NDA 21445/S-040

APPROVAL LETTER

Merck Sharp & Dohme Corp.
US Agent for MSD International GmbH
Attention: Marisa Ulmer
Principal Scientist, Global Regulatory Affairs
351 North Sumneytown Pike, P.O. Box 1000
North Wales, PA 19454

Dear Ms. Ulmer:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 27, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zetia (ezetimibe) tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the change of the color of ink used for the "10 mg" on the ten-count blister pack from (b) (4) green (b) (4) to black.

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.

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

{See appended electronic signature page}

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

Enclosure(s):
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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