



January 14, 2020

Steven Giardino  
President and CEO  
Medical Research Collaborative, LLC  
7901 4<sup>th</sup> Street N. STE 4081  
St. Petersburg, FL 33702

Re: Docket Number FDA-2019-P-3266

Dear Mr. Giardino:

This responds to your citizen petition dated July 8, 2019, under docket number FDA-2019-P-0913, requesting that “ethyl ester, re-esterified triglyceride, free-fatty acid (aka ‘carboxylic-acid’), mono- and di-glyceride forms of omega-3 fatty acids be officially ruled by the FDA as being dietary ingredients.”

The Food and Drug Administration (we) are advising you, in accordance with 21 CFR 10.30(e)(2), that we have not reached a decision on your petition within the first 180 days due to competing agency priorities. However, be advised that our staff is evaluating your petition.

Sincerely,

Steven J. Tave  
Director  
Office of Dietary Supplement Programs  
Center for Food Safety  
and Applied Nutrition

CC: Dockets Management Branch, HFA-305

U.S. Food & Drug Administration  
Center for Food Safety & Applied Nutrition  
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College Park, MD 20740