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RESEARCH**

APPLICATION NUMBER:

21-749

21-751

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-160

25 JUNE 2004

NDA: 21-749/21-751

Drug Product Name

Proprietary: _____
Non-proprietary: Ca-DTPA and Zn-DTPA
Drug Product Priority Classification: P

Review Number: 1

Subject of this Review

Submission Date: 1 April 2004
Receipt Date: 5 April 2004
Consult Date: 15 April 2004
Date Assigned for Review: 19 April 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: Hameln Pharmaceuticals gmbh
Address: Langes Feld 13; 31789 Hameln Germany
Representative: Helen Ribbans (B&H consulting Services)
Telephone: 908-704-1691 ext 211

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: Hameln Pharamaceuticals gmbh
Langes Feld 13
31789 Hameln
Germany
 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile Solution for iv injection, in a glass ampoule, 5 mL per ampoule
 5. METHOD(S) OF STERILIZATION: _____
 6. PHARMACOLOGICAL CATEGORY: Elimination of plutonium, americium or curium.
- B. SUPPORTING/RELATED DOCUMENTS: N/A
- C. REMARKS: _____

filename: 21-749.doc

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)
Peter H. Cooney, Ph.D. (Microbiology Supervisor)
- C. **CC Block**
N/A

3 page(s) have been
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trade secret
and/or
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this page is the manifestation of the electronic signature.**

/s/

Bryan Riley
6/30/04 10:54:08 AM
MICROBIOLOGIST

Peter Cooney
6/30/04 11:16:27 AM
MICROBIOLOGIST