



NDA 21687/S-032

**SUPPLEMENT APPROVAL**

Merck & Co., Inc., Agent for  
MSP Singapore Company, LLC  
Attention: Sandra Mackenzie, B.Sc., Director, Regulatory Affairs  
126 E. Lincoln Avenue, PO Box 2000, RY33-208  
Rahway, NJ 07065-0900

Dear Ms. Mackenzie:

Please refer to your supplemental new drug application dated May 12, 2009, received May 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vytarin (ezetimibe/simvastatin) Tablets.

We acknowledge receipt of your submission dated June 8, 2009.

This “Changes Being Effected” supplemental new drug application provides for the addition of “erythema multiforme” to the **ADVERSE REACTIONS**, *Post-Marketing Experience*, subsection of the Vytarin package insert. “Raised red rash, sometimes with target-shaped lesions” was added to the patient package insert under the section entitled, “**What are the possible side effects of Vytarin?**”

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text, which is identical to the content of labeling [21 CFR 314.50(1)(1)(i)] in structured product labeling (SPL) format submitted on May 13, 2009.

**CONTENT OF LABELING**

We note that your June 8, 2009 submission includes final printed labeling (FPL) for your package insert and patient package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

**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(s) 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 <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **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 Fishers Lane, Room 12B05  
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 (DMEP)  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure  
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21687	SUPPL-32	MSP SINGAPORE CO LLC	VYTORIN(EZETIMIBE/SIMVAST ATIN) TABLETS

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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ERIC C COLMAN  
11/06/2009