

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 019643/S055

Trade Name: MEVACOR TABLETS

Generic Name: LOVASTATIN

Sponsor: MERCK RESEARCH LABORATORIES

Approval Date: 03/11/99

INDICATION(s): IN THE PRIMARY PREVENTION OF CORONARY HEART DISEASE IN PATIENTS WITHOUT SYMPTOMATIC CARDIOVASCULAR DISEASE WHO HAVE AVERAGE TO MODERATELY ELEVATED TOTAL-C AND LDL-C AND BELOW AVERAGE HDL-C.

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APPLICATION: 019643/S055

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tentative Approval Letter				X
Approvable Letter				X
Printed Labeling				X
Medical/Statistical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)	SEE ABOVE			
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)				X
Administrative/ Correspondence Document(s)	X			

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APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-643/S-055

Merck Research Laboratories
Attention: Charles Hyman, M.D.
Director, Regulatory Affairs
Sumneytown Pike, P.O. Box 4
BLA-20
West Point, PA 19486

MAR 11 1999

Dear Dr. Hyman:

Please refer to your supplemental new drug application dated April 28, 1998, received April 29, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mevacor (lovastatin) Tablets.

We acknowledge receipt of your submissions dated May 19 and 20, June 12 and 18, August 10 and 14, September 3, October 27, and December 8, 1998, and January 22 and 28, and February 2 and 17, 1999.

This supplemental new drug application provides for a new indication for the use of Mevacor (lovastatin) Tablets in the primary prevention of coronary heart disease in patients without symptomatic cardiovascular disease who have average to moderately elevated total-C and LDL-C and below average HDL-C.

We have completed the review of this supplemental application, 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, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted February 17, 1999).

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 "FPL for approved supplement NDA 19-643/S-055." Approval of this submission by FDA is not required before the labeling is used.

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 Health Care 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

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,

/s/ 

3/9/99

Solomon Sobel, M.D.

Director

Division of Metabolic and Endocrine Drug Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research