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**

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:
   Proprietary:
   Proposed:
   Drug Priority Classification:
   
   Org31540/SR90107A
   Arixtra™
   fondaparinux sodium
   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: 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

APPEARS THIS WAY 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**
    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:
   Proprietary: Org31540/SR90107A
   Proposed: Xantidar™
   Drug Priority Classification:
   fondaparinux sodium
   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 

D. CONCLUSIONS: The submission is approvable pending resolution of 
microbiological deficiencies. Specific comments regarding the 
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 
Initialed by P. Cooney

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

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

APPEARS THIS WAY
ON ORIGINAL