

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-261/S007

Trade Name: Lescol Capsules

Generic Name: flusvastatin sodium

Sponsor: Sandoz Pharmaceutical Corporation

Approval Date: October 17, 1995

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 20-261/007

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:
NDA 20-261/S007

APPROVAL LETTER

NDA 6-035/S-057
NDA 17-247/S-040
NDA 20-261/S-007

OCT 17 1995

Sandoz Pharmaceuticals Corporation
Attention: John Taylor, Ph.D.
Director, Regulatory Manufacturing and Controls
59 Route 10
EAST HANOVER NJ 07936

Dear Dr. Taylor:

Please refer to your April 17, 1995, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following drug products:

Methergine	(methylergonovine maleate)	NDA 6-035
Sanorex	(mazindol tablets)	NDA 17-247
Lescol	(fluvastatin sodium tablets)	NDA 20-216

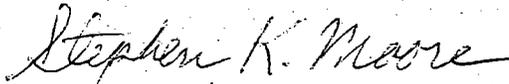
These supplemental applications provide for the deletion of the pH specification from the specifications ~~_____~~ excipient of the drug product.

We have completed the review of these supplemental applications and they are approved. However we recommend that you develop an SOP protocol, including a pH test, for evaluation of new sources/suppliers ~~_____~~

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. Christina Kish at (301) 443-3510.

Sincerely yours,



Stephen K. Moore, Ph.D.
Acting Supervisory Chemist II
Office of New Drug Chemistry, OPS,
at Division of Metabolism and
Endocrine Drug Products (HFD-510)
Center for Drug Evaluation and Research

NDA 6-035/S-057 (+2 others)

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cc:

Arch NDA(3)

HFD-510(3)

DISTRICT OFFICE

HFD-510/MRhee/HDavies/WBerlin/SMarkofsky/SMoore

HFD-80

HFD-510/CKish/10.16.95/n6035.57

Concurrences:HDavies 10.16.95/EGalliers 10.16.95/MRhee 10.16.95

SUPPL. APPROVALS

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APPLICATION NUMBER:
NDA 20-261/S007

CHEMISTRY REVIEW(S)

5 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-261
5007

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APPLICATION NUMBER:
NDA 20-261/S007

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date APR 24 1995

NDA No. 20-261

• Sandoz Pharmaceuticals Inc.
59 Route 10
East Hanover, NJ 07936-1080

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-007

Date of Supplement: April 17, 1995

Date of Receipt: April 20, 1995

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

ORIGINAL ^{SCS}
SANDOZ

NDA NO. 2026 | REF. NO. 007

NDA SUPPL FOR SCS

DRUG REGISTRATION & REGULATORY AFFAIRS

April 17, 1995

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 **NDA SUPPLEMENT**
LESCOL® (fluvastatin sodium)
Capsules

SUPPLEMENTAL NEW
DRUG APPLICATION

CHEMISTRY



Dear Dr. Sobel:

In accordance with 21 CFR 314.70, Sandoz Pharmaceuticals Corporation herewith submits a supplemental new drug application for LESCOL® (fluvastatin sodium) Capsules. This supplement provides for deletion of the pH test from the specifications of an excipient of the drug product _____

Currently the Sandoz specifications _____ include a test for pH, although it is not known why the test was added originally. We have not failed a batch based on the pH test, and the pH of _____ does not affect the product. Furthermore, the pH test is not a compendial test found in the USP monograph _____

For the aforementioned reasons we propose deleting the pH test from the specifications _____ All other tests will remain the same. For your information we are enclosing pH test results and a copy of the Sandoz current control procedures and specifications _____

This supplement is being concurrently submitted to several other NDAs since _____ used in many of our products. In the interest of efficiency, Sandoz has requested a coordinated review through the office of the Director of Chemistry.

A certified copy of this NDA supplement is being provided to your district office in compliance with the preapproval inspection requirements. If you have any questions or comments regarding this submission, please contact me at (201) 503-6984.

REVIEWS COMPLETED	
CSO ACTION:	Sincerely,
<input checked="" type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I.
<i>[Signature]</i>	<i>[Signature]</i>
CSO INITIALS	DATE
	Norma P. Loeffler
	Senior Manager
	Regulatory Manufacturing and Controls

/meb

Attachments

- cc: Marilyn Apfel, MD, HFD-004 (letter only)
- Robert Jerrusi, MD, HFD-004 (letter only)
- Matthew Lewis, Newark District Office