



NDA 21687/S-051

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 Ms. Kohler:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 6, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vytorin™ (ezetimibe/simvastatin) Tablet.

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

This “Changes Being Effected” supplemental new drug application provides for labeling changes of the approved New Drug Application for Vytorin™ to support the transition of the current “branded” labeling to the Optimized Package Design.

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 submitted carton and immediate container labels, except with the revisions listed above, 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 21687/S-051.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product 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