DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-687/S-021

SUPPLEMENT APPROVAL

Merck & Co., Inc., Agent for
MSP Singapore Company, LLC
Attention: Sandra Mackenzie, B.Sc., Director, Regulatory Affairs
126 E. Lincoln Avenue, PO Box 2000, RY33-208
Rahway, NJ 07065-0900

Dear Ms. Mackenzie:

Please refer to your supplemental new drug application dated June 28, 2007, received June 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vytorin (ezetimibe/simvastatin) Tablets.

We acknowledge receipt of your submission dated July 19, 2007.

This "Changes Being Effected" supplemental new drug application provides for labeling revisions to the package insert regarding the addition of "dizziness" to the **ADVERSE REACTIONS**, *Ezetimibe*, *Postmarketing Experience*, subsection and the addition of "hepatic failure" to the **ADVERSE REACTIONS**, *Simvastatin*, subsection of the Vytorin package insert. Labeling changes relating to these adverse reactions were made to the patient package insert under the section entitled, "**What are the possible side effects of Vytorin?**"

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

CONTENT OF LABELING

We note that your July 19, 2007, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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 Margaret Simoneau, M.S., R.Ph., Regulatory Project Manager, at (301) 796-1295.

Sincerely,

{See appended electronic signature page}

Mary Parks, M.D.
Director
Division of Metabolism and Endocrinology Products (DMEP)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Eric Colman
12/12/2007 08:57:51 AM
Eric Colman for Mary Parks