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

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Reviews / Information Included in this NDA Review.	
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Medical Review(s)	
Chemistry Review(s)	X
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Administrative/Correspondence Document(s)	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-261/S009

APPROVAL LETTER

ORIGINAL

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 [redacted] 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 2-7-96

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

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

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	2. NDA NUMBER
	DMEDP II, HFD-510	20,261
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Sandoz Pharmaceutical Corporation 59 Route 10 East Hanover, NJ 07936-1080		SCS-009, 9/26/95
5. NAME OF THE DRUG	6. PROPRIETARY NAME	7. AMENDMENTS, REPORT, DATE
Fluvastatin Sodium	Lescol	

8. SUPPLEMENT PROVIDES FOR

Replacement of [redacted] as the regulatory method for determination of water in the drug substance.

9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
Antihypercholestremic	RX	
12. DOSAGE FORM	13. POTENCY	
Tablets for Oral ingestion	20, 40 mg	

14. CHEMICAL NAME AND STRUCTURE

see chemistry review #1.

15. COMMENTS

Both of the methods were described in the submission. The [redacted] is equivalent [redacted]. Analysis of water in [redacted] samples of Fluvastatin sodium (Batch # 945066) were provided, and averaged [redacted] with [redacted] maximum and [redacted] minimum values being recorded (table p. 13). Comparative data for water content determined by both methods for [redacted] batches (table p. 15) were provided, and the mean difference between the two methods was [redacted] For the same [redacted] batches, the water content by the [redacted] method averaged [redacted] with [redacted] maximum and [redacted] minimum values. Thus, it was demonstrated that the [redacted] method is more variable and that overall, the methods are roughly equivalent. As the [redacted] method is not specific for water, The [redacted] is the method of choice. The specification for the water content remains unchanged at NMT [redacted]

16. CONCLUSION AND RECOMMENDATION

The implementation of the [redacted] method for determination of water in Fluvastatin Sodium Drug Substance is acceptable. Issue an approval letter.

17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
WILLIAM K. BERLIN		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

FORM FDA 3217c (3/93)

NDA NO. 20261 SUPPL. NO. 009 ORIGINAL

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

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