CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-261/S-014

Trade Name: Lescol

Generic Name: (fluvastatin sodium)

Sponsor: Sandoz Pharmaceuticals Corporation

Approval Date: April 21, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-014

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Reviews / Information Included in this NDA Review.	
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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-014

APPROVAL LETTER

NDA 20-261/S-014

APR 21 1997

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

Dear Mr. Clark:

Please refer to your supplemental new drug application dated January 21, 1997, received January 23, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lescol® (fluvastatin sodium) Capsules.

The User Fee goal date for this application is July 23, 1997.

The supplemental application provides for [redacted] of the 20 mg and 40 mg strength capsules. The application was submitted as a change being effected under 21 CFR 314.70(c) and was implemented on March 1, 1997.

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

Sincerely yours,

Stephen K. Moore 4/21/97

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

NDA Orig. 20-261
HFD-510
HFD-510/WBerlin/SMoore
HFD-511/MSimoneau
HFD-92/DDM-DIAB
DISTRICT OFFICE

cc:WBerlin 4/9/SMoore 4/18/EGalliers 4/8/97

Final:JWeber 4/21/97

JWeber/N20261/014/04/08/97

Approval Date:

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-014

CHEMISTRY REVIEW(S)

ORIGINAL

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER FEB 13 1997
	DMEDP II, HFD-510	20-261
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Sandoz Pharmaceuticals Corp. 59 Route 10 East Hanover, NJ 07936-1080		SCP-014 1-21-97
5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE
Lescol® Capsules	Fluvastatin Sodium	
8. SUPPLEMENT PROVIDES FOR		
; of the 20 and 40 mg-strength capsules.		
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
antihypercholestremic	OTC	
12. DOSAGE FORM	13. POTENCY	
Capsules, oral	20, 40 mg	
14. CHEMICAL NAME AND STRUCTURE		
See Chemistry Review #1		
15. COMMENTS		
The sponsor the 20 and 40 mg capsules of Lescol®, as a prior approval supplement. Robert Clark of Sandoz notified this reviewer and Dr. Stephen Moore by telephone (8-26-96) that the		
16. CONCLUSION AND RECOMMENDATION		
The sponsor has provided examples of the with the data to be provided in the annual reports. This supplement is acceptable as a "CBE" because the Issue an approval letter.		
17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
WILLIAM K. BERLIN		2-13-97
DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE		

Stephen K. Moore
2/13/97

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-014

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date FEB 5 1997

NDA No. 20-261

SANDOZ PHARMACEUTICALS CORPORATION
59 Route 10
East Hanover, New Jersey 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 (fluvastatin sodium) Capsules

NDA Number: 20-261

Supplement Number: S-014

Date of Supplement: January 21, 1997

Date of Receipt: January 23, 1997

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on MAR 24 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 SUPPLEMENT ORIGINAL

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

SANDOZ

NDA NO. 20261 REF. NO. 014
NDA SUPPL FOR SE8

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL. 201 503 7500
FAX 201 503 6325

2/10/97

January 21, 1997

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

SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED

FINAL PRINTED LABELING

Dear Dr. Sobel:

In accordance with 21 CFR §314.70(c), Sandoz Pharmaceuticals Corporation herewith submits a supplemental new drug application for Lescol® (fluvastatin sodium) capsules. This supplement provides for [redacted] for the 20 and 40 mg Capsules.

Currently, Lescol® Capsules are being marketed [redacted] bottles with a 30 capsule count and a [redacted] with a 100 capsule count. Sandoz has made special arrangements with [redacted] The [redacted] will be distributed to that organization only. The proposed [redacted] will be the same [redacted] Please refer to the telephone conversation between the undersigned and Dr. William Berlin (reviewing chemist, Division of Metabolic and Endocrine Drug Products) which took place on August 26, 1996. During that conversation the above scenario was described to Dr. Berlin. Following additional discussions with Dr. Moore (Dr. Berlin's Supervisor), it was decided that the proposed [redacted] could be submitted as *"changes being effected"*. Please note that additional discussions were conducted regarding a [redacted] which will be submitted in a separate *"prior approval"* NDA supplement.

S. Sobel, MD NDA # 20-261

Therefore, please find enclosed

We are also providing the Agency with a stability commitment for the proposed We plan to implement this change on or about March 1, 1997.

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

Sincerely,

Robert J. Clark
Senior Manager, Regulatory
Manufacturing and Controls

Attachments
Submitted in duplicate
12 copies of final printed labeling

REVIEWS COMPLETED

CSO ACTION:
[X] LETTER [ ] N.A.I. [ ] MEMO

CSO INITIALS 4/21/97 DATE