GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

October 8, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane. Room 1061
Rockville. Maryland 20852
(submitted via www.regulations.gov)

RE: Docket No. FDA-2018-N-2381. FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy

Dear Sir/Madam:

The Global Organization for EPA and DHA Omega-3s (GOED) is an international trade association of processors, refiners, manufacturers, distributors, marketers, retailers and supporters of products containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acids. GOED's membership represents a broad range of businesses, from small entrepreneurs to multinational food companies. The Organization's objectives are to educate consumers about the health benefits of EPA and DHA and to collaborate with government groups, the healthcare community and the industry on issues related to omega-3s, while setting high standards for our business sector. GOED appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA's) Comprehensive, Multi-Year Nutrition Innovation Strategy.

While GOED was not in attendance at the July 26, 2018 meeting to discuss the FDA's nutrition strategy, we have reviewed the meeting materials (e.g. presentations, transcript, etc…) and would like to reiterate the need to consider a more efficient review strategy for evaluating qualified health claims. While we don't have any specific recommendations on how to increase efficiency, the current system isn't working and GOED knows this from first-hand experience.

On August 8, 2014, GOED's qualified health claim petition for EPA and DHA and reduction of blood pressure in the general population was filed for review. Over four years later, the petition remains under review. In fact, on October 5, 2018, the FDA contacted GOED and requested a 16th extension to review the petition. With each extension request, there are two options and neither is overly palatable. We can either grant the extension, in which case the petition remains under review or we can deny the extension, in which case you will cease reviewing the petition.

Should the FDA deliver a decision by the next "agreed upon" deadline of February 1, 2019, the petition will have taken 1,638 days to review. At this point, I don't think it's unreasonable to characterize the delay as unacceptable, particularly given the documented cardiovascular benefits of increasing EPA/DHA intake.

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The relationship between hypertension and cardiovascular disease (CVD), the leading cause of death in the U.S., is well-documented and supported by all lines of biological evidence. As small as a 2 mmHg reduction in blood pressure may reduce death from stroke, coronary heart disease (CHD), and total mortality by 6%, 4%, and 3%, respectively. Thus, it is of great public health importance to identify factors that may reduce blood pressure. The meta-analysis GOED presented in its petition showed statistically significant reductions in both systolic and diastolic blood pressure after provision with EPA+DHA. Approved qualified health claims provide an opportunity to increase awareness of diet and disease relationships. Approval of qualified health claim language regarding EPA+DHA and blood pressure reduction would help policy-makers, healthcare professionals, educators, and consumers recognize the benefit of these nutrients and subsequently reduce U.S. morbidity and mortality from CHD and stroke.

Once again, thank you for the opportunity to provide comments.

Sincerely,

Harry B. Rice
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