



Food and Drug Administration  
Rockville MD 20857

NDA 19-766/S-026  
NDA 19-766/S-028

JUL 10 1998

Merck & Co., Inc.  
Attention: Charles Hyman, M.D.  
P.O.Box 4  
West Point, PA 19486

Dear Dr. Hyman:

Please refer to your supplemental new drug applications dated August 4, 1997, received August 5, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zocor (simvastatin) Tablets.

We acknowledge receipt of your submissions for supplement S-026 dated August 4, 15, November 13, December 4, 16, 18, 26, 1997, and January 16, 23, March 26, April 1, 24, May 27, June 12 (2), 15, 23, 25, 26(3), and July 2, 6, 7, and 8 (fax), 1998.

We acknowledge receipt of your submissions for supplement S-028 dated August 4, November 13, 19, 1997, and April 6, and June 15, 1998. The user fee goal date for both supplemental applications is August 5, 1998.

These supplemental new drug applications provide for the use of a new dosage strength and dosing regimen (80 mg per day) of Zocor (simvastatin) Tablets, (S-028) and for a new indication for the treatment of patients with homozygous familial hypercholesterolemia (S-026).

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert dated July 2, 1998, and immediate container label dated August 4, 1997). Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten 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-026, S-028." Approval of these submissions by FDA is not required before the labeling is used.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your submission dated July 8, 1998. These biopharmaceutical commitments, along with any completion dates agreed upon, are listed below.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND not be required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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-40  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Healthcare Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

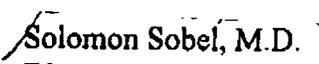
MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Margaret Simoneau, R.Ph., Regulatory Management Officer, at (301) 827-6418.

Sincerely yours,

 Solomon Sobel, M.D.

Director  
Division of Metabolic and Endocrine Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research