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RESEARCH**

APPLICATION NUMBER:

21-759

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-150

13 DECEMBER 2004

NDA: 21-759

Drug Product Name

Proprietary: Eloxatin Injection

Non-proprietary: oxaliplatin

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 31 March 2004

Receipt Date: 31 March 2004

Consult Date: 24 May 2004

Date Assigned for Review: 7 June 2004

Submission History (for amendments only)

Date(s) of Previous Submission(s): N/A

Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor

Name: Sanofi-Synthelabo Inc.

Address: 9 Great Valley Parkway, PO Box 3026, Malvern, PA 19355

Representative: Mark Moyer

Telephone: 610-889-6417

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** N/A
 2. **SUPPLEMENT PROVIDES FOR:** N/A
 3. **MANUFACTURING SITE:** Ben Venue
Bedford, OH
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile Aqueous Solution for iv administration, 50 mg/10 mL and 100 mg/20 mL in glass vial.
 5. **METHOD(S) OF STERILIZATION:**
 6. **PHARMACOLOGICAL CATEGORY:** Treatment of metastatic colon cancer
- B. **SUPPORTING/RELATED DOCUMENTS:** NDA 21-492
- C. **REMARKS:** The drug product was approved as a lyophilized powder in NDA 21-492. This submission is for an aqueous solution made using essentially the same process as the approved product with the exception of the lyophilization step. This application was submitted electronically in the CTD format.

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Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
- B. **Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

II. Summary of Microbiology Assessments

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is ~~_____~~
~~_____~~
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Microbiology Supervisor
- C. **CC Block**
N/A

4 Page(s) Withheld

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Draft Labeling

Deliberative Process

Withheld Track Number: Microbiology-1

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Bryan Riley
12/20/04 07:44:51 AM
MICROBIOLOGIST

David Hussong
12/20/04 08:39:10 AM
MICROBIOLOGIST