CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 19-766 S048

Trade Name: Zocor Tablets

Generic Name: simvastatin

Sponsor: Merck & Company, Inc

Approval Date: April 10, 2001

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APPLICATION NUMBER:
NDA 19-766 S048

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APPLICATION NUMBER:

NDA 19-766 S048

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-766/S-048

Merck & Co., Inc.
Attention: Michael C. Elia, Ph.D., DABT
Director, Regulatory Affairs
BLA-20
P.O. Box 4
West Point, PA 19486

Dear Dr. Elia:

Please refer to your supplemental new drug application dated December 18, 2000, received December 20, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zocor (simvastatin) Tablets.

This supplemental new drug application provides for the deletion of the finished product specification [redacted] from the stability protocol for the 80 mg dose.

We have completed the review of this supplemental application, and it is approved.

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, call Margaret Simoneau, R.Ph., Regulatory Project Manager, at (301) 827-6418.

Sincerely,

{See appended electronic signature page}

Stephen K. Moore, Ph.D.
Chemistry Team Leader I, DNDC II for the
Division of Metabolic and Endocrine Drug Products,
(HFD-510)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

/s/

Stephen Moore
4/10/01 09:57:46 AM

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APPLICATION NUMBER:

NDA 19-766 S048

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

1. ORGANIZATION CDER/HFD-510
Division of Metabolism and Endocrine Drug Products

2. NDA # 19-766
Original NDA approved: 23-DEC-1991

3. NAME AND ADDRESS OF APPLICANT
Merck & Co., Inc.
P.O. Box 4
West Point PA 19486 (Phone): 610-397-2944

4. SUPPLEMENT SCM-048
18-DEC-2000 (Rec. 20-DEC-2000)

5. Name of the Drug
ZOCOR™

6. Nonproprietary Name
Simvastatin

7. SUPPLEMENT PROVIDES for the deletion of the finished product specification [redacted] from the stability protocol for the 80 mg dose.

8. AMENDMENT

9. PHARMACOLOGICAL CATEGORY
HMG-CoA inhibitor used to treat hyperlipidemia

10. HOW DISPENSED
Oral

11. RELATED
-N. A. -

12. DOSAGE FORM Tablet

13. POTENCY 5, 10, 20, 40, 80 mg

14. CHEMICAL NAME AND STRUCTURE

Butanoic acid, 2,2-dimethyl-,1,2,3,7,8,8α-hexahydro-3,7-dimethyl-8-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)-ethyl]-1-naphthalenyl ester, [1S-[1α,3α,7β,8β(2S*,4S*),-8αβ]]; $C_{25}H_{38}O_5$, F.W. = 418.57, CAS 56180-94-0 (For the structure, see Chemistry Review #1, dated 16-MAR-1988 in Vol. 3.1 of NDA 19-766).

15. COMMENTS See next page.

16. CONCLUSIONS AND RECOMMENDATIONS Satisfactory CMC information has been provided to remove the [redacted] testing from the stability specifications. From the Chemistry point of view, this supplement can be approved.

17. REVIEWER NAME (AND SIGNATURE) **DATE COMPLETED** 04-APR-2001
Sharon Kelly, PhD
R/D INITIATED BY

filename: 19766#48 NDASup

DISTRIBUTION: Original: sNDA 19-766 cc: HFD-510 Division File CSO Reviewer

AP

2 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry-19-766
5048

/s/

Sharon Kelly
4/6/01 12:32:08 PM
CHEMIST

Potency 5, 10, 20, 40, 80 mg

Stephen Moore
4/6/01 04:26:43 PM
CHEMIST