



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

NDA 21-687/S-003

Merck & Co., Inc., Agent for  
MSP Singapore Company, LLC  
Attention: Vijay Tammara, Ph.D.  
Director, Regulatory Affairs  
Sumneytown Pike, P.O. Box 104, BLA-20  
West Point, PA 19486

Dear Dr. Tammara:

Please refer to your supplemental new drug application dated December 2, 2004, received December 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vytarin (ezetimibe/simvastatin) Tablets.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the package insert and patient package insert:

1. To the WARNINGS, Myopathy/Rhabdomyolysis subsection, statements regarding concomitant use with danazol or telithromycin were added.
2. Changes to the PRECAUTIONS section, Drug Interactions subsection with the addition of telithromycin. PRECAUTIONS section, Other drug interactions subsection, adds information on danazol and on amiodarone or verapamil with higher doses of Vytarin.
3. The addition of six types of adverse reactions based on post-marketing experience with ezetimibe.
4. The patient package insert adds "danazol" and "telithromycin" and several adverse reactions.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the final printed labeling submitted on December 2, 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 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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Mary Parks  
6/3/05 04:41:49 PM  
for Dr. Orloff