CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-261/S-003

Trade Name: Lescol

Generic Name: fluvastatin sodium

Sponsor: Sandoz Pharmaceuticals Corporation

Approval Date: November 28, 1994

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-003

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	X
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:

20-261/S-003

APPROVAL LETTER

NDA 20-261/S-003

NOV 28 1994

Sandoz Pharmaceuticals Corporation
Attention: Robert J. Clark, Senior Manager
Regulatory Manufacturing and Controls
59 Route 10
EAST HANOVER NJ 07936-1080

Dear Mr. Clark:

Please refer to your May 25, 1994, supplemental new drug application submitted under section 505(b) of the Federal Food, Dug, and Cosmetic Act for Lescol (fluvastatin sodium) Capsules.

The supplemental application provides for the introduction of a new child-resistant closure system [redacted].

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Should you have any questions, please contact:

Mr. Stephen T. Trostle
Consumer Safety Officer
Telephone: 301-443-3520.

Sincerely yours,

RCB

Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products (HFD-510)
Center for Drug Evaluation and Research

cc: Original NDA
DISTRICT OFFICE
HFD-80
HFD-510
HFD-510/SAurecchia/MRhee/EBarbehenn/XYsern
HFD-510/STrostle/11/21/94/stt/ft/11/23/94 \N20261AP.003

ST 11/23/94

Concurrence: MRhee, YChiu 11.21; EGalliers 11.23.94

SUPPLEMENT APPROVAL (AP/S-003)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-003

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

1. Organization
DMEDP HFD-510

2. NDA Number
20-261

NOV 18 1994

3. Name amd Address of Applicant
Sandoz Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936
201-503-7500

4. Supplement
S-003
5-25-94

ORIGINAL

5. Name of Drug
Lescol

6. Nonproprietary Name
fluvastatin sodium capsules

7. Supplement Provides For
Introduction of a new child-resistant closure system

8. Amendment

9. Pharmacological Category
Lipid altering agent

10. How Dispensed
RX

11. Related
IND/NDA/DMF

12. Dosage form
Capsules for oral administration

13. Potency
20 and 40mg/capsule

14. Chemical Name and Structure
6-heptenoic acid, 7-[3-(4-fluorophenyl)-1-(methylethyl)-1H-indole-2-yl]-3,5-dihydroxy-, monosodiumm salt

15. Comments
This supplement was submitted to replace current child-resistant closure system with a new one which has will be the same as those previously approved. The firm claims that the drug product will not come in contact with the new closure syatem as those previously approved. (cont'd)

16. Conclusion and Recommendation
The supplement is approvable. Issue an approval letter.

17. Name
Moo-Jhong Rhee, Ph.D.

Reviewer's Signature

Date
11-18-94

Distribution **Original Jacket** **Reviewer** **Division File**
R/D initialed by
SL.217
11/18/94

2 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-261 / SOQB

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-003

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date JUN - 1 1994

NDA No. 20-261

Sandoz Pharmaceuticals Corp.
59 Route 10
East Hanover, NJ 07936

Attention: Robert J. Clark

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: LESCOL

NDA Number: 20-261

Supplement Number: S-003

Date of Supplement: May 25, 1994

Date of Receipt: June 01, 1994

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)

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

SANDOZ

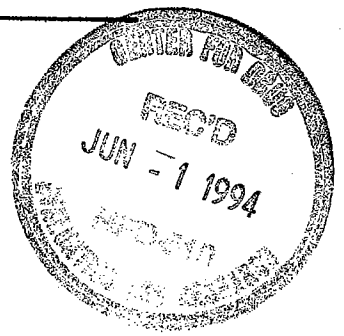
NDA NO. 20261 REF. NO. 003

NDA SUPPL FOR SCP

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL. 201 503 7500
FAX 201 503 6325

ORIGINAL



May 25, 1994

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(c), Sandoz Pharmaceuticals Corporation herewith submits a supplemental new drug application for Lescol® (fluvastatin) capsules. This supplement provides for the use of [redacted] instead of [redacted] Approval of this supplement will also permit Sandoz to use [redacted] as vendors for the container closure system.

The proposed materials have been evaluated as comparable to the currently used container closure system. They have also been USP tested and found to be acceptable. All of the proposed [redacted] Therefore, the drug product will not be coming in contact with any new materials.

We feel that equivalency between the current and proposed container closure systems has been demonstrated, and more than adequate documentation is being submitted in support of this change.

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.

Solomon Sobel, MD NDA No. 20-261

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

Sincerely,

Robert J. Clark
Senior Manager, Regulatory
Manufacturing and Controls

/dlf
Attachments
Submitted in duplicate

cc Mr. Matthew Lewis, Newark District Office