



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

2 August 2023

Ministerio de Salud  
Dirección Nacional de Dispositivos Médicos (National Directorate for Medical Devices)  
Calle Culebra, Ancón Antiguo Hospital Gorgas, detrás del Instituto Oncológico  
Panamá, Panama  
Email: [consultapublicadnfd@minsa.gob.pa](mailto:consultapublicadnfd@minsa.gob.pa)

RE: *Resolución Ministerial "Que establece la reglamentación para la inscripción de Suplementos Vitamínicos, Dietéticos y Alimenticios con Propiedades Terapéuticas"*

Dear Ramón Jaén Peralta:

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a mission to increase consumption of EPA and DHA omega-3s around the world. The membership is built on a quality standard unparalleled in the market and members must comply with quality and ethics guidelines that ensure members produce quality products that consumers can trust. Our 170+ members represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands.

GOED appreciates the opportunity to provide comments on Ministerial Resolution "Which establishes the regulations for the registration of Vitamin, Dietary and Food Supplements with Therapeutic Properties" notified on May 4, 2023 under the symbol (G/TBT/N/PAN/128).

GOED's comments are specific to Appendix 2 – "Substances with nutritional or physiological effect that can be used in the manufacture of dietary supplements." In the first table regarding fatty acids, a maximum daily limit of three grams EPA+DHA is indicated. For the reasons found in the following paragraphs, we respectfully request that this limit be increased to at least five grams EPA+DHA.

The daily three gram limit is based upon bleeding concerns from an outdated report commissioned by the US FDA over 30 years ago.<sup>1</sup> The de facto three gram limit, which has been promulgated globally, was in place until 19 June 2019, when the US FDA responded in a letter of enforcement discretion<sup>2</sup> to a health claim petition submitted by GOED. A safety review is included in that letter of enforcement discretion on pages six through nine. "With regard to bleeding risk, we concluded that consumption of less than or equal to 5 grams/day of EPA and DHA does not increase the risk of excessive bleeding based on clinical trials that measured clinical outcomes such as bleeding episodes and blood loss." For your reference, a more extensive review of the scientific literature on EPA and DHA intake and risk of

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<sup>1</sup>Hsia, M.T.S., Marvis, R.D., DeSesso, J.M., 1989. Health Effects of Refined Menhaden Oil. Prepared by Mitre Corp., Civil Systems Division, McLean, Virginia for US Food and Drug Administration (US FDA), Washington, DC (PB89-182398).

<sup>2</sup>Letter Responding to Health Claim Petition dated April 24, 2014: "Eicosapentaenoic Acid and Docosahexaenoic Acid and Reduction of Blood Pressure in the General Population" (June 19, 2019). <https://www.fda.gov/media/128043/download>



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excessive bleeding is provided in an FDA memo,<sup>3</sup> which is referenced in the letter of enforcement discretion. What's particularly interesting is that the daily five gram upper limit appears to only apply when the qualified health claim (QHC) is used. While a little confusing, a short explanation should clarify the situation.

If you look at page nine of the aforementioned letter of enforcement discretion, specifically, "Because the current scientific evidence does not show that dietary supplements that provide more than 5 g/day EPA and DHA are adulterated under the food safety provisions of the Federal Food, Drug, and Cosmetic Act, such products are lawful." Internally, we have had extensive discussions about that sentence and our interpretation is that the FDA was only setting a daily upper limit when an EPA/DHA QHC is used; otherwise, there is no upper limit. Regardless of our interpretation, a daily five gram upper limit for EPA+DHA is without question.

To conclude, GOED encourages Panama to increase the daily three gram EPA+DHA upper limit to five grams based upon the most recent safety assessment conducted by the United States.

Thank you in advance for your consideration of this feedback. Should you have any questions about GOED's comments, please let me know. We are at your disposal, now and in the future, to answer any EPA/DHA related questions.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Harry B. Rice'.

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

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<sup>3</sup><https://downloads.regulations.gov/FDA-2014-Q-1146-0094/content.pdf>