

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: ██████████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 _____TM 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

12 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

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