

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

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RESEARCH**

APPLICATION NUMBER:

20-261/S-014

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Reviews / Information Included in this NDA Review.

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APPROVAL LETTER

NDA 20-261/S-014

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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)

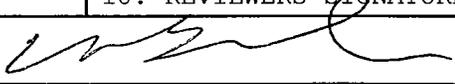
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APPLICATION NUMBER:

20-261/S-014

CHEMISTRY REVIEW(S)

ORIGINAL

CHEMISTS REVIEW		1. ORGANIZATION DMEDP II, HFD-510	2. NDA NUMBER FEB 13 1997 20-261
3. NAME AND ADDRESS OF APPLICANT Sandoz Pharmaceuticals Corp. 59 Route 10 East Hanover, NJ 07936-1080		4. SUPPLEMENT NUMBER, DATE SCP-014 1-21-97	
5. PROPRIETARY NAME Lescol® Capsules	6. NAME OF THE DRUG Fluvastatin Sodium	7. AMENDMENTS, REPORT, DATE	
8. SUPPLEMENT PROVIDES FOR / - /, of the 20 and 40 mg-strength capsules.			
9. PHARMACOLOGICAL CATEGORY antihypercholesteremic	10. HOW DISPENSED OTC	11. RELATED IND, NDA, DMF	
12. DOSAGE FORM Capsules, oral	13. POTENCY 20, 40 mg		
14. CHEMICAL NAME AND STRUCTURE See Chemistry Review #1			
15. COMMENTS The sponsor / 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 / the 20			
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 WILLIAM K. BERLIN	18. REVIEWERS SIGNATURE 	19. DATE COMPLETED 2-13-97	
DISTRIBUTION: ORIGINAL JACKET		CSO	REVIEWER DIVISION FILE

Stephen K. Moore
2/13/97

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**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

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

NDA SUPPLEMENT

ORIGINAL



SANDOZ

DRUG REGISTRATION & REGULATORY AFFAIRS

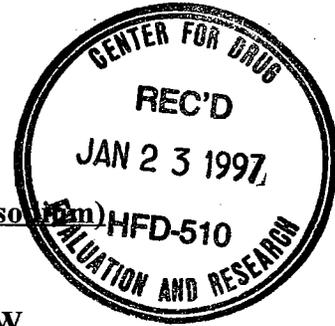
TEL. 201 503 7500
FAX 201 503 6325

NDA NO. 20261 REF. NO. 014

NDA SUPPL FOR 504

Metel
Ses
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 _____ for the 20 and 40 mg Capsules.

Currently, Lescol® Capsules are being marketed _____ bottles with a 30 capsule count and a _____ with a 100 capsule count. Sandoz has made special arrangements with _____

_____ The _____ will be distributed to that organization only. The proposed _____ will be the same _____

_____ 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 _____ could be submitted as "changes being effected". Please note that additional discussions were conducted regarding a _____ 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	
OSD ACTION:	
<input checked="" type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS	DATE
<i>JW</i>	<i>4/21/97</i>