DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205060/S-004

SUPPLEMENT APPROVAL

AstraZeneca Pharmaceuticals
Attention: Michael Garvin
Regulatory Affairs Director
One MedImmune Way
Gaithersburg, MD 20878

Dear Mr. Garvin:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 7, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Epanova (omega-3-carboxylic acids) capsules.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the replacement of (b) (4) with AstraZeneca Pharmaceuticals (Newark, DE) as packing and labeling site for the drug product. In addition, the supplement revises the container closure system for the trade and sample packages. The 60-count trade bottle is being changed (b) (4) to a 190 cc HDPE bottle. The 6-count physician sample pack is being changed (b) (4) to a 75 cc HDPE bottle with associated labeling revisions.

APPROVAL & 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 text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 205060/S-004**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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, Senior Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities 1
Office of Lifecycle Drug Products
Center for Drug Evaluation and Research

ENCLOSURE: Container Labeling (6-count sample)

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
12/30/2016