DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-687/S-001

Merck & Co., Inc., Agent for
MSP Singapore Company, LLC
Attention: Vijay Tammara, Ph.D.
Director, Regulatory Affairs
Sumneytown Pike, P.O. Box 104, BLA-20
West Point, PA 19486

Dear Dr. Tammara:

Please refer to your supplemental new drug application dated August 16, 2004, received August 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vytorin (ezetimibe/simvastatin) Tablets, 10 mg/10 mg, 10 mg/20 mg.

We acknowledge receipt of your submission dated February 4, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application provides for (1) an additional bottle package configuration, a 96 oz. (b)(4) bottle with foil induction seal and (b)(4) non-child resistant cap containing 10,000 tablets, for Vytorin™ Tablets, 10/10 and 10/20 strengths and (2) an additional drug product packaging site, Merck & Co., Inc., Wilson, SC.

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

The final printed labeling (FPL) must be identical to the submitted labeling (container labels submitted on February 4, 2005).

Please submit an electronic version of the FPL according to the guidance for industry titled "*Providing Regulatory Submissions in Electronic Format-NDA"*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-687/S-001**." Approval of this submission by FDA is not required before the labeling is used.

Please note that chemistry supplements that require labeling must include FPL to qualify as a Changes Being Effected-0 or -30.

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

If you have any questions, call Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

Sincerely,

{See appended electronic signature page}

Stephen K. Moore, Ph.D.
Chemistry Team Leader I for the
Division of Metabolic & Endocrine Drug Products, HFD-510
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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

/s/

Xavier Ysern
2/16/05 01:20:16 PM
Xavier Ysern, PhD signing for Stephen Moore, PhD