

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-877

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-150

5-October-2005

NDA: 21-877

Drug Product Name

Proprietary: Arranon
Non-proprietary: nelarabine injection
Drug Product Priority Classification:

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
4/29/05	4/29/05	5/5/05	5/10/05

Submission History (for amendments only): Not applicable

Applicant/Sponsor

Name: GlaxoSmithKline
Address: 2301 Renaissance Boulevard
P.O. Box 61540
King of Prussia, PA 19406-2772

Representative: Ellen S. Cutler
Telephone: 610-787-3733

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original NDA
2. **SUBMISSION PROVIDES FOR:** /
3. **MANUFACTURING SITE:** GlaxoSmithKline
Global Manufacturing and
Supply
Barnard Castle, UK
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- Injection
 - Intravenous
 - 5 mg/mL
5. **METHOD(S) OF STERILIZATION:**
6. **PHARMACOLOGICAL CATEGORY:** Cancer treatment
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** Electronic Submission

filename: N021977r1.doc

Executive Summary**I. Recommendations**

- A. Recommendation on Approvability -**
NDA 21-877 is recommended for approval from the standpoint of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**
Not applicable

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**
/
- B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable.

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
Microbiology Supervisor/Team Leader Name
- C. CC Block**
N/A

10 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

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/s/

Stephen Langille
10/7/2005 02:19:41 PM
MICROBIOLOGIST

Bryan Riley
10/7/2005 03:00:46 PM
MICROBIOLOGIST