DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-445/S-020 and S-021

**SUPPLEMENT APPROVAL**

Schering Corporation, Agent for
MSP Singapore Co., LLC
Attention: Patricia Kay-Mugford DVM, MSc
Associate Director, Global Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, N.J. 07033

Dear Dr. Kay-Mugford:

Please refer to your supplemental new drug applications dated December 14, 2007, received December 17, 2007 (S-020); and dated February 11, 2008, received February 12, 2008 (S-021), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zetia (Ezetimibe) Tablets.

We acknowledge receipt of your submissions to S-020 dated February 26, April 21, May 19, 27, and 29, and June 5 (email), 2008.

**Supplement-020** provides the results of a pediatric study of the use of Zetia in adolescent boys and postmenarchal girls, ages 10 to 17 years of age, with heterozygous familial hypercholesterolemia. This supplemental application responds to our Written Request of April 15, 2004, as amended November 23, 2004.

**Supplement-021** provides for the addition of "paresthesia" to the **ADVERSE REACTIONS**, *Postmarketing Experience*, subsection of the Zetia package insert and to the patient package insert under the section entitled, "**What are the possible side effects of Zetia?**"

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

## CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert submitted June 5, 2008, by email.) Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-445/S-020, S-021**."

**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, 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

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
6/5/2008 12:29:49 PM
Eric Colman for Mary Parks