DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

JUN 3 2014

David B. Shirley, D.V.M.
8201 Yacht Club Drive
Rowlett, TX 75089

Re: Docket No. FDA-2013-P-1612/CP12

Dear Dr. Shirley:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on December 13, 2013. Your petition requests that the Agency (1) overturn the decision to rescind the special protocol assessment (SPA) agreement for the ANCHOR trial conducted with Vascepa (icosapent ethyl) capsules, (2) conduct an independent scientific review of the three outcomes trials cited by the FDA reviewing division that were asserted to reveal substantial scientific issues and were the bases for rescinding the ANCHOR SPA, (3) determine that these three outcomes trials show that patients with high triglyceride levels (≥ 200 milligram/deciliter) and low high-density lipoprotein, the patient population covered by the ANCHOR SPA, had a reduction in cardiovascular disease risks, and (4) delay the PDUFA goal date for Vascepa's supplemental new drug application for the ANCHOR indication (NDA 202057/s005).

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research