DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA XXXXXX

SUSPENSION OF REVIEW

Sponsor Name
Street Address
City, State Zip
Attention:

Dear Sir/Madam:

This letter is in reference to your abbreviated new drug application (ANDA) dated <insert date>, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Icosapent Ethyl Capsules, 1 g.

The Basis of Submission cited in your ANDA is Vascepa Capsules, 1 g, NDA 202057 from Amarin Pharmaceuticals. As currently listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book), NDA 202057 has been granted a single three-year period of Hatch Waxman exclusivity. This exclusivity is identified in the Orange Book as a New Product (NP) exclusivity that will expire on July 26, 2015. As of the date of this letter, NP exclusivity remains the only exclusivity reflected in the Orange Book for Vascepa.

As you may already be aware, the U.S. District Court for the District of Columbia (Court) issued a decision on May 28, 2015, in *Amarin Pharmaceuticals Ireland Limited v. Food and Drug Administration*, Civil Action No. 14-CV-00324(RDM). This litigation challenged the FDA's denial of New Chemical Entity (NCE) exclusivity to Amarin's Vascepa drug product. The Court granted Amarin's motion for summary judgment, vacated FDA's determination that Vascepa did not qualify for NCE exclusivity, and remanded the matter back to FDA.

In light of the Court's order, FDA will suspend review of this application. If, after further review, FDA determines that Vascepa qualifies for NCE exclusivity, the exclusivity will bar an applicant from submitting an ANDA which references Vascepa until July 26, 2017 or an ANDA containing a certification of patent invalidity or noninfringement described in subclause (IV) of section 505(j)(2)(A)(vii) of the FD&C Act until July 26, 2016. 21 U.S.C. 355(j)(5)(F)(ii); 21 CFR 314.101(e).

If you have any questions, please contact NAME at (240) XXX-XXXX.

Sincerely yours,

Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research