

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-629

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-510

22 DECEMBER 2003

NDA: 21-629

Drug Product Name

Proprietary: Apidra

Non-proprietary: Insulin glulisine

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 18 June 2003

Receipt Date: 20 June 2003

Consult Date: N/A

Date Assigned for Review: 28 June 2003

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: Aventis Pharmaceutical inc.

**Address: 200 Crossing Blvd; PO Box 6890; Bridgewater, New Jersey
08807**

Representative: Steve Caffè, MD

Telephone: 908-231-5863

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:** Aventis Pharma
Frankfurt, Germany
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile liquid for injection in a 10 mL vial, 100 IU/mL
 5. **METHOD(S) OF STERILIZATION:** _____
 6. **PHARMACOLOGICAL CATEGORY:** Diabetes
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This was an electronic submission in the CTD-Q.

filename: 21629.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** – The drug product is manufactured using a validated _____ process. Therefore, the drug product presents 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

8 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

(b4)

A-03

**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
1/23/04 08:23:34 AM
MICROBIOLOGIST

Peter Cooney
1/23/04 09:20:45 AM
MICROBIOLOGIST