GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

July 15, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Submitted electronically via www.regulations.gov

RE: Docket No. FDA–2019–N–1388: *Responsible Innovation in Dietary Supplements; Public Meeting; Request for Comments*

To Whom It May Concern:

GOED, the Global Organization for EPA and DHA Omega-3s, is a trade association representing 170+ companies worldwide that are active in the EPA and DHA omega-3 industry. GOED's membership includes all segments of the omega-3 supply chain from fishing and seafood companies to refiners, supplement manufacturers, food and beverage marketers and pharmaceutical companies. GOED's members agree to adhere to product quality and ethical standards that represent the benchmark for quality in the omega-3 market. GOED's mission is to increase global consumption of EPA and DHA and ensure that our members produce quality products that consumers can trust.

GOED thanks the Agency for holding the public meeting on May 16, 2019 to give interested parties an opportunity to present ideas for facilitating responsible innovation in the dietary supplement industry while preserving and strengthening FDA's ability to efficiently and effectively protect the public from unsafe and unlawful products. For your reference, GOED's comments delivered during that meeting can be found below.

While the market for EPA- and DHA-rich dietary supplements has exploded since the passage of the DSHEA of 1994, the first fish oil, a cod liver oil known as Scott's Emulsion was launched in 1790 in the United State and continues to be marketed, thus representing what GOED believes to be the oldest continuously marketed dietary supplement in the U.S. In addition to cod liver oil, prior to October 15, 1994, multiple forms of fish oil were launched, including: fish body oil, concentrates (both ethyl esters and re-esterified triglycerides) and salmon oil. In common to all past and present EPA- and DHA-rich omega-3 ingredients is that their primary composition is EPA, DHA and a mixture of minor fatty acids.

GOED believes the major sources of EPA- and DHA-rich ingredients, including concentrates, are being lawfully sold, since they were marketed as dietary ingredients prior to October 15, 1994. To support this position, GOED has a considerable amount of documentation, including, but not limited to patents, popular press articles, advertisements, labels, peer-reviewed scientific articles and information from the NIH's Biomedical Test Materials Program from the 1980s and early 90s.

For years, EPA- and DHA-rich ingredients have been sourced from multiple organisms and species. Since the FDA issued its Final Rule on June 5, 1997 affirming menhaden oil as generally recognized as safe (GRAS) with limitations on the maximum use levels in specific food categories in order to ensure that daily intakes of EPA+DHA did not exceed 3.0 grams per day, EPA and DHA have been considered the valuable components to which these oils are standardized, and the products are principally comprised of EPA, DHA and a mixture of minor fatty acids. Subsequent to the Final Rule, more than 10 companies wishing to market their fish oils for addition to food have received letters of no objection from the FDA. Despite minor differences among the oils in fatty acid composition, FDA has raised no potential safety issues given that all companies indicated that intake of EPA+DHA would not exceed 3.0 grams per day. From a whole food perspective, consider that a single serving of salmon contains more EPA, DHA and a range of other minor fatty acids than the majority of fish oil supplements on the market.

Over the years, innovation has resulted in manufacturing changes to make the same or similar products on the market, but such changes should not yield an NDI. These manufacturing changes should be addressed by the Final Rule for Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. GOED believes the focus should be on whether or not a change to the manufacturing process alters the safety profile or identity of the ingredient and not be specific to the manufacturing change itself. After all, the principal ingredient produced is always an omega-3 rich-oil, with the predominant fatty acids being EPA and DHA, along with a mixture of minor fatty acids.

Sincerely,

Harry B. Rice, Ph.D.
Vice-President, Regulatory & Scientific Affairs