

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

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APPROVAL LETTER

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/s/

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

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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 _____, _____ 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, C ₂₄ H ₂₅ FNO ₄ .Na Salt/Base Ratio 1.053			
15. COMMENTS This supplement is part of a bundle to add _____, _____ 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 _____ is acceptable. Issue Approval letter.			
17. REVIEWER NAME (AND SIGNATURE) COMPLETED 01-FEB-2002 Sharon Kelly, PhD R/D INITIATED BY		DATE	
filename: 20261#031 NDA			
DISTRIBUTION: Original: NDA 20261 cc: HFD-510 Division File CSO Reviewer			

AP

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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

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APPLICATION NUMBER:

20-261/S031

21-192/S003

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**

NDA 21-223/S-001
NDA 17-808/S-022
NDA 20-261/S-031

NDA 20-036/S-025
NDA 18-202/S-019
NDA 21-192/S-003

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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

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NDA 18-202/S-019
NDA 21-192/S-003

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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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