

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-261/S-004

Trade Name: Lescol

Generic Name: fluvastatin sodium

Sponsor: Sandoz Pharmaceuticals Corporation

Approval Date: November 10, 1994

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-004

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-004

APPROVAL LETTER

NDA 20-261 / S-004

NOV 10 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 our October 14, 1994, 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 _____
_____ from the drug
substance _____.

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

In addition, please provide a revised _____
_____.

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,

St. Trostle
Jan 11-8-94

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
HFD-510/STrostle/11/02/94/ft/stt/11/08/94 \N20261AP.004

Concurrence: *STu/02/94* MRhee, YChiu 11.02; JShort for EGalliers 11.08.94

SUPPLEMENT APPROVAL (AP/S-004)

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-261/S-004

CHEMISTRY REVIEW(S)

OCT 27 1994

CHEMIST'S REVIEW

1. Organization
DMEDP HFD-510

2. NDA Number
20-261

3. Name and Address of Applicant
Sandoz Research Institute
Route 10
East Hanover, NJ 07936
201-503-7500

ORIGINAL

4. Supplement
S-004
10-14-94

5. Name of Drug
Lescol

6. Nonproprietary Name
Fluvastatin sodium capsules

7. Supplement Provides For:

8. Amendment

the drug substance in

9. Pharmacological Category
Lipid altering agent

10. How Dispensed
RX

11. Related
IND/NDA/DMF

12. Dosage form
Capsules

13. Potency
20mg, 40mg

14. Chemical Name and Structure

6-heptenoic acid, 7-[3-(4-fluorophenyl)-1-(1-methylethyl)-1H-indol-2-yl]-3,5-dihydroxy-, monosodium salt, [R*,S*-(E)]-(±)-;

C₂₄H₂₅FNNaO₄
MW:433.45

15. Comments

16. Conclusion and Recommendation

From chemistry, manufacturing and controls point of view, this supplement is approvable. Issue an approval letter with a request that the firm submit a revised reflecting the change.

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

Reviewer's Signature

Date
10-27-94

Distribution
R/D initialed by
SL.213

Original Jacket

Reviewer

Division File

M. Chiu
10/27/94

(cont'd)

The firm (Robert Clark, 201-503-6325) gave me a call on 10-6-94 saying that they

After discussion with Dr. Chiu of this Division, I called the firm on 10-14-94 and told him that he should submit "a prior approval supplement" with expedite review request. This supplement was submitted in response to that request.

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APPLICATION NUMBER:

20-261/S-004

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date OCT 20 1994

NDA No. 20-261

Sandoz Pharmaceuticals Corporation
59 Route 10
E. 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-004

Date of Supplement: October 14, 1994

Date of Receipt: October 17, 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

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

S SANDOZ

NDA NO. 20261 SUPP. NO. 004

NDA SUPPL FOR SCS

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL 201 503 7500
FAX 201 503 6325

October 14, 1994

ORIGINAL

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

SUPPLEMENTAL NEW DRUG APPLICATION

EXPEDITED REVIEW REQUESTED

CHEMISTRY

Solomon Sobel, M.D.
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

Dear Dr. Sobel:

In accordance with 21 CFR §314.70(b)(1)(iii), Sandoz Pharmaceuticals Corporation herewith submits a supplemental new drug application for Lescol® (fluvastatin sodium) Capsules. This supplement provides

_____ (fluvastatin sodium).



Recently, Sandoz _____

_____ / fluvastatin sodium / _____

The above mentioned situation has been discussed in telephone conversations between myself and Dr. Moo Jhong Rhee, Reviewing Chemist at the Division of Metabolism and Endocrine Drug Products on October 6 and 14, 1994. During the October 14, 1994 telephone conversation, Dr. Rhee advised me to submit a "prior approval supplement" so as to have the _____

Solomon Sobel, MD

NDA No. 20-261

We are requesting expedited review of this supplement such that

~~_____~~
also like to thank Dr. Rhee for graciously volunteering to take care of this matter expeditiously.

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 additional questions or comments, please contact me at (201) 503-7005.

Sincerely,



Robert J. Clark
Senior Manager, Regulatory
Manufacturing and Controls

Attachments

Submitted in duplicate

cc: Mr. Matthew Lewis, Newark District Office

Desk Copy: Dr. Moo Jhong Rhee, HFD-510

REVIEWS COMPLETED	
AP 11/10/94	
CSO ACTION:	
<input checked="" type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I.
SC 11/14/94	
INITIALS	DATE