have much lower levels of EPA and therefore do not provide the same health benefits as concentrated Omega-3 products.

Amarin's product, which is a drug indicated and intended to treat a disease or health condition, is not directly competitive with the dietary supplements Amarin seeks to exclude. Specifically, Vascepa® is a drug "indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia." Compl. ¶ 11. In

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https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153913.htm, (last accessed Sept. 14, 2017).

contrast, dietary supplements can be taken to maintain and support health. Thus, exclusion of Respondents' Concentrated Omega-3 products would leave many U.S. consumers who seek the health benefits of concentrated Omega-3 products, but who do not have the severe hypertriglyceridemia for which Vascepa® is indicated, with no means to obtain concentrated Omega-3 products.

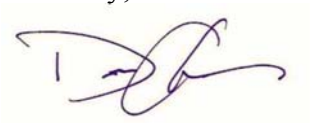
D. Amarin Can Not Replace the Respondents' Products If Its Requested Relief Is Granted

The lack of like or directly competitive articles, and the general exclusionary relief requested by Amarin, leads to the inescapable conclusion that, if Amarin is granted the relief requested, there would be no replacement for Respondents' products. Amarin seeks to preclude consumers from obtaining concentrated Omega-3 products without a prescription; accordingly, if the requested remedial orders are granted, consumers would be forced to go without the health benefits associated with the Respondents' dietary supplements or to convince doctors that it is "medically appropriate" for them to prescribe Omega-3 drugs for "off-label" uses as dietary supplements, at a higher price, and sold through different channels.[6]

E. The Commission Should Delegate Public Interest Issues to the ALJ to Take Evidence Regarding the Likely Effects of the Relief Requested

For the reasons detailed above, each category of information sought by the Commission strongly supports a conclusion that the requested relief would have negative effects on the public interest. If the Commission determines to institute the requested investigation, which it should not, for reasons stated separately,[7] CRN requests that the Commission direct the ALJ to take evidence and issue a recommended determination regarding the effect on the public interest. Should any violation be found, CRN anticipates that the evidence will demonstrate that this case presents the rare scenario in which the requested relief should not be granted due to the dramatic negative effects it would have on the public interest.

Sincerely,



Deanna Tanner Okun

[6] FDA "Understanding Unapproved Use of Approved Drugs "Off Label," *available at* www.fda.gov/forpatients/other/offlabel/default.htm (last accessed Sept. 14, 2017).

[7] *See supra* at n.1.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the **COUNCIL FOR RESPONSIBLE NUTRITION'S PUBLIC INTEREST COMMENTS** was served to the parties, in the manner indicated below, this 14TH day of September 2017:

The Honorable Lisa R. Barton
Secretary to the Commission
United States International Trade Commission
500 E Street, SW
Washington, DC 20436

☒ **VIA ELECTRONIC FILING**
☒ **VIA HAND DELIVERY – 8 COPIES**

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☒ **VIA U.S. FIRST CLASS MAIL**

/s/ B. Nicole Robinson
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