CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 19-766 S047

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 S047

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-766/S-047

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 15, 2000, received December 19, 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 assay test and specification for [redacted] used in the manufacturing process for the drug substance.

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 09:54:38 AM

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APPLICATION NUMBER:

NDA 19-766 S047

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-047 15-DEC-2000 (Rec. 19-DEC-2000)
	5. Name of the Drug ZOCOR™
	6. Nonproprietary Name Simvastatin
7. SUPPLEMENT PROVIDES for the deletion of the assay test and specification for — used in the manufacturing process for the drug substance.	**8. AMENDMENT**

9. PHARMACOLOGICAL CATEGORY HMG-CoA inhibitor used to treat hyper-lipidemia	**10. HOW DISPENSED** Oral	**11. RELATED** -N. A. -
12. DOSAGE FORM Tablet	**13. POTENCY** ? 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 The identification test for the raw material, — is performed — Only the assay test is removed from the specification.

16. CONCLUSIONS AND RECOMMENDATIONS Satisfactory CMC information has been provided to remove the assay test and specification for the raw materia — used in the manufacturing process for simvastatin drug substance. From the Chemistry point of view, this supplement can be approved.

17. REVIEWER NAME (AND SIGNATURE) **DATE**
COMPLETED 05-APR-2001
Sharon Kelly, PhD
R/D INITIATED BY

filename: 19766#47 NDASup

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

AP

/s/

Sharon Kelly
4/5/01 09:02:03 AM
CHEMIST

Stephen Moore
4/6/01 10:28:45 AM
CHEMIST