CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 19-766 S050

Trade Name: Zocor Tablets

Generic Name: simvastatin

Sponsor: Merck & Company, Inc

Approval Date: September 13, 2001

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APPLICATION NUMBER:
NDA 19-766 S050

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APPLICATION NUMBER:

NDA 19-766 S050

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-766/S-050

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

Dear Dr. Elia:

Please refer to your supplemental new drug application dated March 20, 2001, received March 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zocor (simvastatin) Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate batch size for the 80 mg tablets produced at Merck's Cramlington, United Kingdom facility.

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

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/s/

Stephen Moore
9/13/01 04:08:22 PM

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APPLICATION NUMBER:

NDA 19-766 S050

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** SCS-050 20-MAR-2001 (Rec. 21-MAR-2001)
	5. Name of the Drug ZOCOR™
	6. Nonproprietary Name Simvastatin
7. SUPPLEMENT PROVIDES for an alternate batch size for the 80 mg tablets produced at Merck's Cramlington, UK facility.	**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** 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 support an alternate batch size for the 80 mg tablet. From the Chemistry point of view, this supplement can be approved.

17. REVIEWER NAME (AND SIGNATURE) **DATE COMPLETED** 06-SEPT-2001
Sharon Kelly, PhD
R/D INITIATED BY

filename: 19766#50 NDASup

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

AP

1 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 19 766
5050

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/s/

Sharon Kelly
9/10/01 04:00:11 PM
CHEMIST

Paper copy signed Sept. 10, 2001

Stephen Moore
9/10/01 04:53:11 PM
CHEMIST

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APPLICATION NUMBER:

NDA 19-766 S050

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-766/S-050

CBE-30 SUPPLEMENT

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

Dear Dr. Elia:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Zocor (simvastatin) Tablets

NDA Number: 19-766

Supplement Number: S-050

Date of Supplement: March 20, 2001

Date of Receipt: March 21, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes an alternate batch size for Zocor (simvastatin) Tablets, 80 mg.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 20, 2001, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be September 21, 2001.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room, 14B-19
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-6411.

Sincerely,

{See appended electronic signature page}

Margaret Simoneau, R.Ph.
Regulatory Project Manager
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

/s/

Margaret Simoneau
3/30/01 11:17:46 AM