Robert E. Silverman, M.D., Ph.D.
Senior Director
Regulatory Affairs

DUPLICATE
NEW CORRESP
SNC

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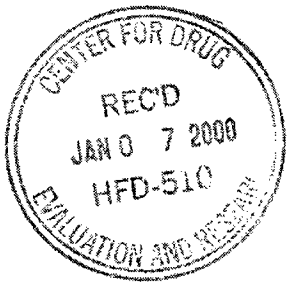
Merck & Co., Inc.
P.O. Box 4
West Point PA 19486
Fax 610 397 2516
Tel 610 397 2944
215 652 5000

January 6, 2000

MERCK
Research Laboratories

Mary A. Holovac, RPh
Center for Drug Evaluation and Research
Division of Data Management and Services
Information Service Team
HFD-090, Room 235
Food and Drug Administration
5516 Nicholson Lane
Rockville, MD 20895




Dear Ms. Holovac:

**NDA 19-766: ZOCOR® Tablets**
**(Simvastatin)**

**TIME SENSITIVE PATENT INFORMATION**
**Under *21 CFR 314.53***

Enclosed is a copy of the amended patent information for the approved product, ZOCOR®, under NDA 19-766, submitted pursuant to *21 CFR 314.53*. The original was sent to the Division of Metabolism and Endocrine Drug Products in duplicate. The owner of US Patent No. 36,481 is Merck & Co., Inc.

Questions concerning this information should be directed to Robert E. Silverman, MD, PhD (610-397-2944) or, in my absence, to Bonnie J. Goldmann, MD (610-397-2383).

Sincerely,

Michelle W. Kloss
for Robert E. Silverman, MD, PhD
Senior Director, Regulatory Affairs

RES/ped
Attachments
Federal Express

2 Official Copies (with attachments): Solomon Sobel, M.D., Director
HFD-510, Room 14B-04
Federal Express #2

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

# APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

*(Title 21, Code Of Federal Regulations, 314)*

*Form Approved OMB No. 0910-0338.*
*Expiration Date: April 30, 2000*
*See OMB Statement on last page.*

**FOR FDA USE ONLY**

APPLICATION NUMBER

**APPLICANT INFORMATION**

| NAME OF APPLICANT | DATE OF SUBMISSION |
|---|---|
| Merck & Co., Inc. | January 6, 2000 |
| TELEPHONE NO. *(Include Area Code)* (610) 397-2944 | FACSIMILE (FAX) Number *(Include Area Code)* (610) 397-2516 |
| APPLICANT ADDRESS *(Number, Street, City, State, Country, Zip Code or Mail Code, and U.S. License number if previously issued)* Sumneytown Pike, P.O. Box 4<br>BLA-20<br>West Point, PA 19486 | AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE |

**PRODUCT DESCRIPTION**

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 19-766

| ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)* | PROPRIETARY NAME *(trade name)* IF ANY |
|---|---|
| Simvastatin | ZOCOR |

CHEMICAL/ BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)* [1S-[1α, 3α,7β,8β(2S*,4S*),8aβ]]-1,2,3,7,8a-hexahydro-3,7-dimethyl-8-[2-tetrahydro-4-hydroxy-6-ozo-2H--pyran-2-yl)ethyl]-1-napthalenyl-2,2-dimethylbutanoate

CODE NAME *(If any)*

| DOSAGE FORM | STRENGTHS | ROUTE OF ADMINISTRATION |
|---|---|---|
| Tablet | 5 mg, 10 mg, 20 mg, 40 mg, 80 mg | Oral |

(PROPOSED) INDICATION(S) FOR USE: Reduction of risk of total mortality by reducing coronary death, reduction of risk for non-fatal myocardial infarction and reduction of the risk for undergoing myocardial revascularization procedures in patients with coronary heart disease and hypercholesterolemia. Reduction of elevated total and LDL cholesterol levels in patients with primary hypercholesterolemia (Types IIa and IIb).

**APPLICATION INFORMATION**

APPLICATION TYPE *(Check one)*
☑ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☑ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCED LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug — Holder of Approved Application

TYPE OF SUBMISSION (check one)
☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☑ OTHER

REASON FOR SUBMISSION Time Extension Patent Information

PROPOSED MARKETING STATUS (check one) ☑ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 — THIS APPLICATION IS ☑ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

**ESTABLISHMENT INFORMATION**

Provide locations of all manufacturing, packaging and control sites for the drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

**Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)**

| This application contains the following items: *(Check all that apply)* | |
|---|---|
| | 1. Index |
| | 2. Labeling (check one) ☐ Draft Labeling ☐ Final Printed Labeling |
| | 3. Summary (21 CFR 314.50 (c)) |
| | 4. Chemistry Section |
| | A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21 CFR 601.2) |
| | B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request) |
| | C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2) |
| | 5. Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2), 21 CFR 601.2) |
| | 6. Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3), 21 CFR 601.2) |
| | 7. Microbiology section (21 CFR 314.50 (d) (4)) |
| | 8. Clinical data section (21 CFR 314.50 (d) (5), 21 CFR 601.2) |
| | 9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2) |
| | 10. Statistical section (21 CFR 314.50 (d) (6), 21 CFR 601.2) |
| | 11. Case report tabulations (21 CFR 314.50 (f) (1), 21 CFR 601.2) |
| | 12. Case reports forms (21 CFR 314.50 (f) (1), 21 CFR 601.2) |
| ✓ | 13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c)) |
| | 14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A)) |
| | 15. Establishment description (21 CFR Part 600, if applicable) |
| | 16. Debarment certification (FD&C Act 306 (k) (1)) |
| | 17. Field copy certification (21 CFR 314.5 (k) (3)) |
| | 18. User Fee Cover Sheet (Form FDA 3397) |
| | 19. OTHER (Specify) |

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In case of a prescription drug product or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on reports in 21 CFR 314.80, 314.81, 600.80 and 600.81.
7. Local, State and Federal environmental impact laws

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001

| SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT | TYPED NAME AND TITLE | DATE |
|---|---|---|
| Robert E. Silverman | Robert E Silverman, M.D., Ph.D.<br>Senior Director, Regulatory Affairs | 06-JAN-2012 |

| ADDRESS (Street, City, State, and ZIP Code) | Telephone Number |
|---|---|
| Sumneytown Pike, P.O. Box 4<br>BLA-20<br>West Point, PA 19486 | (610) 397-2944 |

**Public reporting burden for this collection of information** is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0338)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Please DO NOT RETURN this form to this address.



FORM FDA 356h (4/97)

Patent Submission Suggested Format

Time Sensitive Patent Information

pursuant to 21 C.F.R. 314.53

for

NDA # 19-766

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

- Trade Name: Zocor®
- Active Ingredient(s): Simvastatin
- Strength(s): 5, 10, 20, 40 and 80 mg.
- Dosage Form: Tablets, oral

## A. This section should be completed for each individual patent

This format repeats to allow up to three patents. If there are additional patents, please copy and attach.

U.S. Patent Number: Re.36,481

Expiration Date: July 10, 2007

Type of Patent--indicate all that apply:

1. Drug Substance(Active Ingredient) _x_Y ___N
2. Drug Product(Composition/Formulation) ___Y _x_N
3. Method of Use _x_Y ___N

a. If patent claims method(s) of use, please specify approved method(s)of use or method(s) of use for which approval is being sought that are covered by patent indicated for the reduction of elevated total and LDL cholestrol levels in patients with primary hypercholesterolemia.

Name of Patent Owner: Merck & Co., Inc.

U.S. Agent (if patent owner or applicant does not reside or have place of business in the US):

---

U.S. Patent Number:

Expiration Date:

Type of Patent--indicate all that apply:

1. Drug Substance(Active Ingredient) ___Y ___N
2. Drug Product(Composition/Formulation) ___Y ___N
3. Method of Use ___Y ___N

a. If patent claims method(s) of use, please specify approved method(s)of use or method(s) of use for which approval is being sought that are covered by patent_____

Name of Patent Owner:

U.S. Agent (if patent owner or applicant does not reside or have place of business in the US):

---

- **U.S. Patent Number:**

**Expiration Date:**

**Type of Patent–Indicate all that apply:**

1. Drug Substance(Active Ingredient) ___Y ___N
2. Drug Product(Composition/Formulation) ___Y ___N
3. Method of Use ___Y ___N

a. If patent claims method(s) of use, please specify approved method(s)of use or method(s) of use for which approval is being sought that are covered by patent:_____

**Name of Patent Owner:**

**U.S. Agent (if patent owner or applicant does not reside or have place of business in the US):**

---

## B. The following declaration statement is required if any of the above listed patents have Composition/Formulation or Method of Use claims.

This format repeats to allow up to three patents. If there are additional patents, please copy and attach.

The undersigned declares that the above stated United States Patent Number Re. 36,481 covers the composition, formulation and/or method of use of Zocor® (name of drug product). This product is:

- x currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act)

OR

- ___the subject of this application for which approval is being sought.)

---

The undersigned declares that the above stated United States Patent Number _____ covers the composition, formulation and/or method of use of _____(name of drug product). This product is:

- ___currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act)

OR

- ___the subject of this application for which approval is being sought.)

---

The undersigned declares that the above stated United States Patent Number _____ covers the composition, formulation and/or method of use of _____(name of drug product). This product is:

- ___currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act)

OR

- ___the subject of this application for which approval is being sought.)

---

Signed: Carol S. Quagliato - Carol S. Quagliato
Date: January 5, 2000
Title (optional): Senior Patent Attorney
Telephone Number (optional): 732-594-3809

---

A copy of the above information should be submitted to the NDA with the original application or as correspondence to an existing NDA. For patents issued after the NDA is filed or approved, the applicant is required to submit the information within 30 days of the date of issuance of the patent.

To expedite publication in the *The Orange Book*,* a deskcopy should be submitted to:

Mailing address: (US Mail)

U.S. Food and Drug Administration
Center for Drug Evaluation and Research

Division of Data Management and Services
Information Services Team
HFD-93
5600 Fishers Lane
Rockville, MD 20857

OR

Location address: (for FedX deliveries)

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services
Information Services Team
Building A
HFD-93 Room #235
Nicholson Lane Research Center
5516 Nicholson Lane
Kensington, MD 20895

OR faxed to: (301)-594-6463

* - Please note that patents for unapproved compositions, formulations, or uses will NOT be published in the *The Orange Book*.

Previous Page

Robert E. Silverman, M.D., Ph.D.
Senior Director
Regulatory Affairs

DUPLICATE

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not desk copies.

Merck & Co., Inc.
P.O. Box 4
West Point PA 19486
Fax 610 397 2516
Tel 610 397 2944
215 652 5000

January 19, 2000

Mary A. Holovac, RPh
Center for Drug Evaluation and Research
Division of Data Management and Services
Information Service Team
HFD-090, Room 235
Food and Drug Administration
5516 Nicholson Lane
Rockville, MD 20895



MERCK
Research Laboratories

Dear Ms. Holovac:

**NDA 19-766: ZOCOR® Tablets**
**(Simvastatin)**

**TIME SENSITIVE PATENT INFORMATION**
**Under *21 CFR 314.53***

Enclosed is a copy of the amended patent information for the approved product, ZOCOR®, under NDA 19-766, submitted pursuant to *21 CFR 314.53*. The original was sent to the Division of Metabolism and Endocrine Drug Products in duplicate. The owner of US Patent No. 36,520 is Merck & Co., Inc.

Questions concerning this information should be directed to Robert E. Silverman, MD, PhD (610-397-2944) or, in my absence, to Bonnie J. Goldmann, MD (610-397-2383).

Sincerely,

Robert E. Silverman, MD, PhD
Senior Director, Regulatory Affairs

RES/ped
Attachments
Federal Express #1

2 Official Copies (with attachments): John Jenkins, M.D., FCCP, Acting Director
HFD-510, Room 14B-04
Federal Express #2

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

# APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

*(Title 21, Code Of Federal Regulations, 314)*

*Form Approved OMB No. 0910-0338.*
*Expiration Date: April 30, 2000*
*See OMB Statement on last page.*

FOR FDA USE ONLY

APPLICATION NUMBER

## APPLICANT INFORMATION

| NAME OF APPLICANT | DATE OF SUBMISSION |
|---|---|
| Merck & Co., Inc. | January 19, 2000 |
| TELEPHONE NO. *(Include Area Code)* (610) 397-2944 | FACSIMILE (FAX) Number *(Include Area Code)* (610) 397-2516 |

APPLICANT ADDRESS *(Number, Street, City, State, Country, Zip Code or Mail Code, and U.S. License number if previously issued)*:
Sumneytown Pike, P.O. Box 4
BLA-20
West Point, PA 19486

AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

## PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 19-766

| ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)* | PROPRIETARY NAME *(trade name)* IF ANY |
|---|---|
| Simvastatin | ZOCOR |

CHEMICAL/ BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)* [1S-[1α, 3α,7β,8β(2S*,4 S*),8αβ]]-1,2,3,7,8a-hexahydro-3,7-dimethyl-8-[2-tetrahydro-4-hydroxy-6-ozo-2H--pyran-2-yl)ethyl]-1-napthalenyl-2,2-dimethylbutanoate

CODE NAME *(If any)*

| DOSAGE FORM | STRENGTHS: | ROUTE OF ADMINISTRATION |
|---|---|---|
| Tablet | 5 mg, 10 mg, 20 mg, 40 mg, 80 mg | Oral |

(PROPOSED) INDICATION(S) FOR USE: Reduction of risk of total mortality by reducing coronary death, reduction of risk for non-fatal myocardial infarction and reduction of the risk for undergoing myocardial revascularization procedures in patients with coronary heart disease and hypercholesterolemia. Reduction of elevated total and LDL cholesterol levels in patients with primary hypercholesterolemia (Types IIa and IIb).

## APPLICATION INFORMATION

APPLICATION TYPE *(Check one)*
☑ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☑ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCED LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug — Holder of Approved Application

TYPE OF SUBMISSION (check one)
☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☑ OTHER

REASON FOR SUBMISSION: Time Sensitive Patent Information

PROPOSED MARKETING STATUS (check one) ☑ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 — THIS APPLICATION IS ☑ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

## ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for the drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

**Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)**



EF

| This application contains the following items: *(Check all that apply)* | |
|---|---|
| | 1. Index |
| | 2. Labeling (check one) ☐ Draft Labeling ☐ Final Printed Labeling |
| | 3. Summary (21 CFR 314.50 (c)) |
| | 4. Chemistry Section |
| | A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21 CFR 601.2) |
| | B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request) |
| | C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2) |
| | 5. Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2), 21 CFR 601.2) |
| | 6. Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3), 21 CFR 601.2) |
| | 7. Microbiology section (21 CFR 314.50 (d) (4)) |
| | 8. Clinical data section (21 CFR 314.50 (d) (5), 21 CFR 601.2) |
| | 9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2) |
| | 10. Statistical section (21 CFR 314.50 (d) (6), 21 CFR 601.2) |
| | 11. Case report tabulations (21 CFR 314.50 (f) (1), 21 CFR 601.2) |
| | 12. Case reports forms (21 CFR 314.50 (f) (1), 21 CFR 601.2) |
| | 13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c)) |
| | 14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A)) |
| | 15. Establishment description (21 CFR Part 600, if applicable) |
| | 16. Debarment certification (FD&C Act 306 (k) (1)) |
| | 17. Field copy certification (21 CFR 314.5 (k) (3)) |
| | 18. User Fee Cover Sheet (Form FDA 3397) |
| ✓ | 19. OTHER (Specify) |

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In case of a prescription drug product or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on reports in 21 CFR 314.80, 314.81, 600.80 and 600.81.
7. Local, State and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate. **Warning:** a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

| SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT | TYPED NAME AND TITLE | DATE |
|---|---|---|
| | Robert E. Silverman, M.D., Ph.D.<br>Senior Director, Regulatory Affairs | 19-JAN-00 |

| ADDRESS (Street, City, State, and ZIP Code) | Telephone Number |
|---|---|
| Sumneytown Pike, P.O. Box 4<br>BLA-20<br>West Point, PA 19486 | (610) 397-2944 |

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DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0338)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

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FORM FDA 356h (4/97)

Patent Submission Suggested Format

Time Sensitive Patent Information

pursuant to 21 C.F.R. 314.53

for

NDA # 19-766

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

- Trade Name: Zocor®
- Active Ingredient(s): Simvastatin
- Strength(s): 5,10,20,40 and 80mg.
- Dosage Form: Tablets, oral

## A. This section should be completed for each individual patent

This format repeats to allow up to three patents. If there are additional patents, please copy and attach.

U.S. Patent Number: Re. 36,520

Expiration Date: May 26, 2009

Type of Patent--Indicate all that apply:

1. Drug Substance(Active Ingredient) _x_Y ___N
2. Drug Product(Composition/Formulation) ___Y _x_N
3. Method of Use _x_Y ___N

a. If patent claims method(s) of use, please specify approved method(s)of use or method(s) of use for which approval is being sought that are covered by patent: indicated for the reduction of elevated total and LDL cholestrol levels in patients with primary hypercholesterolemia

Name of Patent Owner:

U.S. Agent (if patent owner or applicant does not reside or have place of business in the US):

U.S. Patent Number:

Expiration Date:

Type of Patent--Indicate all that apply:

1. Drug Substance(Active Ingredient) ___Y ___N
2. Drug Product(Composition/Formulation) ___Y ___N
3. Method of Use ___Y ___N

a. If patent claims method(s) of use, please specify approved method(s)of use or method(s) of use for which approval is being sought that are covered by patent:_____

Name of Patent Owner:

U.S. Agent (if patent owner or applicant does not reside or have place of business in the US):

U.S. Patent Number:

Expiration Date:

Type of Patent--Indicate all that apply:

1. Drug Substance(Active Ingredient) ___Y ___N
2. Drug Product(Composition/Formulation) ___Y ___N
3. Method of Use ___Y ___N

a. If patent claims method(s) of use, please specify approved method(s)of use or method(s) of use for which approval is being sought that are covered by patent_____

Name of Patent Owner:

U.S. Agent (if patent owner or applicant does not reside or have place of business in the US):

---

## B. The following declaration statement is required if any of the above listed patents have Composition/Formulation or Method of Use claims.

This format repeats to allow up to three patents. If there are additional patents, please copy and attach.

The undersigned declares that the above stated United States Patent Number Re. 36,520 covers the composition, formulation and/or method of use of Zocor® (name of drug product). This product is:

- X currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act)

OR

- ___the subject of this application for which approval is being sought.)

---

The undersigned declares that the above stated United States Patent Number _____ covers the composition, formulation and/or method of use of _____(name of drug product). This product is:

- ___currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act)

OR

- ___the subject of this application for which approval is being sought.)

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The undersigned declares that the above stated United States Patent Number _____ covers the composition, formulation and/or method of use of _____(name of drug product). This product is:

- ___currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act)

OR

- ___the subject of this application for which approval is being sought.)

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Signed: Carol S. Quagliato  Carol S. Quagliato
Date: January 18, 2000
Title (optional): Senior Patent Attorney
Telephone Number (optional): (732)-594-3809

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A copy of the above information should be submitted to the NDA with the original application or as correspondence to an existing NDA. For patents issued after the NDA is filed or approved, the applicant is required to submit the information within 30 days of the date of issuance of the patent.

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