



NDA 19-766/S-067, S-068

Merck & Co., Inc.
Attention: Andrew M. Tershakovec, M.D.
Director, Regulatory Affairs
Sumneytown Pike, P.O.Box 4, BLA-20
West Point, PA 19486

Dear Dr. Tershakovec:

Please refer to your supplemental new drug applications, S-067, dated August 28, 2003, received August 29, 2003, and S-068, dated November 10, 2003, received November 12, 2003, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for Zocor (simvastatin) Tablets.

We acknowledge receipt of your submission dated February 20, 2004.

Supplement-067 provides for revisions to the **PRECAUTIONS, Geriatric Use** subsection of the package insert.

To the **PRECAUTIONS, Geriatric Use** subsection, a new last sentence has been added to read:

There were no overall differences in safety between older and younger patients in either 4S or HPS.

Supplement-068 provides for revisions to the **DOSAGE AND ADMINISTRATION** section of the package insert.

To the **DOSAGE AND ADMINISTRATION** section, second paragraph, last sentence has been changed to read:

See below for dosage recommendations in special populations (i.e., homozygous familial hypercholesterolemia, adolescents and renal insufficiency) or for patients receiving concomitant therapy (i.e., cyclosporine, amiodarone, verapamil, or gemfibrozil).

We completed our review of these applications, as amended. These applications are 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 submitted draft labeling (package insert submitted February 20, 2003)(copy enclosed).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-766 /S-067, S-068." Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Margaret Simoneau, R.Ph., Regulatory Project Manager, at (301) 827-6411.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
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/

David Orloff

2/24/04 03:25:00 PM