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
# Reviews / Information Included in this NDA Review.

<table>
<thead>
<tr>
<th>Reviews / Information</th>
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<td>Approval Letter</td>
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<td>Approvable Letter</td>
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<td>Labeling</td>
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<td>Medical Review(s)</td>
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<tr>
<td>Chemistry Review(s)</td>
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<tr>
<td>Pharmacology Review(s)</td>
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<td>Statistical Review(s)</td>
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<td>Microbiology Review(s)</td>
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<td>Clinical Pharmacology/ Biopharmaceutics Review(s)</td>
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<tr>
<td>Administrative/Correspondence Document(s)</td>
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APPLICATION NUMBER:
NDA 19-766 S047

APPROVAL LETTER
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 [content removed] 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
CENTER FOR DRUG EVALUATION AND RESEARCH

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  
| 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  
| 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**

<table>
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<tr>
<th>9. PHARMACOLOGICAL CATEGORY</th>
<th>HMG-CoA inhibitor used to treat hyperlipidemia</th>
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<tbody>
<tr>
<td>10. HOW DISPENSED</td>
<td>Oral</td>
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<tr>
<td>11. RELATED</td>
<td>N. A.</td>
</tr>
<tr>
<td>12. DOSAGE FORM</td>
<td>Tablet</td>
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<td>13. POTENCY ? mg</td>
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</table>

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)]; C₂₅H₃₈O₅, 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 material ___ 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)**

**COMPLETED** 05-APR-2001  
Sharon Kelly, PhD  
R/D INITIATED BY  

**DATE**

**filename:** 19766#47 NDASup  
**DISTRIBUTION:** Original: sNDA 19-766  
**cc:** HFD-510 Division File  
**CSO Reviewer**  
AP