

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205029Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

2/04/2013

NDA 205029

Drug Product Name

Proprietary: (b) (4)

Non-proprietary: Epinephrine Injection, USP

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
12/04/2012	12/04/2012	12/17/2012	12/20/2012
2/04/2013	2/04/2013	N/A	N/A

Submission History (for amendments only): None

Applicant/Sponsor

Name: Belcher Pharmaceuticals, LLC

Address: 6911 Bryan Dairy Road, Suite 210, Largo FL 33777

Representative: Mihir Taneja

Telephone: 727-471-0850 Ext. 250

Name of Reviewer: Steven P. Donald, M.S.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original NDA
2. **SUBMISSION PROVIDES FOR:** Manufacture and marketing of a sterile drug product.
3. **MANUFACTURING SITE:** Sintetica S.A., Via Penate, 5 CP 1764, Mendrisio, Switzerland CH-6850
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile solution for injection, intravenous, 1 mg/ml in glass ampoules
5. **METHOD(S) OF STERILIZATION:** [REDACTED] (b) (4)
6. **PHARMACOLOGICAL CATEGORY:** Adrenergic agonist
- B. **SUPPORTING/RELATED DOCUMENTS:** DMF [REDACTED] (b) (4) Epinephrine, [REDACTED] (b) (4) LOA from [REDACTED] (b) (4) dated 9/13/2012 is provided for reference to the manufacture of the drug substance.
- C. **REMARKS:** An information request was sent to the sponsor on 1/23/2013 and a response was received on 2/04/2013. The additional information provided is included in this review.

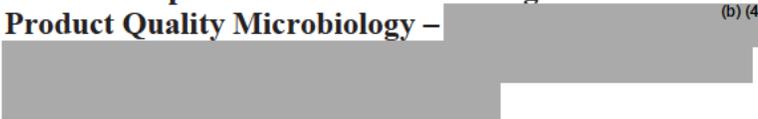
filename: N205029r1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability –**
NDA 205029 is recommended for approval.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology –** (b) (4)

- B. Brief Description of Microbiology Deficiencies-** No product quality microbiology deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -** None.

III. Administrative

- A. Reviewer's Signature** _____
Steven P. Donald, M.S.
- B. Endorsement Block** _____
Stephen Langille, Ph.D.
Senior Microbiology Reviewer
- C. CC Block**
N/A

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/s/

STEVEN P DONALD
02/15/2013

STEPHEN E LANGILLE
02/15/2013

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 205029

Applicant: Belcher
Pharmaceuticals LLC

Letter Date: 12/04/2012

Drug Name: Epinephrine
Injection USP

NDA Type: 505 (b)(2)

Stamp Date: 12/04/2012

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	x		eCTD format: 2.3.P.3 and 3.2.P.2.5
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	x		3.2.P.3.3: Description of Manufacturing Process
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	x		3.2.P.3.5: Process validation
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		x	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?		x	N/A
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	x		3.2.P.5.1: Specifications
7	Has the applicant submitted the results of analytical method verification studies?	x		3.2.P.5.2: Analytical Procedures
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?		N/A	
9	If sterile, are extended post-constitution and/or post-dilution hold times in the draft labeling supported by microbiological data?		N/A	For IV injection; no post constitution or dilution is described
10	Is this NDA fileable? If not, then describe why.	x		

Additional Comments:

(b) (4)

Steven P. Donald, M.S.

1/02/2012

Reviewing Microbiologist

Date

Stephen Langille, Ph.D.

1/02/2012

Microbiology Secondary Reviewer

Date

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/s/

STEVEN P DONALD
01/02/2013

STEPHEN E LANGILLE
01/02/2013