CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-261/S031
21-192/S003

Trade Name: Lescol Capsules
Lescol XL Extended Release Tablets

Generic Name: (fluvastatin sodium)

Sponsor: Novartis Pharmaceutical Corporation

Approval Date: February 11, 2002

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APPLICATION NUMBER:

20-261/S031

21-192/S003

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APPLICATION NUMBER:

20-261/S031

21-192/S003

APPROVAL LETTER

NDA 20-261/S-031 Lescol (fluvastatin sodium) Capsules
NDA 21-192/S-003 Lescol XL (fluvastatin sodium) Tablets

Novartis Pharmaceuticals Corporation
Attention: Leslie Martin-Hischak
CMC, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Martin-Hischak:

Please refer to your supplemental new drug applications dated October 30, 2001, received October 31, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the above supplemental applications.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for the use of an additional site located at [redacted] to perform analytical testing for the drug substances/and or drug products.

We have completed the review of these supplemental applications, and they are 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 call Ms. Jena Weber, Regulatory Project Manager, at (301) 827-6422.

Sincerely,

{See appended electronic

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

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/s/

Stephen Moore
2/11/02 02:16:37 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S031

21-192/S003

CHEMISTRY REVIEW(S)

1. ORGANIZATION CDER/HFD-510 Division of Metabolism and Endocrine Drug Products	**2. NDA #** 20-261 Original NDA approved:
3. NAME AND ADDRESS OF APPLICANT Novartis Pharmaceuticals Corporation 59 Route 10 East Hanover, NJ 07936-1080	**4. SUPPLEMENT** SCM-031 30-OCT-2001 Rec. 31-OCT-2001)
	5. Name of the Drug Lescol Capsules™
	6. Nonproprietary Name Fluvastatin sodium
7. SUPPLEMENT PROVIDES for [redacted] as an additional facility to perform analytical testing for drug substance and/or drug product.	**8. AMENDMENT** --

9. PHARMACOLOGICAL CATEGORY Hypercholesterolemia	**10. HOW DISPENSED** Oral	**11. RELATED** -N. A. -
12. DOSAGE FORM Capsule	**13. POTENCY** 20 mg and 40 mg	

14. CHEMICAL NAME AND STRUCTURE

7-[3-(4-fluorophenyl)-1-(1-methylethyl)-1H-indol-2-yl]-3,5-dihydroxy-6-heptenoic acid, monosodium salt, Mol wt = 433.46, C24H25FNO4.Na Salt/Base Ratio 1.053

15. COMMENTS This supplement is part of a bundle to add [redacted], as a testing laboratory. The EES overall recommendation is acceptable

16. CONCLUSIONS AND RECOMMENDATIONS There are no outstanding CMC issues for this supplement. The EES overall recommendation for [redacted] is acceptable. Issue Approval letter.

17. REVIEWER NAME (AND SIGNATURE) **DATE COMPLETED** 01-FEB-2002
Sharon Kelly, PhD
R/D INITIATED BY

filename: 20261#031 NDA

DISTRIBUTION: Original: NDA 20261 cc: HFD-510 Division File CSO Reviewer

AP

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 20261/031
Stamp: 31-OCT-2001
Regulatory Due: 30-APR-2002
Applicant: NOVARTIS PHARM
59 RT 10
EAST HANOVER, NJ 079361080
Priority: 1S
Org Code:
FDA Contacts: S. KELLY (HFD-510)
S. MOORE (HFD-510)
Overall Recommendation: ACCEPTABLE

Action Goal:
District Goal: 26-MAR-2002
Brand Name: LESCOL
Estab. Name:
Generic Name:FLUVASTATIN SODIUM

Dosage Form:(CAPSULE)
Strength:20, 40 MG
301-827-6394 , Review Chemist
301-827-6430 , Team Leader
on 25-JAN-2002
by M. GARCIA(HFD-322)301-594-0095

Establishment: [redacted]

DMF No:
Responsibilities: [redacted]
Profile: CTL

AADA:
OAI Status: NONE

Estab. Comment: PART OF BUNDLE: ADDITIONAL ANALYTICAL TESTING LABORATORY TO PERFORM TESTING ON DRUG SUBSTANCE AND/OR DRUG PRODUCT.
(on 24-JAN-2002 by S. KELLY (HFD-510) 301-827-6394)

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason
Creator				
SUBMITTED TO OC	24-JAN-2002 KELLYS			
OC RECOMMENDATION	25-JAN-2002 GARCIAM			ACCEPTABLE BASED ON PROFILE

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/s/

Sharon Kelly
2/1/02 02:41:33 PM
CHEMIST

paper copy signed Feb. 01, 2002

Stephen Moore
2/1/02 03:43:37 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S031

21-192/S003

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-223/S-001 NDA 20-036/S-025
NDA 17-808/S-022 NDA 20-261/S-031
NDA 21-192/S-003 NDA 18-202/S-019

CBE-30 SUPPLEMENT

Novartis Pharmaceuticals Corporations
Attention: Leslie Martin-Hischak
Assistant Director
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Martin-Hischak:

We have received your supplemental drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Name
21-223	S-001	Zometa (zolendronic acid) for injection
20-036	S-025	Aredia (pamidronate disodium) for injection
17-808	S-022	Miacalcin (salmon calcitonin) for injection
20-261	S-031	Lescol (fluvastatin sodium) Capsules
21-192	S-003	Lescol XL (fluvvastatin sodium) Tablets
18-202	S-019	Cytadren (aminoglutethimide, USP) Tablets

Date of Supplements: October 30, 2001

Date of Receipt: October 31, 2001

These supplemental applications, submitted as "Supplement - Changes Being Effected in 30 days" supplements, propose the to use the '[redacted] site as an additional facility to perform analytical testing for these drug products.

Unless we notify you within 60 days of our receipt date that the applications are not sufficiently complete to permit a substantive review, these applications will be filed under section 505(b) of the

Act on December 30, 2001, in accordance with 21 CFR 314.101(a). If the applications are filed, the user fee goal date will be April 30, 2002.

Please cite the application numbers listed above at the top of the first page of any communications concerning these applications. All communications concerning these supplemental applications should be addressed as follows:

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room 14B-19
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions regarding the following supplemental NDA's, call the following project managers:

Randy Hedin, R.Ph., Senior Regulatory Management Officer at (301) 827-6392

NDA 21-223/S-001
NDA 20-036/S-025
NDA 17-808/S-022

William Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412

NDA 20-261/S-031
NDA 21-192/S-003

Jena Weber, Regulatory Project Manager, at (301) 827-6422

NDA 18-202/S-019

Sincerely,

{See appended electronic signature page}

Kati Johnson
Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Kati Johnson
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