DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 16 1994

Date: Sept 13 1994

In response refer to File Number F94-34943

124176

This is in response to your request dated AUG 30 1994, in which you requested THE APPROVAL LETTER AND LABELING FOR MEVACOR TABLETS WHICH WAS APPROVED ON MAY 17, 1994.

Your request was received in the Center for Drug Evaluation and Research on Sept 3 1994.

✓ Enclosed are the documents you requested.

_____ A search of the records of the Center for Drug Evaluation and Research
___ did not locate any disclosable documents responsive to your request.
___ did not locate any documents responsive to your request.
___ did not locate an approved New Drug Application nor an approved Abbreviated New Drug Application for this/these product/products.
___ found that final printed labeling is not yet available.

_____ Summary Basis of Approval (SBA) are no longer being prepared.

_____ Due to severe resource restrictions, these documents are only available on microfiche. Paper copy cannot be provided. You may wish to view the document at your local library or request a local company provide paper copies from the fiche.

_____ The minutes of the meeting/meetings you requested are still in preparation and are not yet available.

_____ The document you requested is available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161, 703-487-4650.

_____ The portion of your request regarding _____ has been referred to the Agency's Freedom of Information Staff Office (HFI-35). They can be reached at 301-443-6310, ext 273.

_____ In order to reduce processing time and costs, certain material may have been deleted from the record(s) furnished to you, because a preliminary review indicated that the deleted material is not required to be publicly disclosed. If, however, you wish to review any deleted material, identify the specific deletion and submit an additional request for this information.

✓ This concludes your request.

_____ You can expect a further response from _____.

The following charges will be included in a monthly invoice:

Reproduction $_____ Search $ 6.50 Review $ 6.50 Other _____

Total $_____ **DO NOT SEND PAYMENT UNTIL YOU RECEIVE AN INVOICE**

If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number. Thank you for your request.

Sincerely yours,

Seymour Fishman
Freedom of Information Officer
Center for Drug Evaluation
and Research, HFD-19

EXHIBIT
Ex. 1014

foi

FOI Services, Inc.
12315 Wilkins Avenue
Rockville MD 20852-1877 USA
Phone: 301/881-0410
Fax: 301/881-0415

FOOD & DRUG ADMINISTRATION
FREEDOM OF INFORMATION STAFF
5600 FISHERS LANE
ROCKVILLE, MD 20857

8/30/94

CONTROL NUMBER 124176

PURSUANT TO THE PROVISIONS OF THE FREEDOM OF INFORMATION ACT, PLEASE PROVIDE US WITH A PAPER COPY (NOT MICROFICHE) OF THE FOLLOWING DOCUMENTS. IF THE COST OF PROVIDING THESE DOCUMENTS WILL EXCEED 100.00, PLEASE CALL US FIRST FOR AUTHORIZATION OF THE CHARGES, UNLESS INDICATED OTHERWISE BELOW.

PLEASE REFER TO OUR CONTROL NUMBER IN YOUR REPLY.

ATTENTION: CENTER FOR DRUGS

COPY OF ALL DISCLOSABLE APPROVAL INFORMATION, INCLUDING APPROVAL LETTER AND LABELING FOR THE LABELING REVISION APPROVED 5/17/94 FOR MEVACOR TABLETS 10MG, 20MG & 40MG MANUFACTURED BY MERCK.

94-34943

RECEIVED
SEP 01 1994
FDA FOI STAFF (HFI-35)

NDA 19-643/S-032
NDA 19-643/S-033

MAY 17 1994

Merck & Co., Inc.
Attention: Robert E. Silverman, M.D., Ph.D.
Director, Regulatory Affairs
BLA-30
West Point, PA 19486

Dear Dr. Silverman:

Please refer to your March 1 (Supplement-032) and August 19, 1993, (Supplement-033) supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mevacor (lovastatin) Tablets.

The supplemental applications provide for changes to the package insert regarding the following: Supplement-032 - Deletion of A.H.F.S. categories, editorial revisions to the "Clinical Studies" subsection of the CLINICAL PHARMACOLOGY section, additions to the "Hypersensitivity Reaction" and "Skin" subsections of the ADVERSE REACTIONS section, and class labeling revisions; and Supplement-033 - Revisions to the INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION sections based on the revised National Cholesterol Education Program (NCEP) Guidelines dated June 15, 1993, and includes the changes submitted in Supplement-032.

We have completed our review of these supplemental applications 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 July 1993, final printed labeling submitted in Supplement-033 on August 19, 1993. Accordingly, the supplemental applications are approved effective on the date of this letter.

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

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

Should you have any questions, please contact:

Mr. Stephen T. Trostle
Consumer Safety Officer
Telephone: 301-443-3520.

Sincerely yours,

Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products (HFD-510)
Center for Drug Evaluation and Research

cc:
Original NDA
HF-2 (with labeling)
HFC-130/JAllen
HFD-80 (with labeling)
HFD-240 (with labeling)
HFD-600 (with labeling)
HFD-730 (with labeling)
HFD-500/LRipper (with labeling)
HFD-510
HFD-510/SAurecchia/CNiu/EBarbehenn
HFD-510/STrostle/05/12/94/ft/stt/05/16/94 \N19643AP.032
Concurrence: EGalliers, SAurecchia 05.12; GTroendle, MRhee, YChiu, AJordan for EBarbehenn, AJordan 05.16.94

SUPPLEMENT(S) APPROVAL (AP-032/AP-033)

Request letter dated 07/14/93. No notable difference. ST 05/12/94

Robert E. Silverman, M.D., Ph.D.
Director
Regulatory Affairs

Three copies not desk copies.

Merck & Co., Inc.
BLA-30
West Point PA 19486
Fax 215 397 2335
Tel 215 397 2944
215 652 5000

RECEIVED
AUG 23 1993
DATE

NDA NO 19643 REF. NO. 033
NDA SUPPL FOR SNR

MERCK
Research Laboratories

August 19, 1993

noted
but we disagreed
to put the proposed
changes into labeling
EKB
8/30/93

CENTER FOR DRUG EVALUATION AND RESEARCH
RECEIVED
AUG 20 1993
HFD-510

Solomon Sobel, M.D. - Director
Division of Metabolism and Endocrine
Drug Products HFD-510, Room 14B-04
Office of Drug Evaluation II (CDER)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Sobel:

SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED

NDA 19-643: MEVACOR (Lovastatin)

Pursuant to Section 505(b) of the Food Drug and Cosmetic Act and in accordance with 21 CFR 314.50(c), we submit, for your approval, a supplement to NDA 19-643.

As indicated on the attached Form FDA 356h, the supplemental application provides for changes in Item 4.c.ii of the approved New Drug Application for Mevacor.

Reference is made to our letter dated June 7, 1993 and your letter dated July 14, 1993 concerning incorporation of the new NCEP Guidelines into the approved labeling for Mevacor.

This supplement is being submitted in response to your July 14, 1993 letter and contains a summary of revisions, an annotated revised package circular, and twelve (12) copies of the final printed package circular (No. 7526525). The labeling has been revised under INDICATIONS AND USAGE and DOSAGE AND ADMINISTRATION based on new NCEP Guidelines dated June 15, 1993.

The changes will become effective on or about October 1, 1993 and will apply to all packages of Mevacor distributed from the company's manufacturing facilities at West Point, Pennsylvania.

8/23/93

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