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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)
[REDACTED]
 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.

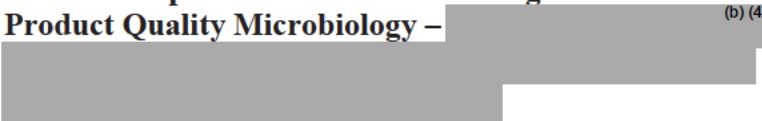
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Executive Summary

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

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

/s/

STEVEN P DONALD
02/15/2013

STEPHEN E LANGILLE
02/15/2013

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