DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21445/S-037

SUPPLEMENT APPROVAL

MSD International GmbH
Attention: Catherine Kohler, Pharm D.
Agent for MSD International GmbH
351 N. Sumneytown Pike
P.O. Box 1000, UG2D-027
North Wales, PA 19454

Dear Dr. Kohler:

Please refer to your Supplemental New Drug Application (sNDA) dated September 6, 2014, and received September 9, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zetia ™ (ezetimibe) Tablet.

We acknowledge receipt of your amendment dated May 30, 2014.

This "Changes Being Effected in 30 days" supplemental new drug application provides for changes in the Labeling Section(s) of the approved New Drug Application for Zetia (ezetimibe) Tablets to support the transition of the current "branded" labeling to the Optimized Package Design (FDA-approved for solid oral dosage products on June 2011).

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

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container 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 21445/S-037**." 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.

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 Priyanka Kumar, Regulatory Project Manager, at (240) 402-3722.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Carton and Container Labeling

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
09/30/2014