DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

July 17, 2019

Steven Giardino
President and CEO
Medical Research Collaborative, LLC
7901 4th Street, Suite 4081
St. Petersburg, FL 33702

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requests that the FDA delays approval of the supplemental New Drug Application (sNDA) 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 07/16/2019.

It was assigned docket number FDA-2019-P-3424. 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
Digitally signed by Dynna Bigby
Date: 2019.07.17 15:54:40 -04'00'

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