DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-445/S-001, S-003, S-004

MSP Singapore Co., LLC
Schering Corporation, US Agent
Attention: Beth J. DiDomenico, PhD, Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. DiDomenico:

Please refer to the following supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zetia (ezetimibe) Tablets, 10 mg:

Supplement -001, submitted April 3, 2003, provides for the addition of a Post-Marketing subsection to the ADVERSE REACTIONS section of the package insert (PI) to include hypersensitivity reactions, including angioedema and rash. The PPI was also revised to include this information.

Supplement -003, submitted April 24, 2003, provides for revisions to the CLINICAL PHARMACOLOGY (Drug Interactions subsection) and PRECAUTIONS (Cyclosporine subsection) sections of the PI to include information from a study of multiple dosing of cyclosporine on the PK of a single dose of ezetimibe.

Supplement -004, submitted May 5, 2004, provides for the following:
-addition of the terms pancreatitis and nausea to the Post-Marketing subsection of the ADVERSE REACTIONS section of the PI. This information has also been included in the Patient Package Insert (PPI) under the section "What are the possible side effects of ZETIA?"
-revision of the OVERDOSE section of the PI.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the attached final printed labeling.
The approved package insert contains the identifier **25751841T, REV 03, Issued April 2004**. The approved patient package insert contains the identifier **25751744T, REV 03, Issued April 2004**.

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

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 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}

David G. Orloff, MD
Director
Division of Metabolic & Endocrine Drug Products
Office of Drug Evaluation II
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/

David Orloff

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