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 Caffe, 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)
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