



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

July 1, 2019

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA delays approval of the supplemental New Drug Application for icosapent ethyl, aka "Vascepa," which is currently under review for a broad label based on the results of the REDUCE-IT trial was received by this office on 06/29/2019.

It was assigned docket number FDA-2019-P-3156. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby  
Supervisory Administrative Proceedings Specialist  
Division of Dockets Management  
FDA/Office of Operations (OO)