

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 19-766/S054

Trade Name: Zocor Tablets

Generic Name: simvastatin

Sponsor: Merck & Company, Inc.

Approval Date: March 21, 2002

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APPLICATION NUMBER:
NDA 19-766/S054

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APPLICATION NUMBER:
NDA 19-766/S054

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-766/S-054

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 September 26, 2001, received September 27, 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 corrections to the documentation for approved supplement -044 concerning the 40 and 80 mg ~~_____~~ packaging configurations.

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) 827-6411.

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
3/21/02 05:51:04 PM

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APPLICATION NUMBER:
NDA 19-766/S054

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 SCP -054 26-SEPT-01 (Rec'd 27-SEPT-01)
		5. Name of the Drug ZOCOR™
		6. Nonproprietary Name Simvastatin
7. SUPPLEMENT PROVIDES for corrections to S-044 concerning the 40 and 80 mg mg packaging configurations.		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 5, 10, 20, 40 & 80 mg	
14. CHEMICAL NAME AND STRUCTURE Butanoic acid, 2,2-dimethyl-,1,2,3,7,8,8 α -hexahydro-3,7-dimethyl-8-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)-ethyl]-1-naphthalenyl ester, [1S-[1 α ,3 α ,7 β ,8 β (2S*,4S*),-8 α β]]; 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 The CMC information provided in this Changes Being Effected Supplement is satisfactory. The request for a Categorical Exclusion to prepare an EA under 21 CFR §25.31(b) is acceptable. From a Chemistry point of view, this supplement can be approved. Issue approval letter.		
17. REVIEWER NAME (AND SIGNATURE) COMPLETED 15-MAR-2002 Sharon Kelly, PhD R/D INITIATED BY		DATE
filename: 19766#054		
DISTRIBUTION: Original: sNDA 19-766 cc: HFD-510 Division File CSO Reviewer		

AP

/ Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 19766
5054

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/s/

Sharon Kelly
3/15/02 01:52:15 PM
CHEMIST
paper copy signed March 15

Stephen Moore
3/15/02 02:01:14 PM
CHEMIST

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APPLICATION NUMBER:
NDA 19-766/S054

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-766/S-054

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-054

Date of Supplement: September 26, 2001

Date of Receipt: September 27, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes corrections to the documentation for approved supplement -044 concerning the 40 and 80 mg packaging configurations.

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 November 26, 2001, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be March 27, 2002.

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

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/s/

Margaret Simoneau
10/23/01 08:29:31 AM