

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-261/S-010

Trade Name: Lescol

Generic Name: (fluvastatin sodium)

Sponsor: Sandoz Pharmaceuticals Corporation

Approval Date: April 30, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S-010

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Medical Review(s)	
Chemistry Review(s)	X
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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-010

APPROVAL LETTER

NDA 20-261/S-010

APR 30 1996

Sandoz Pharmaceuticals Corporation
Attention: Mr. Robert J. Clark
Senior Manager, Regulatory Manufacturing and Controls
59 Route 10
East Hanover, New Jersey 07936-1080

Dear Mr. Clark:

Please refer to your February 2, 1996, 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

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. Julie Rhee, Consumer Safety Officer, at (301) 443-3510.

Sincerely yours,

Stephen K. Moore 4/30/96

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



cc:

Original NDA 20-261
HFD-510/Div. Files
HFD-510/Moore/Berlin
HFD-511/J.Rhee
HFD-80
DISTRICT OFFICE
HFD-232

drafted: JRhee/April 25, 1996/ c:wpfiles/supplement/20261s10.cap
r/d Initials: EGalliers 4-29-96/WBerlin 4-30-96/SMoore 4-30-96
final: JRhee 4-30-96 *jr* 4-30-96

APPROVAL (S-010)

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-261/S-010

CHEMISTRY REVIEW(S)

CHEMISTS REVIEW		1. ORGANIZATION DMEDP II, HFD-510	2. NDA NUMBER 20-261	APR 22 1996
3. NAME AND ADDRESS OF APPLICANT Sandoz Pharmaceuticals Corporation 59 Route 10 East Hanover, NJ 07936		4. SUPPLEMENT NUMBER, DATE SCM-010 02-02-96		
5. NAME OF THE DRUG Fluvastatin sodium	6. PROPRIETARY NAME Lescol	7. AMENDMENTS, REPORT, DATE		
8. SUPPLEMENT PROVIDES FOR An additional _____ at the _____				
9. PHARMACOLOGICAL CATEGORY antihypercholesteremic	10. HOW DISPENSED RX	11. RELATED IND, NDA, DMF		
12. DOSAGE FORM Oral capsules	13. POTENCY 20, 40, 80 mg			
14. CHEMICAL NAME AND STRUCTURE See Chemistry Review #1				
15. COMMENTS <p>_____ location. Additionally, three months accelerated stability data were provided for three commercial-scale lots of the Drug Substance</p> <p>_____ stability data. The sponsor has committed to continue these stability studies and to routine stability testing in the future.</p> <p>_____ The remainder of the stability data will be provided in the annual reports. (continued next page)</p>				
16. CONCLUSION AND RECOMMENDATION The data provided in the supplement are adequate. Issue an approval letter.				
17. NAME WILLIAM K. BERLIN	18. REVIEWER'S SIGNATURE 	19. DATE COMPLETED 4-19-96		
DISTRIBUTION: ORIGINAL JACKET		CSO	REVIEWER	DIVISION FILE

Stephen More
4/22/96

Comments continued:

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Environmental Assessment information for this NDA has been updated (see SE2-006 submission dated 3-23-95, Chemistry review 7-11-95), and is adequate for this supplement. Additionally, the sponsor provided a copy of a letter

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

VS

ESTABLISHMENT EVALUATION REQUEST

TEST TYPE (Check One) <input checked="" type="checkbox"/> Original <input type="checkbox"/> Follow-Up <input type="checkbox"/> FUR	DATE 04-02-1996	PHONE # 301 443-1136	EER ID #
REQUESTOR'S NAME William K. Berlin	DIVISION ONDCII@DMEDP		MAIL CODE HFD-510
APPLICATION AND SUPPLEMENT NUMBER NDA 20-261, SCM-010			
BRAND NAME Lescol	ESTABLISHED NAME Fluvastatin Sodium		
DOSAGE AND STRENGTH Capsules, 20, 40, 80 mg			STERILE <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
PROFILE CLASS CSN	PRIORITY CLASSIFICATION (See SMG CDER-4820.3)		
APPLICANT'S NAME Sandoz Pharmaceuticals Co.			
ADDRESS 59 Route 10 East Hanover NJ 07936			
COMMENTS (NDA 19-758/S-024). Please expedite User fee Goal Date 8/2/96 Div. Goal Date 6/14/96			

FACILITIES TO BE EVALUATED

(Name and Complete Address)	RESPONSIBILITY	DMF NUMBER/ PROFILE CDE	F KEY/ CIRTS ID	HFD-324 USE ONLY
1. /	/	/	/	DC 2-16-95
2.				
3.				
4.				
5.				

FOR HFD-324 USE ONLY	CSO <i>Therette Ferguson</i>	DATE RECEIVED 4/8/96
	CGMP COMPLIANCE STATUS <i>Acceptable</i>	DATE 4/9/96

4 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

**CENTER FOR DRUG EVALUATION AND
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APPLICATION NUMBER:

20-261/S-010

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date FEB - 8 1996

NDA No. 20-261

SANDOZ PHARMACEUTICALS CORPORATION
59 Route 10
East Hanover, New Jersey 07936

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-010

Date of Supplement: February 2, 1996

Date of Receipt: February 5, 1996

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on April 5, 1996 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

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

NDA NO. 20261 REC. NO. 010 ORIGINAL
NDA SUPPL. FOR SCM  **SANDOZ**

NDA SUPPLEMENT

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL 201 503 7500
FAX 201 503 6325

February 2, 1996

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

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

SUPPLEMENTAL NEW
DRUG APPLICATION

CHEMISTRY



Dear Dr. Sobel:

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

Currently the drug substance is /

Please find enclosed documentation in support of the / of fluvastatin sodium / Please also note that this facility has already been approved to /

/ Please find enclosed a copy of the approval letter for the /

/ Please see pages 498 and 513 for an explanation of the changes to the respective procedures. /

S. Sobel, MD

NDA No. 20-261

Please refer to the telephone conversation between the undersigned and Dr. William Berlin on August 22, 1995 (please see the enclosed "Memo of Record"). During that conversation, Dr. Berlin mentioned that Sandoz would need to

Please see the table of contents for a list of all supportive documentation. 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.

REVIEWS COMPLETED

CSO ACTION:	
<input checked="" type="checkbox"/> LETTER ^{AP}	<input type="checkbox"/> N.A.I.
<i>m</i>	4-30-96
CSO INITIALS	DATE

Sincerely

Robert J. Clark
Senior Manager, Regulatory
Manufacturing and Controls

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