CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-345

MICROBIOLOGY REVIEW(S)

REVIEW TO HFD 180
OFFICE OF NEW DRUG CHEMISTRY
Microbiology Staff, HFD-805
Microbiologist's Review #2 of Supplement
July 31, 2001

A. 1. **NDA** **21-345-BC**

2. APPLICANT/SPONSOR: **Fonda BV**

Tripolis 300
Burgerweeshuispad 311
1076 HS Amsterdam,
The Netherlands

Contact: **David Faunce**
(610) 889-8640

3. MANUFACTURING SITE: **SANOFI CHIME**
1, rue de l' Abbaye
76960 Notre Dame De
Bondeville, France

4. DRUG PRODUCT NAME:
Current: **Org31540/SR90107A**
Proprietary: **Arixtra™**
Proposed: **fondaparinux sodium**
Drug Priority Classification: **Priority**

5. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- **Injectable Solution**
- **Subcutaneous injection**
- **2.5 mg/0.5 mL**

6. METHOD(S) OF STERILIZATION: [redacted]

7. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPLE INDICATION:
prophylaxis of venous thromboembolic events (VTE)

B.	1.	DOCUMENT/LETTER DATE:	**February 15, 2001**
	2.	RECEIPT DATE:	**February 28, 2001**
	3.	CONSULT DATE:	**February 27, 2001**
	4.	DATE OF AMMENDMENT:	**July 25, 2001 (Subject of this review)**
	5.	ASSIGNED FOR REVIEW:	**July 30, 2001**
	6.	SUPPORTING/RELATED DOCUMENTS:	

C. REMARKS: **The applicant has responded to Microbiology Deficiencies sent to the applicant in a July 16, 2001 letter.**

D. CONCLUSIONS: **The submission is recommended for approval from the standpoint of microbial product quality.**

Stephen E. Langille, Ph. D.

cc: Original **NDA 21-345-BC**
HFD-180/Division File
HFD-180/Oliver
HFD-180/Al-Hakim
HFD 805/Consult File/Langille
Drafted by S. Langille
Initialed by P. Cooney

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ON ORIGINAL

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/s/

Stephen Langille
7/31/01 12:41:42 PM
MICROBIOLOGIST

Peter Cooney
7/31/01 02:14:34 PM
MICROBIOLOGIST

APPEARS THIS WAY
ON ORIGINAL

REVIEW TO HFD 180
OFFICE OF NEW DRUG CHEMISTRY
Microbiology Staff, HFD-805
Microbiologist's Review #1 of Supplement
June 19, 2001

A. 1. **NDA** **21-345**

2. APPLICANT/SPONSOR: **Fonda BV**

Tripolis 300
Burgerweeshuispad 311
1076 HS Amsterdam,
The Netherlands

Contact: **David Faunce**
(610) 889-8640

3. MANUFACTURING SITE: **SANOFI CHIME**
1, rue de l' Abbaye
76960 Notre Dame De
Bondeville, France

4. DRUG PRODUCT NAME:
Current: **Org31540/SR90107A**
Proprietary: **Xantidar™**
Proposed: **fondaparinux sodium**
Drug Priority Classification: **Priority**

5. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- **Injectable Solution**
- **Subcutaneous injection**
- **2.5 mg/0.5 mL**

6. METHOD(S) OF STERILIZATION:

7. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPLE INDICATION:
prophylaxis of venous thromboembolic events (VTE)

B.	1.	DOCUMENT/LETTER DATE:	**February 15, 2001**
	2.	RECEIPT DATE:	**February 28, 2001**
	3.	CONSULT DATE:	**February 27, 2001**
	4.	DATE OF AMMENDMENT:	
	5.	ASSIGNED FOR REVIEW:	**March 2, 2001**
	6.	SUPPORTING/RELATED DOCUMENTS:	

C. REMARKS: **The applicant states that the drug product is [redacted]**

D. CONCLUSIONS: **The submission is approvable pending resolution of microbiological deficiencies. Specific comments regarding the [redacted] process are provided in "E. Review Notes" and "List of Microbiology Deficiencies and Comments".**

Stephen E. Langille, Ph. D.

cc: Original **NDA 21-345**
HFD-180/Division File
HFD-180/Oliver
HFD-180/Al-Hakim
HFD 805/Consult File/Langille
Drafted by S. Langille [redacted]
Initialed by P. Cooney

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/s/

Stephen Langille
7/12/01 09:58:04 AM
MICROBIOLOGIST

Peter Cooney
7/12/01 12:56:28 PM
MICROBIOLOGIST