

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-261/S009

Trade Name: Lescol Capsules

Generic Name: flusvastatin sodium

Sponsor: Sandoz Pharmaceutical Corporation

Approval Date: February 8, 1996

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 20-261/009

CONTENTS

Reviews / Information Included in this NDA Review.

| | |
|--|----------|
| Approval Letter | X |
| Approvable Letter | |
| Labeling | |
| Medical Review(s) | |
| Chemistry Review(s) | X |
| Pharmacology Review(s) | |
| Statistical Review(s) | |
| Microbiology Review(s) | |
| Clinical Pharmacology/ Biopharmaceutics Review(s) | |
| Administrative/Correspondence Document(s) | X |

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 20-261/S009

APPROVAL LETTER

FEB - 8 1996

NDA 20-261/S-009

Sandoz Pharmaceuticals Corporation
Attention: Robert J. Clark
59 Route 10
East Hanover, New Jersey 07936-1080

Dear Mr. Clark:

Please refer to your September 26, 1995, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lescol® (fluvastatin sodium) Capsules.

The supplemental application provides for the replacement of the _____ as the regulatory method for determination of water content in 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, please contact Ms. Julie Rhee, Consumer Safety Officer, at (301) 443-3510.

Sincerely yours,



Stephen K. Moore, Ph.D.
Acting Supervisory Chemist II
Division of New Drug Chemistry II
Office of New Drug Chemistry, OPS,
at Division of Metabolism and
Endocrine Drug Products (HFD-510)
Center for Drug Evaluation and Research



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NDA 20-261/S-009

cc:

Original NDA 20-261
HFD-510/Div. Files
HFD-510/Chem/Berlin
HFD-511/CSO/J.Rhee
HFD-80
DISTRICT OFFICE
HFD-232

m 2-7-96

drafted: JRhee/February 6, 1996/c:wpfiles/supplement/20261s09.ap
r/d Initials:EGalliers 2-7-96/WBerlin 2-7-96/SMoore 2-7-96
F/T by: JRhee 2-7-96 c:wpfiles/supplement/20261s09.ap

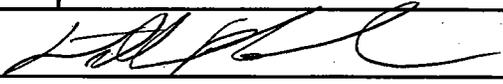
APPROVAL

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 20-261/S009

CHEMISTRY REVIEW(S)

ORIGINAL
JAN 29 1996

| | | | |
|---|---|--|-------------------------|
| CHEMISTS REVIEW | | 1. ORGANIZATION DMEDP II, HFD-510 | 2. NDA NUMBER 20,261 |
| 3. NAME AND ADDRESS OF APPLICANT Sandoz Pharmaceutical Corporation 59 Route 10 East Hanover, NJ 07936-1080 | | 4. SUPPLEMENT NUMBER, DATE SCS-009, 9/26/95 | |
| 5. NAME OF THE DRUG Fluvastatin Sodium | 6. PROPRIETARY NAME Lescol | 7. AMENDMENTS, REPORT, DATE | |
| 8. SUPPLEMENT PROVIDES FOR Replacement of _____ as the regulatory method for determination of water in the drug substance. | | | |
| 9. PHARMACOLOGICAL CATEGORY Antihypercholestremic | 10. HOW DISPENSED RX | 11. RELATED IND, NDA, DMF | |
| 12. DOSAGE FORM Tablets for Oral ingestion | 13. POTENCY 20, 40 mg | | |
| 14. CHEMICAL NAME AND STRUCTURE see chemistry review #1. | | | |
| 15. COMMENTS Both of the methods were described in the submission. The _____ is equivalent _____. Analysis of water in / samples of Fluvastatin sodium (Batch # 945066) were provided, and averaged _____ with _____ maximum and _____ minimum values being recorded (table p. 13). Comparative data for water content determined by both methods for / batches (table p. 15) were provided, and the mean difference between the two methods was _____. For the same / batches, the water content by the _____ method averaged _____ with _____ maximum and _____ minimum values. Thus, it was demonstrated that the _____ method is more variable and that overall, the methods are roughly equivalent. As the _____ method is not specific for water, The _____ is the method of choice. The specification for the water content remains unchanged at NMT _____. | | | |
| 16. CONCLUSION AND RECOMMENDATION The implementation of the _____ method for determination of water in Fluvastatin Sodium Drug Substance is acceptable. Issue an approval letter. | | | |
| 17. NAME WILLIAM K. BERLIN | 18. REVIEWERS SIGNATURE  | 19. DATE COMPLETED 1/29/96 | |
| DISTRIBUTION: ORIGINAL JACKET | | CSO | REVIEWER |
| | | | DIVISION FILE |

Stephen Moore
1-29-96

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 20-261/S009

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date OCT 13 1995

NDA No. 20-261

Sandoz Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936

Attention: John Taylor, PhD, Director

Dear-Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: LESCOL

NDA Number: 20-261

Supplement Number: S-009

Date of Supplement: September 26, 1995

Date of Receipt: October 2, 1995

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control Room 14B-03
5600 Fishers Lane, HFD-510
Rockville, MD 20857

Sincerely yours,

Supervisory Consumer Safety Officer
Division of Metabolism and Endocrine Drug Products
Center for Drug Evaluation and Research

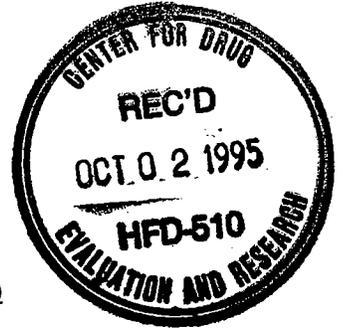
SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10, EAST HANOVER, NEW JERSEY 07936-1080

NDA NO. 20261 SUPPL. NO. 009 ORIGINAL
NDA SUPPL. FOR SCS  **SANDOZ**

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL 201 503 7500
FAX 201 503 6325

September 26, 1995



Solomon Sobel, MD
Director
Division of Metabolism and
Endocrine Drug Products/HFD-510
Office of Drug Evaluation II
Attn: Document Control Room 14B-04
Center for Drug Evaluation and
Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA No. 20-261
LESCOL® (fluvastatin sodium)
Capsules

SUPPLEMENTAL NEW
DRUG APPLICATION

CHEMISTRY

Dear Dr. Sobel:

In accordance with 21 CFR §314.70(b)(1)(ii), Sandoz Pharmaceuticals Corporation herewith submits a supplemental new drug application for Lescol® (fluvastatin sodium) capsules. This supplement provides for a new regulatory method for the determination of residual moisture in the drug substance.

Currently, residual moisture is measured _____ method. This supplement proposes to change to _____ to determine residual moisture. The proposed _____ method uses a much larger sample size. This should help to assure that the data obtained from this test is accurate and representative of the drug substance itself and less sensitive to conditions/analysis times within the testing facility.

A complete list of supportive documentation can be found in the table of contents. A certified copy of this NDA supplement is being provided to our local district office in compliance with the preapproval inspection requirements.

If you have any questions or comments please contact me at (201) 503-7005.

REVIEWS COMPLETED

CSO ACTION:

LETTER

N.A.I.

CSO INITIALS

DATE

Sincerely,

Robert J. Clark
Senior Manager, Regulatory
Manufacturing and Controls

Attachments

Submitted in triplicate

cc Mr. Matthew Lewis, Newark District Office