CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-311

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

10 November 2008

NDA: 22-311

Drug Product Name
Proprietary: Mozobil
Non-proprietary: plerixafor injection
Drug Product Priority Classification: 1

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
June 16, 2008	June 16, 2008	July 10, 2008	July 14, 2008

Submission History (for amendments only) – N/A

Applicant/Sponsor
Name: Genzyme Corporation
Address: 500 Kendall Street, Cambridge, MA 02142
Representative: Laura Mondano, Director Regulatory Affairs
Telephone: Monica Mehta at 617-899-2135

Name of Reviewer: Vinayak B. Pawar, Ph.D.

Conclusion: The application is recommended for approval from microbiology product quality standpoint.

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: New Drug Application

2. SUBMISSION PROVIDES FOR: N/A

3. MANUFACTURING SITE: Patheon UK Ltd. (Swindon, UK) is the planned commercial manufacturer of plerixafor injection, 20 mg/ml.

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: 20 mg/ml solution of Plerixafor in a single-use vial for subcutaneous injection based on 240 mcg/kg actual body weight.

5. METHOD(S) OF STERILIZATION: (b) (4)

6. PHARMACOLOGICAL CATEGORY: Treatment of lymphoma and multiple myeloma.

B. SUPPORTING/RELATED DOCUMENTS:

C. REMARKS:

The original NDA 22-311 is submitted for review of a new drug product Mozobil (plerixafor) for subcutaneous injection, indicated to enhance mobilization of hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma. Genzyme submitted this NDA in an electronic CTD format. At the mid-cycle meeting on November 3, 2008, it was announced that since this NDA had been given a priority review status, the reviews were due by November 7, 2008. Initial Quality Assesment was filed by Dr. Sarah Pope on July 24, 2008.

(b) (4)

Executive Summary

I. Recommendations

A. Recommendation on Approvability – The application is recommended for approval.

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 - (b) (4)

B. Brief Description of Microbiology Deficiencies - None

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature _____
Vinayak B. Pawar, Ph.D.

B. Endorsement Block _____
Bryan S. Riley, Ph.D.

C. CC Block
N/A

12 Page(s) Withheld after this page as B4 (CCI/TS)

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

/s/

Vinayak Pawar
11/12/2008 02:31:45 PM
MICROBIOLOGIST

Recommended for approval.

Bryan Riley
11/12/2008 02:33:21 PM
MICROBIOLOGIST
I concur.