DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring , MD 20993

JUL 2 8 2014

Julie M. Jackle
186 Cazneau Ave
Sausalito, CA 94965

Dear Ms. Jackle,

Thank you for your letter to Jane Axelrad, Associate Director for Policy, Center for Drug Evaluation and Research, Food and Drug Administration (FDA or Agency), in reference to your citizen petition, FDA-2013-P-1612, regarding FDA's rescission of Amarin's Special Protocol Assessment (SPA) for its drug, Vascepa (icosapent ethyl).

Amarin's application for Vascepa for concomitant use with a statin to reduce triglyceride (TG) levels in adults with TG levels of 200-499 mg/dL (referred to as the "ANCHOR" study or indication) is still pending, as FDA has not yet made a decision on the application. Furthermore, several pending citizen petitions have been submitted to FDA that raise similar concerns regarding Amarin's SPA agreement. Information on applications and citizen petitions pending before the Agency is confidential. Thus, with the exception of the information publicly disclosed at the October 16, 2013, Endocrinologic and Metabolic Drug Advisory Committee (EMDAC) meeting, federal law generally prohibits FDA from discussing Amarin's pending application and the pending citizen petitions with third parties.

Please know that FDA is aware of the significant Congressional and stakeholder interest in the Agency's decision on this matter. FDA is making every effort to resolve the matter as expeditiously as possible, while also ensuring that the Agency's decision reflects a full consideration of the issues brought to our attention in light of all the available scientific evidence.

Thank you for contacting us. The Agency will respond to your petition as soon we have reached a decision on your request.

Sincerely,

Nancy Hayes, Acting Director
Office of Regulatory Policy
Center for Drug Evaluation and Research