

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 19-766/S055

Trade Name: Zocor Tablets

Generic Name: simvastatin

Sponsor: Merck & Company, Inc.

Approval Date: February 22, 2002

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APPLICATION NUMBER:
NDA 19-766/55

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APPLICATION NUMBER:
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APPROVAL LETTER



NDA 19-766/S-055

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 October 23, 2001, received October 24, 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 transfer of drug substance stability testing to the Merck facility in Wilson, NC.

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
2/22/02 01:48:46 PM

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APPLICATION NUMBER:
NDA 19-766/S055

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-055 23-OCT-2001 (Rec. 24-OCT-2001)	
		5. Name of the Drug ZOCOR™	
		6. Nonproprietary Name Simvastatin	
7. SUPPLEMENT PROVIDES for transfer of drug substance stability testing to the Merck facility in Wilson, NC.		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 10, 20, 40 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 Submitted as a CBE-30. EER decision: Acceptable for CFN 1036761-Merck, 4633 Merck Road, Wilson, NC. An Environmental Assessment waiver is requested.			
16. CONCLUSIONS AND RECOMMENDATIONS Satisfactory CMC information has been provided to support transfer of the simvastatin drug substance stability testing to the Merck site in Wilson, NC. From the Chemistry point of view, this supplement can be approved.			
17. REVIEWER NAME (AND SIGNATURE) COMPLETED 11-FEB-2002 Sharon Kelly, PhD R/D INITIATED BY		DATE	
filename: 19766#55 NDASup			
DISTRIBUTION: Original: sNDA 19-766 cc: HFD-510 Division File CSO Reviewer			

AP

15-FEB-2002

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Page 1 of 1

Application: NDA 19766/055 Priority: 1S Org Code: 510
Stamp: 24-OCT-2001 Regulatory Due: 24-APR-2002 Action Goal:
District Goal:

20-MAR-2002

Applicant: (SIMVASTATIN) SUMNEYTOWN PIKE
WEST POINT, PA 19486
MERCK Brand Name: ZOCOR
Established Name:
Generic Name: SIMVASTATIN
Dosage Form: TAB (TABLET)
Strength: 10, 20, 40 MG
FDA Contacts: S. KELLY (HFD-510) 301-827-6394 , Review Chemist
S. MOORE (HFD-510) 301-827-6430 , Team Leader

Overall Recommendation:
ACCEPTABLE on 11-FEB-2002 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: 1036761 DMF No:
MERCK AND CO INC AADA No:
4633 MERCK RD
WILSON, NC 27893

Profile: CTL OAI Status: NONE Responsibilities: DRUG SUBSTANCE
STABILITY
Last Milestone: OC RECOMMENDATION TESTER
Milestone Date: 11-FEB-2002
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

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/s/

Sharon Kelly
2/15/02 01:47:19 PM
CHEMIST

Paper copy signed Feb. 15, 2002

Stephen Moore
2/15/02 01:55:47 PM
CHEMIST

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APPLICATION NUMBER:
NDA 19-766/S055

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS



NDA 19-766/S-055

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-055

Date of Supplement: October 23, 2001

Date of Receipt: October 24, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes to transfer drug substance stability testing to the MMD facility in Wilson, NC.

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 December 23, 2001, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be April 24, 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
11/9/01 07:53:45 AM