CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-261/S017

Trade Name: Lescol Tablets

Generic Name: fluvastatin sodium

Sponsor: Novartis Pharmaceutical Corporation

Approval Date: August 5, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-261/S017

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-261/S017

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-261/S-017

AUG - 5 1998

Novartis Pharmaceuticals Corporation
Attention: Leslie Martin-Hischak
CMC, Drug Regulatory Affairs
59 Route 10
East Hanover, New Jersey 07936

Dear Ms. Martin-Hischak:

Please refer to your supplemental new drug application dated June 29, 1998, received July 2, 1998, 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 January 2, 1999.

This supplement was submitted under 21 CFR 314.70(c), Special Supplement - Changes Being Effected, and the Scale-up and Post-Approval Changes (SUPAC) for Immediate-Release Solid Oral Dosage Forms.

This supplemental new drug application provides for the use of the Suffern, New York, facility as an additional site to package 20 and 40 mg capsules of Lescol. Your submission stated June 29, 1998 as the implementation date for the change.

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, contact Margaret Simoneau, R.Ph., Regulatory Management Officer, at (301) 827-6418.

Sincerely,

Stephen K. Moore 8/4/98

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

cc:
Archival NDA 20-261
HFD-510/Div. Files
HFD-510/M. Simoneau
HFD-95/DDMS (with labeling)
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: Mas/July 31, 1998
Initialed by:W.Berlin7.31.98/S.Moore7.31.98/E.Galliers8.4.98
final:Mas8.4.98
filename: 20261.17

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-261/S017

CHEMISTRY REVIEW(S)

JUL 24 1998

ORIGINAL

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DMEDP II, HFD-510	20-261
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Novartis Pharmaceuticals Corp. 59 Route 10 East Hanover, NJ 07936		SCS-017 6-29-98
5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE
Lescol®	fluvastatin sodium	

8. SUPPLEMENT PROVIDES FOR

The use of the Suffern, NY, facility as an additional site to package 20 and 40 mg capsules of Lescol.

9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
antihypercholestremic	RX	
12. DOSAGE FORM	13. POTENCY	
Capsules, oral	20, 40 mg	

14. CHEMICAL NAME AND STRUCTURE

See Chemistry Review #1

15. COMMENTS

This application was submitted as CBE, changes being effected under SUPAC-IR. The change involves the transfer of operations from the East Hanover NJ facility to an additional Novartis site at 25 Old Mill Rd., Suffern NY, to package 20 and 40 mg capsules of Lescol. The packaging presentations covered by this application include 30-count — and 100-count HPDE bottles, and — for each strength. The packaging site, CFN — was recommended as acceptable, based on profile, by the Office of Compliance (see attached CDER Establishment Evaluation Report, dated 7-21-98). The use of the additional site is acceptable.

16. CONCLUSION AND RECOMMENDATION

The additional site at 25 Old Mill Road, Suffern NY, is acceptable for packaging the three presentations of the drug product 20 and 40 mg capsules. The Suffern NY site has been recommended as acceptable by the Office of Compliance (see attached CDER Establishment Evaluation Report, dated 7-21-98). The use of the alternate site is acceptable. Issue an approval letter.

17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
WILLIAM K. BERLIN		7-22-98

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

AP

Stephen K. Moore
7/24/98

CDER Establishment Evaluation Report
for July 21, 1998

Application: **NDA 20261/017**
Priority: **1S**
Org Code: **510**
Stamp: **02-JUL-1998** Regulatory Due: **02-JAN-1999**
Action Goal:
District Goal: **28-SEP-1998**
Applicant: **NOVARTIS PHARM**
59 RT 10
EAST HANOVER, NJ 079361080
Brand Name: **LESCOL (FLUVASTATIN SODIUM)**
Established Name:
Generic Name: **FLUVASTATIN SODIUM**
Dosage Form: **TAB (TABLET)**
Strength: **20, 40 MG**

FDA Contacts:

M. SIMONEAU	**(HFD-510)**	**301-827-6418**	**, Project Manager**
W. BERLIN	**(HFD-510)**	**301-827-6370**	**, Review Chemist**
S. MOORE	**(HFD-510)**	**301-827-6430**	**, Team Leader**

Overall Recommendation:

ACCEPTABLE on 16-JUL-1998 by M. EGAS (HFD-322) 301-594-0095

Establishment: **2416082**
NOVARTIS PHARMA INC (CIBA)
OLD MILL RD
SUFFERN, NY 10901
DMF No:
AADA No:

Profile: **TCM** OAI Status: **NONE**
Responsibilities: **FINISHED DOSAGE PACKAGER**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **16-JUL-1998**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-261/S017

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-261/S-017

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936

JUL 13 1998

Attention: Leslie Martin-Hischak
CMC Drug Regulatory Affairs

Dear Ms. Hischak:

We acknowledge receipt of your supplemental application for the following:

Name of Drug:	Lescol® Capsules
NDA Number:	20-261
Supplement Number:	S-017
Date of Supplement:	June 29, 1998
Date of Receipt:	July 02, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on August 31, 1998, 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, HFD-510
Office of Drug Evaluation II
Attention: Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

for

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-261/S-017
HFD-510/Div. Files
HFD-510/CSO/M. Simoneau

filename: C:\DATA\WPFILES\20261ACK

SUPPLEMENT ACKNOWLEDGEMENT

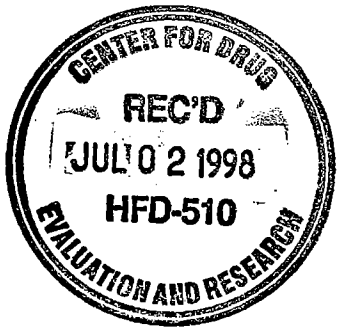
NDA NO. 20261 REF. NO. 017

NDA SUPPL FOR SCM

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 8300

NOVARTIS



ORIGINAL

29-Jun-98

NDA 20-261
Lescol® Capsules
(fluvastatin sodium)

SUPAC-IR, Special Supplement - Changes Being Effected - Chemistry, Manufacturing and Controls

FDA Center for Drug Evaluation and Research
Office of Drug Evaluation II
Document Control Room 14B-19
5600 Fishers Lane
Rockville, Maryland 20857

Attention: Solomon Sobel, MD, Director
Division of Metabolic and Endocrine Drug Products/HFD-510

Dear Dr. Sobel:

In accordance with the guidance for *Scale-up and Post-Approval Changes for Immediate Release Products* (SUPAC-IR, dated 30-Nov-95), Novartis hereby submits a stand alone packaging operations site change for Lescol Capsules. In addition to the SUPAC-IR guidance, reference is also made to a further clarification in the FDA letter to sponsors, dated 18-Feb-97, which specifically addressed the stand alone site changes for packaging operations for immediate release solid dosage forms.

As of January 1, 1997 the former Ciba Pharmaceuticals Division and Sandoz Pharmaceuticals Corporation became Novartis Pharmaceuticals Corporation. A result of the formation of Novartis is the strategic decision to transfer the packaging operations outlined below from the Novartis East Hanover, NJ site to the Suffern, NY facility. The following facility will be used as an additional packager for Lescol Capsules:

Novartis Pharmaceuticals Corporation
25 Old Mill Road
Suffern, NY 10901
CFN # 2416082
Contact: Ms. Camille Pesce, 914-368-6828

This corresponds to a Changes Being Effected supplement as detailed in the reference letter to sponsors, since the same container/closure system will be used and the Suffern NY facility operates in conformance with all current cGMP's. At this time, the following strengths and

sizes of Lescol Capsules will be transferred, using the current NDA approved containers/closure systems, from the Novartis East Hanover facility to the Suffern, NY facility.

Lescol Dosage Strength	NDA Approved Package	Counts/Package
20mg capsules	HDPE Bottle	30's
20mg capsules	HDPE Bottle	100's
20mg capsules		
40mg capsules	HDPE Bottle	30's
40mg capsules	HDPE Bottle	100's
40mg capsules		

Novartis commits that samples from batches of each strength and package configuration of Lescol capsules, packaged at the Suffern, NY facility will be studied within our stability program. Results will be submitted to the FDA via the annual report. Subsequent batches of Lescol capsules packaged at Suffern, NY will be incorporated into our on-going stability program on an annual basis.

As set forth in 21 CFR Part 25.31(a), action on a supplement to an approved NDA is categorically excluded from the requirement to prepare an Environmental Assessment or an Environmental Impact Statement if the action does not increase the use of the active moiety.

Novartis Pharmaceuticals Corporation certifies that this submission **Lescol 20mg and 40mg Capsules** qualifies for a categorical exclusion in accordance with 21 CFR Part 25.31(a) as this action will not increase the use of the active moiety, **Fluvastatin sodium.**

Further, Novartis Pharmaceuticals Corporation states that, to the best of its knowledge, no extraordinary circumstances exist which may significantly affect the quality of the human environment and would thus require the preparation of at least an Environmental Assessment.

If you have questions and or comments regarding this submission, please do not hesitate to contact the undersigned at (908) 277-4801. If you have a question regarding any other Chemistry, Manufacturing and Controls issues pertaining to this product, please contact Ms. Donna Kapples at (973) 781-6929.

8/98 Donna Stevens

Leslie Martin-Hischak

Leslie Martin-Hischak
Chemistry, Manufacturing and Controls
Drug Regulatory Affairs

REVIEWS COMPLETED
AP LTR 8-5-98
CSO ACTION:
☑ LETTER ☐ N.A.I. ☐ MEMO
MG 8-7-98
CSO INITIALS DATE

cc: Ms. Regina Brown
New Jersey District Office, North Brunswick Resident Post - Certified Field Copy