CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-261/S-013

Trade Name: Lescol

Generic Name: (fluvastatin sodium)

Sponsor: Sandoz Pharmaceuticals Corporation

Approval Date: June 16, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-013

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:

20-261/S-013

APPROVAL LETTER

NDA 20-261/S-013

JUN 16 1997

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

Dear Mr. Clark:

Please refer to your supplemental new drug application dated December 10, 1996, received December 16, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lescol® (fluvastatin sodium) Capsules.

We also refer to your amendment dated June 13, 1997.

The User Fee goal date for this application is June 16, 1997.

The supplemental application provides for the

We have completed the review of this supplemental application and it is approved. However, we remind you that the

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. Margaret Simoneau, Consumer Safety Officer, at 301-443-3510.

Sincerely yours,

Stephen K. Moore 6/16/97

Stephen K. Moore, Ph.D.
Chemistry Team Leader I, DNDCII
Division of Metabolic and Endocrine Drug
Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc: Original NDA 20-261
HFD-510
HFD-510/EBerlin/SMoore
HFD-510/MSimoneau
HFD-820/ONDC Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted by: JWeber 6/16/97

cc:WBerlin 6/16/SMoore 6/16/EGalliers 6/16/97

final: JWeber 6/16/97

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-013

CHEMISTRY REVIEW(S)

ORIGINAL

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER JUN 16 1997
	DMEDP II, HFD-510	20-261
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Sandoz Pharmaceuticals Corporation 59 Route 10 East Hanover, NJ 07936		SCS-013 12-10-97
5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE
Lescol® Capsules	fluvastatin sodium	6-13-97
8. SUPPLEMENT PROVIDES FOR		

9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
antihypercholestremic	RX	
12. DOSAGE FORM	13. POTENCY	
Capsules, oral	20, 40 mg	
14. CHEMICAL NAME AND STRUCTURE		
See Chemistry Review #1		

15. COMMENTS

The sponsor has requested the

It should be noted that this acceptance criteria is currently in use in the

16. CONCLUSION AND RECOMMENDATION

The sponsor should be permitted

17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
WILLIAM K. BERLIN		6-16-97

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

Stephen K. Moore
6/16/97

Approved

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-013

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date DEC 19 1996

NDA No. 20-261

SANDOZ PHARMACEUTICALS CORPORATION
59 Route 10
East Hanover, NJ 07936

Attention: Robert J. Clark, Senior Manager, Regulatory Manufacturing and Controls

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: LESCOL

NDA Number: 20-261

Supplement Number: S-013

Date of Supplement: December 10, 1996

Date of Receipt: December 16, 1996

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on FEB 14 1997 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products
Attention: Document Control Room
5600 Fishers Lane, HFD-510
Rockville, MD 20857

Sincerely yours,

Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office Drug Evaluation II
Center for Drug Evaluation and Research

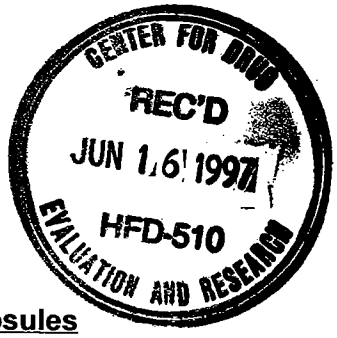
NDA SUPPL AMENDMENT
SCS-013 BC

ORIGINAL

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

NOVARTIS



June 13, 1997

Solomon Sobel, MD
Director
Division of Metabolic 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/S-013
LESCOL®
(fluvastatin sodium) Capsules

AMENDMENT TO A PENDING
SUPPLEMENTAL NEW DRUG APPLICATION

CHEMISTRY

Dear Dr. Sobel:

Please refer to the above cited supplemental new drug application which was submitted to the Agency on December 10, 1996 for the [redacted] Please also refer to the telephone conversations between Dr. William Berlin, Reviewing Chemist at the Division of Metabolic and Endocrine Drug Products and Mr. Robert Clark and Ms. Donna Kapples on June 3, 10, 11, 1997. During those telephone conversations, Dr. Berlin agreed to approve the pending supplement if the [redacted]

This letter serves as a commitment to [redacted] The analytical method that will be employed will be similar to the current method which is being used to [redacted] data) will be provided in the next annual report for Lescol® Capsules.

If you have any questions or comments, please contact me at (973) 503-6929.

Sincerely,

Donna Kapples

Donna Kapples
CMC Project Manager
Drug Regulatory Affairs

REVIEWS COMPLETED
CSO ACTION:
☐ LETTER ☑ N.A.I. ☐ MEMO
CSO INITIALS Mar 6/27/97 DATE

Supplement reviewed w/ FAX copy of this letter
which is Acceptable
NAI 6/26/97

noted EKB 6/26/97

/ajm
Attachments
Submitted in duplicate
cc: Ms. Regina Brown, New Jersey District Office, North Brunswick Resident Post
Desk Copy: Dr. William Berlin, HFD-510

ORIGINAL

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

SANDOZ

NDA NO: 20261 REF. NO. 013
NDA SUPPL FOR SCS

DRUG REGISTRATION & REGULATORY AFFAIRS

December 10, 1996

TEL. 201 503 7500
FAX 201 503 6325

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 EVALUATION AND RESEARCH
RECD
DEC 16 1996
HFD-510

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 for the the fluvastatin sodium

fluvastatin sodium

The specification set for was

Since initial product release, several hundred batches of this drug substance have been manufactured. There have been no batch failures Sandoz has much experience manufacturing this drug substance and would propose We also feel this action is justifiable

Please find enclosed which we feel supports our proposal. This along with additional information can be found in the following pages. 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. ☐ MEMO
mas 6/27/97
CSO INITIALS 6/16/97 DATE
AP letter

Sincerely,

Robert J. Clark
Senior Manager, Regulatory
Manufacturing and Controls

Donna Kapples
201-503-6529
Novartis
6/13/97
"committing letter"

Attachments
Submitted in duplicate
cc: Mr. Matthew Lewis, Newark District Office