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:
[™] injection

Non-proprietary: exenatide

Drug Product Classification: Hypoglycemic agent

Review Number: 1

Subject of this Review

Submission Date:June 29, 2004Receipt Date:June 30, 2004Consult Date:July 2, 2004Date 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

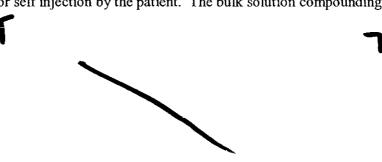
Α.	1.	TYPE OF SUBMISSION: Original NDA
	2.	SUPPLEMENT PROVIDES FOR: NA
	3.	MANUFACTURING SITE:
	4.	DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: in 1.2 to in 1.2 to in the prefilled syringe cartridges for subcutaneous injection.
	5.	METHOD(S) OF STERILIZATION.
	6.	PHARMACOLOGICAL CATEGORY: Hypoglycemic agent
B.	SUP	PORTING/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 . Tin 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

Page(s) Withheld

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

§ 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

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/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