Dear Ms. Mackenzie:

Please refer to your supplemental new drug application dated September 11, 2009, received September 11, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vytorin (ezetimibe/simvastatin) Tablets.

We acknowledge receipt of your submission dated March 9, 2010 (email).

This “Prior Approval” supplemental new drug application provides changes to the DOSAGE AND ADMINISTRATION, WARNINGS AND PRECAUTIONS, DRUG INTERACTIONS and CLINICAL PHARMACOLOGY sections of the Vytorin package insert to add additional information regarding the risk of myopathy in Chinese patients taking lipid-modifying doses (≥1 g/day niacin) of niacin-containing products with Vytorin.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert submitted March 9, 2010, by email). For administrative purposes, please designate this submission, “SPL for approved NDA 21687/S-034.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter,
submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

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

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. 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  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure
<table>
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<th>Submitter Name</th>
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<td>SUPPL-34</td>
<td>MSP SINGAPORE CO LLC</td>
<td>VYTORIN(EZETIMIBE/SIMVASTATIN) TABLETS</td>
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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.

/s/

ERIC C COLMAN
03/10/2010