CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 019766/S027

APPROVAL LETTER

NDA 19-766/S-027

Merck & Co., Inc.
Attention: Robert E. Silverman, M.D., Ph.D.
P.O. Box 4
West Point, PA 19486

MAR 31 1998

Dear Dr. Silverman:

Please refer to your supplemental new drug applications dated August 12, 1997, received August 14, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zocor (Simvastatin) tablets.

We acknowledge receipt of your submissions dated November 13, 1997, March 27, and March 30 (fax), 1998. The User Fee goal date for these applications is August 14, 1998.

These supplemental applications provide for a new indication to reduce the risk of stroke or transient ischemic attack.

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 draft labeling submission dated March 27, 1998, with the revision listed below. Accordingly, this supplemental application is approved effective on the date of this letter. The revision is as follows:

> Delete the entire "Other Concomitant Therapy" paragraph from the "Drug Interactions" subsection of the PRECAUTIONS section of the package insert. This revision is a term of the supplemental NDA approval.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING for approved supplemental NDAs 19-766/S-027." Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material 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 the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

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, please contact Margaret Simoneau, R.Ph., Regulatory Management Officer, at (301) 827-6418.

Sincerely yours,

/S/
3/31/98

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

APPEARS THIS WAY ON ORIGINAL

cc:
Original NDAs 19-766/ S-027
HFD-510/Div. files
HFD-510/CSO/M. Simoneau
HFD-510/D.Orloff/E. Barbehenn/R.Steigerwalt/W.Berlin/S.Moore/E.Galliers
HFD-002/ORM (with labeling)
HFD-102/Office Director
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.
HFI-20/Press Office (with labeling)

Drafted by: Mas/March 30, 1998/19766.27
Initialed by: D.Orloff3.30&31, 1998/E.Barbehenn3.30&31, 1998/R.Steigerwalt3.30&31, 1998/W.Berlin3.30&31, 1998/S.Moore3.30&31,1998/E.Galliers3.30&31, 1998.
final: Mas 3.31.98

APPROVAL (AP)

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.