DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 021445/S-026 and S-027 **APPROVAL LETTER**

Schering Corporation, Agent for
MSP Singapore Co., LLC
Attention: Roy Dodsworth
Senior Director, Global Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, N.J. 07033

Dear Mr. Dodsworth:

Please refer to your supplemental new drug applications dated January 30, 2009, received February 2, 2009 (S-026); and dated May 8, 2009, received May 11, 2009 (S-027), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zetia (Ezetimibe) Tablets.

We acknowledge receipt of your submission dated July 16 (email), 2009.

The "Changes Being Effected" supplemental new drug applications provide for the addition of "abdominal pain and headache" (S-026) and the addition of "erythema multiforme" (S-027) 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 completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the 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 on July 16, 2009, 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 021445/S-026, S-027."**

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
5600 Fisher's Lane, Rm12B05
Rockville, MD 20857

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}

Eric Colman, M.D.
Deputy Director
Division of Metabolism and Endocrinology Products
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

7/21/2009 12:48:39 PM