CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-164/S-038

Name: Lovenox® (Enoxaparin Sodium) Injection

Sponsor: Aventis Pharmaceutical Products, Inc.

Approval Date: June 20, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-164/S-038

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APPLICATION NUMBER:

NDA 20-164/S-038

APPROVAL LETTER

NDA 20-164/S-038

Aventis Pharmaceuticals Products Inc.
Attention: Edmond Roland, M.D.
500 Arcola Road
P.O. Box 1200
Collegeville, PA 19426-0107

Dear Dr. Roland:

Please refer to your supplemental new drug application dated April 6, 2000, received April 10, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovenox® (enoxaparin sodium) Injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate analytical test site, [redacted], for release and stability testing of heparin sodium, which is the intermediate material used in the manufacture of enoxaparin sodium drug substance.

We have completed the review of this supplemental application and it is approved, effective the date of this letter.

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 Karen Oliver, Project Manager, at (301) 827-7457.

Sincerely,

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal and Coagulation Drug Products, (HFD-180)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
Archival NDA 20-164/S-038
HFD-180/Div. Files
HFD-180/K.Oliver
HFD-180/L.Zhou
HFD-180/J.Sieczkowski
HFD-095/DDMS-IMT
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: KO/June 20, 2000
final: KO/06/20/00/c:\data\mydocuments\NDA20164-S-038-06-20-00-AP-cbe.doc

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-164/S-038

CHEMISTRY REVIEW

CHEMIST'S REVIEW #1	1. Organization: HFD-180	2. NDA Number: 20-164	
3. Name and Address of Applicant (City & State): Aventis Pharmaceutical Products 500 Arcola Road Collegeville, PA 19426		4. AF Number: Supplement(s)	
6. Name of Drug: Lovenox® Injection	7. Nonproprietary Name: enoxaparin sodium	Number(s) SCM-038	Date(s) 6 APR 2000
8. Supplement Provides for: the use of ———— ————, as an alternate analytical test site for release and stability testing of heparin sodium which is the intermediate used in the manufacture of enoxaparin sodium drug substance.		9. Amendments and Other (Reports, etc.) Dates:	
10. Pharmacological Category: Anticoagulent	11. How Dispensed: Rx XX OTC	12. Related IND/NDA/DMF(s):	
13. Dosage Form: Injection (SVS)	14. Potency: 100 mg & 150 mg/mL ungraduated & graduated prefilled syringes		
15. Chemical Name and Structure: See NDA Chemistry Review #1		16. Records and Reports: Current Yes No Reviewed Yes No	

17. Comments: PAC-ATLS CBE - (1) Heparin Sodium is an intermediate. (2) Heparin Sodium (intermediate) test and specification requirements are not identical to Heparin Sodium, USP.

cc: NDA 20-164/S-038
HFD-180/Div File/NDA 20-164
HFD-181/CSO/K.Oliver
HFD-180/L.Talarico
HFD-180/J.Sieczkowski
R/D init by:L.Zhou
dob DRAFT 6-7-00/F/T 6-8-00/c:wordfiles\chem\S\20164038.1JS

18. Conclusions and Recommendations: Based on the information submitted in the application, by Aventis Pharmaceutical Products, that complies with "PAC-ATLAS: Postapproval-Analytical Testing Laboratory Sites", the supplement should be approved. An approval letter should be prepared for the Team Leaders signature.

19. Reviewer

Name:	Signature	Date Completed:
Joseph Sieczkowski, Ph.D.		June 2, 2000

Form FDH 2266 (7/75) ALT R

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APPLICATION NUMBER:

NDA 20-164/S-038

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

NDA 20-164/S-038

Aventis Pharmaceuticals Products Inc.:
Attention: Ms.Connie Gombatz
Manager, Regulatory Affairs
500 Arcola Road
P.O. Box 1200
Collegeville, PA 19426-0107

Dear Ms. Gombatz:

We acknowledge receipt of your supplemental application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Lovenox® (enoxaparin sodium) Injection

NDA Number: 20-164

Supplement Number: 038

Date of Supplement: April 06, 2000

Date of Receipt: April 10, 2000

This supplement proposes the following change: an alternate analytical test site, ———— ———————————— , for release and stability testing of heparin sodium, USP, which is the starting material used in the manufacture of enoxaparin sodium drug substance.

This supplement was submitted in accordance with the guidance requirements of Post Approval Changes - Analytical Testing Laboratory Sites (PAC-ATLS).

We have determined that this supplement qualifies for submission under PAC for changes being effected.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on June 9, 2000 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be October 10, 2000.

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

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and
Coagulation Drug Products, HFD-180
Attention: Division Document Room, 6B-24
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, contact me at (301) 827-7457.

Sincerely,

Karen Oliver, RN, MSN
Regulatory Health Project Manager
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Archival NDA 20-164/S-038
HFD-180/Div. Files
HFD-180/RPM/K. Oliver
HFD-180/L. Zhou
HFD-180/J. Sieczkowski
HFD-357
HFD358
DISTRICT OFFICE
Drafted by: hw/4/26/00
Initialed by: ko/4/26/00
Final:
filename: C:\DATA\CSO\N\20164004.0KO

SUPAC SUPPLEMENT ACKNOWLEDGEMENT (AC)