DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-445/S-006

Schering Corporation, Agent for
MSP Singapore Co., LLC
Attention: Beth J. DiDomenico, PH.D., M.B.A.
Regulatory Fellow, Global Regulatory Affairs
2000 Galloping Hill Rd
Kenilworth, NJ 07033

Dear Dr. DiDiomenico:

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 Zetia (ezetimibe) Tablets, 10 mg.

This "Changes Being Effected" supplemental new drug application provides for the addition of "cholelithiasis" and "cholecystitis" to the Adverse Events, Post-marketing Experience subsection of the Zetia package insert. Additionally, "gallstones" and "inflammation of the gallbladder" were added to the patient package insert.

We completed our review of this supplemental new drug application. It is are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 16, 12004.

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, M.D.
Director
Division of Metabolic and Endocrine Drug Products, HFD-510
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/

Mary Parks
9/22/04 08:33:38 AM
for Dr. Orloff