CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-665

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review
Review for HFD-550

18 NOVEMBER 2003

NDA: 21-665

Drug Product Name
Proprietary: Amphadase
Non-proprietary: Hyaluronidase Injection, USP
Drug Product Priority Classification: P

Review Number: 1

Subject of this Review
Submission Date: 6 June 2003
Receipt Date: 13 June 2003
Consult Date: 3 July 2003
Date Assigned for Review: 15 July 2003

Submission History (for amendments only)
Date of Amendment: 28 October 2003
Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor
Name: Amphastar Pharmaceuticals, Inc.
Address: 11570 Sixth St.; Rancho Cucamonga, CA 91730
Representative: Stephen A. Campbell, Esq.
Telephone: 909-980-9484 ext. 2019

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

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** N/A

2. **SUPPLEMENT PROVIDES FOR:** N/A

3. **MANUFACTURING SITE:** Amphastar Pharmaceuticals, inc.
11570 Sixth St.
Rancho Cucamonga, CA 91730
Estab. No. 2032577

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 150 IU/mL (1 mL) in a 2 mL glass vial for parenteral administration.

5. **METHOD(S) OF STERILIZATION:** —

6. **PHARMACOLOGICAL CATEGORY:** Adjuvant, to increase absorption and dispersion of other drugs

B. **SUPPORTING/RELATED DOCUMENTS:** NDA 21-665 amendment dated 28 October 2003

C. **REMARKS:** The amendment dated 28 October 2003 committed the applicant to perform endotoxin tests annually as part of the stability program.

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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 [redacted]

B. **Brief Description of Microbiology Deficiencies** – N/A

C. **Assessment of Risk Due to Microbiology Deficiencies** – The drug product is manufactured using a validated [redacted] manufacturing process. Therefore, the drug product presents a minimal risk from the standpoint of product quality microbiology.

III. **Administrative**

A. **Reviewer's Signature** _____

B. **Endorsement Block**
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Peter H. Cooney, Ph.D. (Microbiology Supervisor)

C. **CC Block**
N/A

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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
11/21/03 07:29:54 AM
MICROBIOLOGIST

Peter Cooney
11/21/03 11:05:42 AM
MICROBIOLOGIST