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RESEARCH**

APPLICATION NUMBER:

22-393

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

3 AUGUST 2009

NDA: 22-393

Drug Product Name

Proprietary: ISTODAX

Non-proprietary: romidepsin

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
12 January 2009	12 January 2009	N/A	7 May 2009

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Gloucester Pharmaceuticals, Inc.

Address: One Broadway, 14th Floor, Cambridge, MA 02142

Representative: Jean Nichols, Ph.D., President and CEO

Telephone: 617-583-1314

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

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA 505(b)(1)
 2. **SUBMISSION PROVIDES FOR:** A sterile parenteral drug product
 3. **MANUFACTURING SITE:** Ben Venue Laboratories
300 Northfield Road
Bedford, Ohio 44146
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile lyophilized powder for intravenous injection in 10 mg/vial. The drug product is supplied with a diluent (80% Propylene Glycol, USP and 20% Dehydrated Alcohol, USP) 2 mL vial. b(4)
 5. **METHOD(S) OF STERILIZATION:** — Fill b(4)
 6. **PHARMACOLOGICAL CATEGORY:** Treatment of cutaneous T-cell lymphoma
- B. **SUPPORTING/RELATED DOCUMENTS:** Product quality microbiology review of DMF 2315 (review dated 14 December 2008).
- C. **REMARKS:** This was an eCTD submission.

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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 _____ filled. b(4)
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. **Reviewer's Signature** _____
Bryan S. Riley, Ph.D.
Senior Review Microbiologist OPS/NDMS
- B. **Endorsement Block** _____
James L. McVey
Team Leader OPS/NDMS
- C. **CC Block**
N/A

6 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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

/s/

BRYAN S RILEY
08/05/2009

JAMES L MCVEY
08/06/2009
I concur.