

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-426

MICROBIOLOGY REVIEW

8.2.04

Product Quality Microbiology Review

Review for HFD-510

15 JULY 2004

NDA: 21-426/BC

Drug Product Name

Proprietary: OMNITROPE

Non-proprietary: Somatropin for Injection

Drug Product Priority Classification: N/A

Review Number: 2

Subject of this Review

Submission Date: 6 July 2004

Receipt Date: 7 July 2004

Consult Date: 8 July 2004

Date Assigned for Review: 8 July 2004

Submission History (for amendments only)

Date(s) of Previous Submission(s): 30 July 2003

Date(s) of Previous Micro Review(s): 20 April 2004

Applicant/Sponsor

Name: Sandoz GmbH

Address: 506 Carnegie Center Drive Suite 499; Princeton, NJ 08540

Representative: Beth Brannan

Telephone: 303-438-4237

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

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** N/A
 2. **SUPPLEMENT PROVIDES FOR:** N/A
 3. **MANUFACTURING SITE:** Novartis Pharma Stein AF
Schaffhauserstrasse
CH-4332 Stein
Switzerland
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile lyophilized powder in 2 mL glass vial, 1.5 and 5.8 mg for subcutaneous injection, also diluent (WFI or 1.5% benzyl alcohol/WFI) in glass vials.
 5. **METHOD(S) OF STERILIZATION:**
 6. **PHARMACOLOGICAL CATEGORY:** Growth Hormone
- B. **SUPPORTING/RELATED DOCUMENTS:** Original Product Quality Microbiology Review (20 April 2004).
- C. **REMARKS:** This submission is in response to product quality microbiology deficiencies in the original 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
- 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)
Microbiology Supervisor
- C. **CC Block**
N/A

2 Page(s) Withheld

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/s/

Bryan Riley
8/2/04 02:03:30 PM
MICROBIOLOGIST

Peter Cooney
8/2/04 02:55:44 PM
MICROBIOLOGIST

Product Quality Microbiology Review

Review for HFD-510

20 APRIL 2004

NDA: 21-426

Drug Product Name

Proprietary: OMNITROPE

Non-proprietary: Somatropin for injection

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 30 July 2003

Receipt Date: 31 July 2003

Consult Date: 14 August 2003

Date Assigned for Review: 25 March 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: Biochemie U.S., Inc.

Address: 506 Carnegie Center Drive Suite 499; Princeton, NJ 08540

Representative: Beth Brannan

Telephone: 303-438-4237

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

Conclusion: Approvable

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** N/A
 2. **SUPPLEMENT PROVIDES FOR:** N/A
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 5. **METHOD(S) OF STERILIZATION:**
 6. **PHARMACOLOGICAL CATEGORY:** Growth Hormone
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This is a resubmission of a previous application.

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/s/

Bryan Riley
5/19/04 09:05:58 AM
MICROBIOLOGIST

Peter Cooney
5/19/04 10:28:49 AM
MICROBIOLOGIST