DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202057/S-001

SUPPLEMENT APPROVAL

Amarin Pharma Inc.
US Agent for Amarin Pharmaceuticals Ireland Limited
Attention: Peggy Berry
VP, Quality and Regulatory Affairs
1430 Route 206, Suite 200
Bedminster, NJ 07921

Dear Ms. Berry:

Please refer to your Supplemental New Drug Application (sNDA) dated August 7, 2012, received August 7, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VASCEPA (icosapent ethyl) Capsules, 1 gram.

This "Changes Being Effected" supplemental new drug application provides for a 120-count sample package and associated labeling.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling.

CARTON AND IMMEDIATE CONTAINER LABELS
Submit the final printed container label that is identical to the enclosed carton label as soon as it is available, but no more than 30 days after it is printed.

REPORTING REQUIREMENTS
We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Acting Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure: 120-count sample bottle label

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RAMESH RAGHAVACHARI
01/31/2013