CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-261/S007

Trade Name: Lescol Capsules

Generic Name: flusvastatin sodium

Sponsor: Sandoz Pharmaceutical Corporation

Approval Date: October 17, 1995

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-261/007

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/S007

APPROVAL LETTER

NDA 6-035/S-057
NDA 17-247/S-040
NDA 20-261/S-007

OCT 17 1995

Sandoz Pharmaceuticals Corporation
Attention: John Taylor, Ph.D.
Director, Regulatory Manufacturing and Controls
59 Route 10
EAST HANOVER NJ 07936

Dear Dr. Taylor:

Please refer to your April 17, 1995, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following drug products:

Methergine	(methylergonovine maleate)	NDA 6-035
Sanorex	(mazindol tablets)	NDA 17-247
Lescol	(fluvastatin sodium tablets)	NDA 20-216

These supplemental applications provide for the deletion of the pH specification from the specifications [redacted] excipient of the drug product.

We have completed the review of these supplemental applications and they are approved. However we recommend that you develop an SOP protocol, including a pH test, for evaluation of new sources/suppliers [redacted]

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. Christina Kish at (301) 443-3510.

Sincerely yours,

Stephen K. Moore

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

cc:
Arch NDA(3)
HFD-510(3)
DISTRICT OFFICE
HFD-510/MRhee/HDavies/WBerlin/SMarkofsky/SMoore
HFD-80
HFD-510/CKish/10.16.95/n6035.57
Concurrences:HDavies 10.16.95/EGalliers 10.16.95/MRhee 10.16.95
SUPPL. APPROVALS

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-261/S007

CHEMISTRY REVIEW(S)

ORIGINAL

OCT 16 1995

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-007, 4/17/95

5. NAME OF THE DRUG	6. PROPRIETARY NAME	7. AMENDMENTS, REPORT, DATE
Fluvastatin Sodium	Lescol	

8. SUPPLEMENT PROVIDES FOR

Deletion of the pH test from the specifications [redacted] an excipient of the drug product.

9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
Antihypercholestremic	RX	Sandoz NDAs: [redacted]

12. DOSAGE FORM	13. POTENCY
Tablets for Oral ingestion	20, 40 mg

14. CHEMICAL NAME AND STRUCTURE

see chemistry review #1.

15. COMMENTS

Refer to Chemist's review of NDA [redacted] reviewed by Wilson Brannon (HFD-120) on 8-23-95. This is a bundled review (draft copy attached). The review performed by Dr. Brannon is deemed to be applicable to the subject Lescol Tablets.

16. CONCLUSION AND RECOMMENDATION

Issue approval letter. The following comment should be communicated to the applicant: "We recommend that you develop an SOP protocol, including a pH test, for evaluation of new sources/ suppliers [redacted]

17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
WILLIAM K. BERLIN	William K. Berlin	10/16/95

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

R/D initialed by: Stephen Moore 10/16/95

5 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-261
5007

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-261/S007

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date APR 24 1995

NDA No. 20-261

Sandoz Pharmaceuticals Inc.
59 Route 10
East Hanover, NJ 07936-1080

Attention: John Taylor, PhD, Director

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Lescol (Fluvastatin sodium)

NDA Number: 20-261

Supplement Number: S-007

Date of Supplement: April 17, 1995

Date of Receipt: April 20, 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

ORIGINAL SCS

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

SANDOZ

NDA NO. 20261 REF. NO. 007

NDA SUPPL FOR SCS

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL 201 503 7500
FAX 201 503 6325

April 17, 1995

NDA SUPPLEMENT

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

CENTER FOR DRUG REC'D APR 20 1995 HFD-510 EVALUATION AND RESEARCH

Dear Dr. Sobel:

In accordance with 21 CFR 314.70, Sandoz Pharmaceuticals Corporation herewith submits a supplemental new drug application for LESCOL® (fluvastatin sodium) Capsules. This supplement provides for deletion of the pH test from the specifications of an excipient of the drug product —

Currently the Sandoz specifications — include a test for pH, although it is not known why the test was added originally. We have not failed a batch based on the pH test, and the pH of — does not affect the product. Furthermore, the pH test is not a compendial test found in the USP monograph —

For the aforementioned reasons we propose deleting the pH test from the specifications — All other tests will remain the same. For your information we are enclosing pH test results and a copy of the Sandoz current control procedures and specifications —

This supplement is being concurrently submitted to several other NDAs since — used in many of our products. In the interest of efficiency, Sandoz has requested a coordinated review through the office of the Director of Chemistry.

A certified copy of this NDA supplement is being provided to your district office in compliance with the preapproval inspection requirements. If you have any questions or comments regarding this submission, please contact me at (201) 503-6284.

REVIEWS COMPLETED
CSO ACTION: ☑ LETTER ☐ N.A.I.
DATE 10/11/95
CSO INITIALS

Sincerely,

Norma P. Loeffler
Senior Manager
Regulatory Manufacturing and Controls

/meb
Attachments
cc: Marilyn Apfel, MD, HFD-004 (letter only)
Robert Jerrusi, MD, HFD-004 (letter only)
Matthew Lewis, Newark District Office