DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-445/S-007

Schering Corporation, Agent for
MSP Singapore Co., LLP
Attention: Beth J. DiDomenico, Ph.D., M.B.A.
Director, Global Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. DiDomenico:

Please refer to your supplemental new drug application submitted September 1, 2004, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zetia (ezetimibe) Tablets, 10 mg.

This "Prior Approval" supplemental new drug application provides for:

- CLINICAL PHARMACOLOGY, *Drug Interactions*, **HMG Co-A Reductase Inhibitors** and PRECAUTIONS, *Drug Interactions*, **HMG Co-A Reductase Inhibitors:** addition of "rosuvastatin" to the list of statins.
- CLINICAL PHARMACOLOGY, *Drug Interactions*, **Cyclosporine**: to describe the increase in AUC of cyclosporine when given concomitant with ezetimibe.
- PRECAUTIONS, *Drug Interactions Cyclosporine:* to state that cyclosporine concentrations should be monitored in patients receiving ZETIA and cyclosporine.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-445/S-010." Approval of this submission by FDA is not required before the labeling is used.

Please note that an analytical study report for ezetimibe concentration determination was lacking in Study P03317. We recommend that analytical reports be submitted for all analytes of interest in future submissions.

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 reporting requirements for an approved NDA (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 Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products, HFD-510
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/

Mary Parks
3/2/05 03:20:43 PM
for Dr. Orloff