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	**Docket No. 337-TA-3247**

STATEMENT OF THE CONSUMER HEALTHCARE PRODUCTS ASSOCIATION ON SOLICITATION OF PUBLIC INTEREST

The Consumer Healthcare Products Association (CHPA) respectfully submits comments to the Commission notice regarding public interest issues raised by Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. ("Amarin") in its Complaint concerning Omega-3 (ω-3) products.

Amarin's requested exclusion order barring importation of ω-3 products in the U.S. raises significant public interest concerns. Amarin's entire Complaint rests on the assertion that ω-3 products are "new drugs" within the meaning of the Federal Food, Drug, and Cosmetic Act (FDCA). The Supreme Court long ago entrusted the question of whether an article is a new drug to the primary jurisdiction of the U.S. Food and Drug Administration (FDA). *See Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 654 (1973). Amarin's complaint improperly seeks Commission interpretation of the FDCA, and therefore provides no basis for institution and undermines public interest.

Further, the requested remedies will harm the public interest by disrupting consumer channels for inexpensive and efficient means of obtaining certain Concentrated ω-3 products. Amarin requests that the Commission exclude from the public widely-available Concentrated ω-3 while simultaneously touting the benefits of Concentrated ω-3 for public health and welfare.

Amarin's prescription product could never cure the public harm it seeks to impose through a general exclusion order against alternative sources of supply. Accordingly, the Commission should deny institution of this investigation or, alternatively, delegate to the ALJ public interest.

I. An Exclusion Order Would Have a Negative Impact on Public Health and Welfare Because It Divests Authority of Enforcing the FDCA from the FDA

In 1973, the Supreme Court held that the FDA has primary jurisdiction to determine what constitutes a "new drug,"

> We think it is implicit in the regulatory scheme . . . that FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided, the "new drug" status of individual drugs or classes of drugs.

Weinberger v. Bentex Pharmaceutics, 412 US at 653. The Supreme Court reasoned that litigation involving the interpretation of the FDCA is contrary to public interest,

> The deluge of litigation that would follow if 'me-too' drugs and OTC drugs had to receive de novo hearings in the courts would inure to the interests of the manufacturers and merchants in drugs, *but not to the interests of the public that Congress was anxious to protect . . .*

Id. (emphasis added).

Weinberger concludes that "the District Court's referral of the 'new drug' and the 'grandfather' issues to the FDA was appropriate, as these are the kinds of issues peculiarly suited to initial determination by the FDA." *Id.* Public interest is best supported through "[u]niformity and consistency" provided by the FDA's primary jurisdiction. *Id.*

Recent case law confirms that the FDA's primary jurisdiction can preclude Lanham Act claims. In *Hi-Tech Pharma*, the court explained that "there are some circumstances when the FDCA does preclude the Lanham Act claims," including where a party asks the court to make determinations about the "classification of new drugs." *Hi-Tech Pharma., Inv. v. Hodges Consulting, Inc.,* 230 F.Supp.3d 1323, 1330 (ND Ga 2016). "[D]etermination of whether a drug

is 'new,' and whether it can be lawfully marketed under the FDCA, involves complex issues of history, public safety, and administrative priorities that Congress has delegated exclusively to the FDA." *Id.* at 1331. And courts should not tread down the path of whether a drug "should have gone through the new drug approval process." *Id.*

In this proposed investigation, the FDA's jurisdiction precludes Amarin's Lanham Act claim. Amarin insufficiently pleads:

> **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.

Complaint at ¶ 1. According to Amarin, when a product is a "new drug," it is excluded from the definition of a "dietary supplement." Complaint at ¶¶ 61, 71. Amarin's theory rests on the FDA's construction of the FDCA in concluding whether products are drugs or dietary supplements, which in turn, determines which regulatory scheme applies to product adulteration and misbranding. The question of whether these products are appropriately labeled as supplements, and are not making claims that would trigger a "new drug" determination, ultimately rests with FDA, and not the Commission.

Amarin's claim further requires the Commission to look at yet another determination tasked to the FDA: whether the ω-3 products are "grandfathered" pursuant to Section 413 of the FDCA, such that they are not subject to the New Dietary Ingredient (NDI) notification requirement. Amarin argues that Respondents' ω-3 products are not dietary supplements because their ingredients do not fall into the FDCA categories of "dietary ingredients." Complaint at ¶ 63. Instead, they argue, because the components do not "naturally occur in fish oil" they

constitute a "new dietary ingredient," and, therefore, cannot be labeled as a dietary supplement. Complaint at ¶ 64.

Amarin, however, fails to mention that "grandfathered" ingredients fall outside the statutory definition of "new dietary ingredient." A NDI is defined in the FDCA Section 413(c) as "a dietary ingredient that was not marketed in the United States before October 15, 1994, and does not include any dietary ingredient which was marketed in the United States before October 15, 1994." The components of Respondents' products, including ω3/6/9, EPA, fish oil, and fish liver oils are all on the industry grandfathered lists, indicating pre-1994 usage. FDA has sponsored a public hearing on October 3, 2017 to discuss the creation of a list of grandfathered ingredients further demonstrating that the question of grandfathered status ultimately rests with FDA, and not the Commission.

II. Exclusion Would Harm Public Interest

Amarin's Complaint requests that the Commission issue a general exclusion order, excluding all ω-3 products where E-EPA and rTG-EPA are predominant components ("Concentrated ω-3 Products") regardless of source. The Concentrated ω-3 products Amarin seeks to exclude have undeniable health benefits. Even the Vascepa® website touts its product for patients with very high triglycerides. *See* https://www.vascepa.com/about-triglycerides.html

The notion that replacing Concentrated ω-3 Products with common fish oil could protect public interest in the event of exclusion is belied by Amarin's complaint. Amarin Public Interest Statement at 4 ("fish oil would also remain available to supplement diet and support body structures and function"). *Id.* at 4. Yet, Amarin represents that Respondents' products have undergone the "removal of unwanted components, like saturated fat" that remain in fish oil. *Id.* at 1. Moreover, Amarin concedes fish oil is not a substitute – "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." Complaint at ¶ 77. A website promoting Vascepa® further highlights that common fish oil is a poor alternative to Concentrated ω-3 Products. Without concentrated EPA, 10 to 40 fish oil capsules would be required to obtain the 4 grams per day of EPA found in Vascepa® resulting in the consumption of large amounts of saturated fat, which Amarin contends is "known to be unhealthy." *See* https://www.vascepa.com/prescription-vs-supplements.html.

Moreover, Amarin's claim that it could supply market demand is unsupportable. Amarin does not compete with the accused Concentrated ω-3 dietary supplement products. Consumers can easily obtain Concentrated ω-3 Products from grocery and retail stores and online retailers, generally for $10-20 per bottle. Amarin's Vascepa® is only available by prescription to treat disease. Even had Vascepa® competed with the accused products, Amarin's tepid contention that it has "potential capacity for expansion" is wrong. In 2015, ω-3 dietary supplements accounted for roughly 1.2 billion dollars in sales. Vascepa® sales are a fraction of that. Complaint at ¶ 232. Even if Amarin's conclusory statements about Vascepa® are to be believed, they say nothing to address the fundamental problem: consumers will only have access to Vascepa® through a prescription at prices 10-20 times that of the available dietary supplement products. Complaint at ¶ 235. Amarin's complaint is an unfounded claim to exclude legitimate competition to the detriment of US consumers and would set a concerning precedent for future trade restrictions.

III. Conclusion

For the foregoing reasons, the Commission should deny institution of this investigation or, alternatively, delegate to the ALJ public interest.

Date: September 14, 2017

Respectfully submitted,

By:_____

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CERTIFICATE OF SERVICE

I hereby certify that copies of the **STATEMENT OF THE CONSUMER HEALTHCARE PRODUCTS ASSOCIATION ON SOLICITATION OF PUBLIC INTEREST** were served on the following parties on this 14th day of September, 2017 in the manner indicated below:

The Honorable Lisa R. Barton Secretary to the Commission U.S. International Trade Commission 500 E Street, SW, Room 112 Washington, DC 20436	Via EDIS Via Overnight Mail (8 copies)
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