CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-773

MICROBIOLOGY REVIEW
Product Quality Microbiology Review
Review for HFD-510

18 March 2005

NDA: 21-773

Drug Product Name
Proprietary: Exenatide(TM) injection
Non-proprietary: Exenatide
Drug Product Classification: Hypoglycemic agent

Review Number: 1

Subject of this Review
Submission Date: June 29, 2004
Receipt Date: June 30, 2004
Consult Date: July 2, 2004
Date Assigned for Review: July 9, 2004

Submission History (for amendments only)
Date(s) of Previous Submission(s): NA
Date(s) of Previous Micro Review(s): NA

Applicant/Sponsor
Name: Amylin Pharmaceuticals, Inc.
Address: San Diego, CA
Representative: David Furlano, Ph.D.
Telephone: 858-642-7248

Name of Reviewer: Vinayak B. Pawar

Conclusion: The application is recommended for approval from microbiological standpoint.
Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA

2. SUPPLEMENT PROVIDES FOR: NA

3. MANUFACTURING SITE: __________

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: _____ in 1.2 to ____ mL pre-filled syringe cartridges for subcutaneous injection.

5. METHOD(S) OF STERILIZATION: __________

6. PHARMACOLOGICAL CATEGORY: Hypoglycemic agent

B. SUPPORTING/RELATED DOCUMENTS: DMF __________

C. REMARKS: The consult requests review of NDA 21-773 for the drug product __________ injection solution for improving glycemic control of patients with Type II Diabetes Mellitus. The application is an electronic submission with two hard copy volumes [containing an overview and volume 1 of 1] submitted for review.

_filename_: C:\my documents\review\NDA\N021773R1
Executive Summary

I. Recommendations
   A. Recommendation on Approvability -
      The application is recommended for approval based on product
      quality microbiology review.
   B. Recommendations on Phase 4 Commitments and/or
      Agreements, if Approvable -
      NA

II. Summary of Microbiology Assessments
   A. Brief Description of the Manufacturing Processes that relate to
      Product Quality Microbiology -
      (exenatide) injection follows standard methods for
      compounding, sterile filtration and . in a pen-injector
      for self injection by the patient. The bulk solution compounding

B. Brief Description of Microbiology Deficiencies -
   None
C. Assessment of Risk Due to Microbiology Deficiencies -

III. Administrative
   A. Reviewer's Signature _____________________________

B. Endorsement Block
   Vinayak B. Pawar, Ph.D., Microbiology Reviewer
   David Hussong, Ph.D., Microbiology Supervisor

C. CC Block
   cc: Original NDA 21-773
   HFD- 510/Division File/Lina AlJuburi
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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Vinayak Pawar
3/22/05 10:28:42 AM
MICROBIOLOGIST

Recommended for approval from microbiological standpoint

David Hussong
3/22/05 11:06:32 AM
MICROBIOLOGIST