CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-261/S002

Trade Name: Lescol Capsules

Generic Name: (fluvastatin sodium)

Sponsor: Sandoz Pharmaceuticals Corporation

Approval Date: March 21, 1994

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S002

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-261/S002

APPROVAL LETTER

NDA 20-261/S-002

MAR 21 1994

Sandoz Pharmaceuticals Corporation
Attention: Ms. Hedy M. Ries
59 Route 10
East Hanover, NJ 07936-1080

Dear Ms. Ries:

Please refer to your March 2, 1994, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lescol (fluvastatin sodium) Capsules (20 mg and 40 mg).

The supplemental application provides for a new physicians' sample package containing 14 capsules (20 mg and 40 mg) in a HDPE bottle which replaces the original physicians' sample package containing 6 capsules (20 mg and 40 mg) in a blister package.

We have completed our review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the October 1993 final printed labeling submitted on March 2, 1994. Accordingly, the supplemental application is approved effective on the date of this letter.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Should you have any questions, please contact:

Mr. Stephen T. Trostle
Consumer Safety Officer
Telephone: 301-443-3520.

Sincerely yours,

3/21/94

Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products (HFD-510)
Center for Drug Evaluation and Research

cc:
Original NDA
HF-2 (with labeling)
HFC-130/JAllen
HFD-80 (with labeling)
HFD-240 (with labeling)
HFD-638 (with labeling)
HFD-732 (with labeling)
HFD-500/LRipper (with labeling)
HFD-510
HFD-510/SAurecchia/MRhee/EBarbehenn
HFD-510/STrostle/03/16/94/ft/stt/03/21/94 \N20261AP.002
ST 03/21/94
Concurrence: EGalliers 03.17; MRhee, YChiu, EBarbehenn, SAurecchia, GTroendle 03.18; AJordan 03.21;94
NDA Approval Date: 12/31/93

SUPPLEMENT APPROVAL (AP-002)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-261/S002

CHEMISTRY REVIEW(S)

MAR 8 1994

CHEMIST'S REVIEW

1. Organization
DMEDP HFD-510

2. NDA Number
20-261

ORIGINAL

3. Name amd Address of Applicant
Sandoz Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936
201-503-7500

4. Supplement
S-002
3-2-94

5. Name of Drug
Lescol

6. Nonproprietary Name
fluvastatin sodium

7. Supplement Provides For
New physicians sample package containing 14 capsules (20 and 40 mg) in a HDPE bottle replacing the original 6 capsules (20 and 40mg) in a blister package.

8. Amendment

9. Pharmacological Category
Lipid altering agent

10. How Dispensed
RX

11. Related
IND/NDA/DMF

12. Dosage form
Capsules for oral administration

13. Potency
20 and 40mg/capsule

14. Chemical Name and Structure

15. Comments
This supplement was submitted to introduce a new physicians sample package to replace the originally approved sample package (a blister package containing 6 capsules). The new sample package has 14 capsules packaged into a 60cc HDPE bottle container [redacted]. To claim 2-year expiration date of the physicians samples, comparative stability data (appearance, dissolution, assay) of 15-capsule bottles and 30-capsule bottles were submitted (physicians samples have 14 capsules in a bottle). According to the reported data, there was no significant difference between 15-capsule and 30-capsule samples [redacted] b(4) b(4) b(4) b(4) b(4) b(4) 3-18-94 satisfactory.

16. Conclusion and Recommendation
This supplement is now approvable. Issue an approval letter. ~~with a statement that three production batches of physicians samples be put on the stability program and results be repoted in the Annual Report.~~

not necessary since the difference in amount is one capsule only.
Y Chiu 3/18/94

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

Reviewer's Signature

Date
3-7-94

Distribution
R/D initialed by
SL.203

Original Jacket

Reviewer

Division File

Y Chiu 3/8/94

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-261/S002

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date MAR - 4 1994

NDA No. 20-261

Sandoz Pharmaceuticals Corporation
59 Route 10
East 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-002

Date of Supplement: March 02, 1994

Date of Receipt: March 03, 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

SANDOZ

NDA 20-261 REF. NO. 002
SLR

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL. 201 503 7500
FAX 201 503 6325

March 2, 1994

ORIGINAL

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

EXPEDITED REVIEW REQUESTED

FINAL PRINTED LABELING

CSO Review of FPL.
all carton and sticky label appear to be the same for 20486
ST 03/16/94

Dear Dr. Sobel:

In accordance with 21 CFR §314.70(b)(3), Sandoz Pharmaceuticals Corporation herewith submits a supplemental new drug application for Lescol® (fluvastatin sodium) Capsules. This supplement provides for a new physicians' sample package for both the 20 mg and 40 mg dose strengths.

The physicians' sample packaging that was described in the original new drug application (submitted on March 31, 1992 and approved on December 31, 1993) has been changed. The original labeling, submitted in draft form (examples are included) was for a packaging.

The proposed physicians' sample package is for a 14 capsule starter kit. The capsules are to be placed in a 60 cc HDPE bottle. Please note that this is the same bottle/container closure as is being used in the approved 30 capsule bottle which is to be used for the trade samples (approximately ⅓ the amount of capsules in the approved package). The HDPE bottle is to be placed into a sample box which will contain promotional information (a pamphlet). Please note that the sample box, along with the promotional pamphlet has been submitted to the Division of Drug Marketing, Advertising and Communication. Please also note that the physicians' samples will have the same expiration dating as the trade samples (i.e. 2 years).

Finally, please note that the bottles with 14 capsules have been put into our stability program as a precautionary measure since there will be additional head space in the physicians' sample containers. Also please note that we are providing some stability data using the approved container/closure system on

3/15/94 mailed

noted EES 3/15/94

the 20 mg capsules for bottles containing 15 capsules (with a comparison to bottles containing 30 capsules). This data has been excerpted from the original NDA.

Accordingly, we herewith submit twelve (12) copies of final printed labeling as follows:

Label #	Description
25353001	**20mg Sample Bottle Label**
15153001	**20mg 14 Capsule Starter Pack**
25353101	**40mg Sample Bottle Label**
15153101	**40mg 14 Capsule Starter Pack**

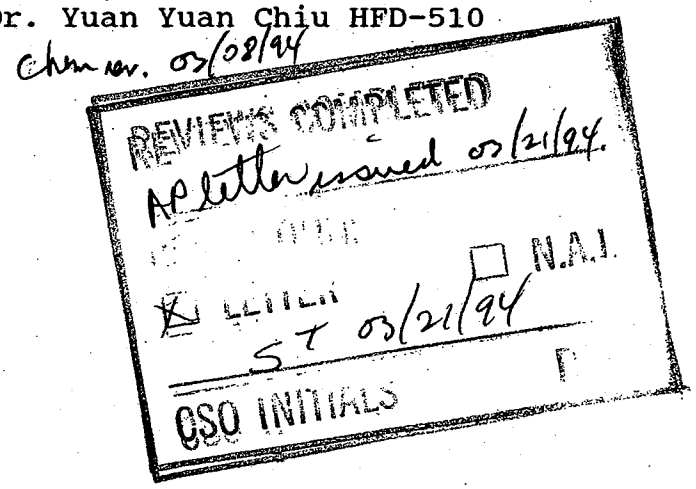
Please note that since the physicians' sample packaging has been changed, and as our product launch is imminent, we are requesting that this supplement be reviewed as soon as possible. Any assistance that you can provide to us in this matter will be greatly appreciated.

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

Sincerely,

Robert J. Clark
Senior Manager, Regulatory
Manufacturing and Controls

/ras
Attachments
12 copies final printed labeling
Desk Copy and TeleFax to Dr. Yuan Yuan Chiu HFD-510



See package insert for dosage information.

Store and dispense: Below 86°F (30°C); tight container. Protect from light.

Sandoz Pharmaceuticals Corporation
East Hanover, New Jersey 07936

PROFESSIONAL SAMPLE

Lescol®
(fluvastatin sodium) capsules

equivalent to
20 mg 14 Capsules
fluvastatin

NOT FOR SALE
CAUTION: Federal law prohibits dispensing without prescription.
25353001

SAMPLE LABEL

LOT

EXP.

Store and dispense: Below 86°F (30°C). Protect from light.
See enclosed patient information booklet and full prescribing information.

NEW

14 CAPSULE STARTER PACK

LESCOL®
(fluvastatin sodium)
20 mg capsules
Equivalent to 20 mg fluvastatin

AN HMG-CoA REDUCTASE INHIBITOR
STARTING DOSAGE: 20 MG ONCE DAILY

CAUTION: Federal law prohibits dispensing without prescription.
Professional Sample—Not For Sale

NEW LESCOL®
(fluvastatin sodium)
20 mg capsules
Equivalent to 20 mg fluvastatin

14 CAPSULE STARTER PACK

SAMPLE LABEL

Lot

EXP.

1

SEND IN FOR MORE HELP IN CONTROLLING CHOLESTEROL

Sandoz Pharmaceuticals Corporation would like to assist you with your continuing efforts to control cholesterol. Send in this postage-paid business reply card to receive *Lower Your Cholesterol, Now!*, a video guide to deciphering nutritional claims and reading food labels. Hosted by a registered dietician, *Lower Your Cholesterol, Now!* will help you separate nutrition from nonsense and select the most healthful choices from your supermarket shelves.

❑ **Please send my free video, *Lower Your Cholesterol, Now!***

Name

Address

City State Zip

Physician

Physician's phone number ( )

10/93 Printed in USA

SANDOZ
SANDOZ PHARMACEUTICALS CORPORATION
EAST HANOVER, NEW JERSEY 07936

SANDOZ PHARMACEUTICALS CORPORATION
East Hanover, New Jersey 07936

10/93 Printed in USA

1515001
923901

PROFESSIONAL SAMPLE

Lescol®

(fluvastatin sodium) capsules

equivalent to

40 mg fluvastatin 14 Capsules

NOT FOR SALE

CAUTION: Federal law prohibits dispensing without prescription.

25353101

See package insert for dosage information.

Store and dispense: *Below 86°F (30°C). light container. Protect from light.*

Sandoz Pharmaceuticals Corporation East Hanover, New Jersey 07936

SAMPLE LABEL

LOT

EXP.

Store and dispense: See enclosed patient information booklet and full prescribing information. Below 86°F (30°C). Protect from light.

NEW

LESCOL®

(fluvastatin sodium)

40 mg capsules

Equivalent to 40 mg fluvastatin

AN HMG-CoA REDUCTASE INHIBITOR

DOSAGE: 40 MG ONCE DAILY

CAUTION: Federal law prohibits dispensing without prescription.

Professional Sample—Not For Sale

14 CAPSULE STARTER PACK

NEW LESCOL® (fluvastatin sodium)

40 mg capsules

Equivalent to 40 mg fluvastatin

14 CAPSULE STARTER PACK

SEND IN FOR MORE HELP IN CONTROLLING CHOLESTEROL

Sandoz Pharmaceuticals Corporation would like to assist you with your continuing efforts to control cholesterol. Send in this postage-paid business reply card to receive *Lower Your Cholesterol, Now!*, a video guide to deciphering nutritional claims and reading food labels. Hosted by a registered dietician, *Lower Your Cholesterol, Now!* will help you separate nutrition from nonsense and select the most healthful choices from your supermarket shelves.

☐ **Please send my free video, *Lower Your Cholesterol, Now!***

Name

Address

City State Zip

Physician

Physician's phone number ( )

10/93

Printed In USA

SANDOZ

SANDOZ PHARMACEUTICALS CORPORATION
EAST HANOVER, NEW JERSEY 07936

SAMPLE LABEL

Lot

Exp.

113

SANDOZ PHARMACEUTICALS CORPORATION
East Hanover, New Jersey 07936

10/93

Printed in USA

151310I
923401

USER FEE DATA ENTRY/VALIDATION FORM Ver.2(9/1/93)

NDA # 20261 DOCUMENT ID/LETTER DATE SLR-002 3.2.94

APPLICANT NAME SANDOZ

PRODUCT NAME LESCOL

FORM MUST BE COMPLETED BY (10 DAYS FROM DOCUMENT RECEIPT): 3/13/94

1. YES (NO) **CLINICAL DATA?**
[Check YES if contains study reports or literature reports of what are explicitly or implicitly represented by the applicant to be adequate and well-controlled trials. "Clinical data" do not include data used to modify the labelling to add a restriction that would improve the safe use of the drug (e.g., to add an adverse reaction, contraindication or warning to the labeling).]

REF **IF NO CLINICAL DATA IN SUBMISSION, INDICATE IF CLINICAL DATA ARE CROSS REFERENCED IN ANOTHER SUBMISSION?**

IF SUPPLEMENT and NO CLINICAL DATA INCLUDED, SKIP TO ITEM 11!

2. YES NO **505(b)(2) NDA?** An application in which one or more of the pivotal studies (rather than all) was not conducted or sponsored by the applicant and the applicant does not have a right of reference to that study. In addition, the firm must have made a patent certification under section 505(b)(2)(A) and (B) of the Act and must have cited a reference listed drug on which it is basing its application.

YES NO **If 505(b)(2) NDA - FEE APPLIES?**
[Check YES if application is for a new chemical entity or Indication. Check NO if application is for a previously approved drug substance or indication.]

3. YES NO **LARGE VOLUME PARENTERAL APPROVED BEFORE 9/1/92?** [Check YES only if a supplement with clinical data submitted to an LVP application first approved before 9/1/92.]

4. YES NO **505(j) NDA?** Abbreviated Application **IF YES, SKIP TO ITEM 11!**

5. YES NO **506 NDA?** Insulin Product **IF YES, SKIP TO ITEM 11!**

6. YES NO **NDA BEING SPLIT FOR ADMINISTRATIVE CONVENIENCE** (OTHER THAN BUNDLING)? IF YES, list ALL NDA numbers, review divisions & indicate those for which application fees apply.

NDA #	DIVISION		
N_____	_____	FEE	NO FEE
N_____	_____	FEE	NO FEE

7. YES NO **BUNDLING POLICY APPLIED CORRECTLY?** NO DATA ENTRY REQUIRED FOR ELEMENT
[Check YES if application is properly designated as one application or is properly submitted as a supplement instead of an original application. Check NO if application should be split into more than one application or submitted as an original instead of a supplement. IF NO, list resulting NDA numbers, and review divisions.]

NDA #	DIVISION	NDA #	DIVISION
N_____	_____	N_____	_____

8. YES NO **SMALL BUSINESS EXCEPTION GRANTED?** [Check YES only if the NDA contains a copy of a written notice from the FDA Waiver Officer that a exception has been granted.]

9. YES NO **WAIVER GRANTED?** [Check YES only if the NDA contains a copy of a written notice from the FDA Waiver Officer that a waiver has been granted.]

10. YES NO **PRIORITY SUBMISSION?** [Check YES if Priority. Check NO if Standard.]

S. Truth 03/04/94
11. CSO SIGNATURE/DATE

DMGallies 3/14/94
SCSO CONCURRENCE SIGNATURE/DATE

COPY DISTRIBUTION: ORIGINAL TO ARCHIVAL AFTER DATA ENTRY, ONE COPY EACH TO DIVISION FILE AND CDER, ASSOCIATE DIRECTOR FOR POLICY HFD-1-1