CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 019643/S055

ADMINISTRATIVE/CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-643/S-055

Merck Research Laboratories
Sumneytown Pike, P.O. Box 4
BLA-20
West Point, PA 19486

Attention: Charles L. Hyman, M.D.
Director, Regulatory Affairs

Dear Dr. Hyman:

We acknowledge receipt of your supplemental application for the following:

Name of Drug:	Mevacor™ (Lovastatin)
NDA Number:	19-643
Supplement Number:	S-055
Date of Supplement:	April 28, 1998
Date of Receipt:	April 29, 1998

- Orloff
- Berlin
- Steigerwalt

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on June 28, 1998, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Attention: Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Charles L. Hyman, M.D.
Director
Regulatory Affairs

Merck & Co., Inc.
P.O. Box 4
West Point PA 19486
Fax 610 397 2516
Tel 610 397 2850
215 652 5000

February 2, 1999

Solomon Sobel, M.D., Director
Division of Metabolism and Endocrine Drug Products
HFD-510, Rm. 14B04
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

MERCK
Research Laboratories

Dear Dr. Sobel:

Supplemental New Drug Application: NDA 19-643/S-055
MEVACOR™ (Lovastatin)

Reference is made to the Supplemental New Drug Application 19-643/S-055 (AFCAPS/TexCAPS) for MEVACOR™ (Lovastatin) submitted on April 28, 1998. Reference is also made to the January 29, 1999 teleconference between the Food and Drug Administration (FDA) and Merck Research Laboratories (MRL) during which the labeling for AFCAPS/TexCAPS was discussed. By this letter, MRL is providing revised labeling that incorporates those changes agreed to during the January 29, 1999 teleconference.

We consider the information included in this submission to be a confidential matter, and request that the Food and Drug Administration not make its content, nor any future communications in regard to it, public without first obtaining the written permission of Merck & Co., Inc.

If I can be of further assistance please do not hesitate to contact Charles L. Hyman, M.D. (610/397-2850) or, in my absence, Robert E. Silverman, M.D., Ph.D. (610/397-2944).

Sincerely,

for Charles Hyman, M.D.

Charles L. Hyman, M.D.
Director, Regulatory Affairs

Attachments
Hand-delivered

Desk Copies: Hand-delivered to: Dr. Joy Mele, HFD-715, Rm. 14B45
Hand-delivered to: Dr. David Orloff, HFD-510, Rm. 14B04
Hand-delivered to: Dr. Mary Parks, HFD-510, Rm. 14B04
Hand-delivered to: Ms. Margaret Simoneau, HFD-510, Rm. 14B04

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ITEM 13
PATENT AND EXCLUSIVITY INFORMATION
MERCK RESEARCH LABORATORIES

1)	Active Ingredient(s)	Lovastatin
2)	Strength(s)	10, 20 and 40 mg
3)	Trade Name	MEVACOR®
4)	Dosage Form, Route of Administration	Tablets, Oral
5)	Applicant Firm Name	Merck Research Laboratories
6)	NDA Number	19-643
7)	Approval Date	
8)	Exclusivity - Date First ANDA could be approved	3 years after approval date
	Length of Exclusivity Period	3 years
9)	Applicable patent numbers and expiration date of each	4,231,938 Expiration date 6/15/2001 w/PTR

Q/MURAKAMI/MEVACOR/APCAPS/PATENT

Melvin Winokur
Patent Counsel

Merck & Co., Inc.
126 East Lincoln Avenue
RY60-30
Rahway NJ 07065-0907
Fax 732 594 2300
Tel 732 594 7234
Email mel_winokur@merck.com

MERCK

February 20, 1998

MEVACOR®
NDA 19-643
Lovastatin

Item 14

Pursuant to the provisions of Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act 21 U.S.C. § 355 (b)(1) and in accordance with Title 21 C.F.R. 314.70(b), attached hereto please find the patent information for the above-identified application.

The undersigned declares that U.S. Patent No. 4,231,938 covers the formulation, composition and/or method of use of MEVACOR® the subject of this application for which approval is being sought.

U.S. Patent No. 4,231,938, has an expiration date of June 15, 2001. This patent claims the compound lovastatin. This patent is assigned to Merck & Co., Inc.

A claim of infringement could be asserted if a person not licensed by the owner of U.S. Patent No. 4,231,938 engaged in the manufacture, use or sale of MEVACOR®.

Sincerely,

Melvin Winokur
Patent Counsel

APPEARS THIS WAY ON ORIGINAL

ea/

EXCLUSIVITY SUMMARY FOR NDA # 19-643 SUPPL # 055

Trade Name MEVACOR Generic Name LOVASTATIN

Applicant Name MERCK HFD # 510

Approval Date If Known MARCH 1999

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

a) Is it an original NDA?

YES /___/ NO /✓/

b) Is it an effectiveness supplement?

YES /✓/ NO /___/

If yes, what type? (SE1, SE2, etc.) SE1

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES /✓/ NO /___/

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

NA

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

NA

d) Did the applicant request exclusivity?

YES /✓/ NO /___/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request? 3 years 21 CFR 314.108(b)(4)

e) Has pediatric exclusivity been granted for this Active Moiety?

No (PEDIATRIC WRITTEN REQUEST LETTER ISSUED 2/3/99)

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx to OTC switches should be answered NO-please indicate as such)

YES /___/ NO /✓/

If yes, NDA #_____. Drug Name _____.

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /✓/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved.

Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /✓/ NO /___/

APPEARS THIS WAY ON ORIGINAL