CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206030Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

25 August 2014

NDA: **206030**

Drug Product Name
Proprietary: CARABELLA™ injection
Non-proprietary: carbamazepine

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
20 December 2013	23 December 2013	26 December 2013	6 January 2014
13 June 2014	13 June 2014	N/A	N/A
5 August 2014	5 August 2014	N/A	N/A

Applicant/Sponsor
Name: Lundbeck, LLC.
Address: 4 Parkway North
Deerfield, IL 60015

Representative: Wendy Tian
Telephone: 847-282-5769

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original submission – orphan drug

2. SUBMISSION PROVIDES FOR: A sterile injectable form of carbamazepine.

3. MANUFACTURING SITE: Baxter Pharmaceutical Solutions, LLC
P.O. Box 3068
927 S. Curry Pike
Bloomington, IN 47403

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- Sterile Injection
- Intravenous
- 200 mg/20 mL
- 20 mL tubing vials

5. METHOD(S) OF STERILIZATION: (b) (4)

6. PHARMACOLOGICAL CATEGORY: Epilepsy treatment

B. SUPPORTING/RELATED DOCUMENTS: None

C. REMARKS: The submission was arranged in eCTD format. An information request was sent to the applicant on 27 May 2014. The applicant responded with two electronic amendments submitted on 13 June 2014 and 6 August 2014.

filename: N206030r1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability - Recommended for Approval

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -
Not applicable

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -
The drug product is [redacted] (b) (4).

B. Brief Description of Microbiology Deficiencies -
No efficiencies were identified based upon the information provided.

C. Assessment of Risk Due to Microbiology Deficiencies –
Not applicable

D. Contains Potential Precedent Decision(s)- ☐ **Yes** ☒ **No**

III. Administrative

A. Reviewer's Signature _____
Stephen E. Langille, Ph.D.
Senior Microbiology Reviewer

B. Endorsement Block _____
Bryan Riley, Ph.D.
NDMS Acting Team Leader

C. CC Block
N/A

11 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

STEPHEN E LANGILLE
08/26/2014

BRYAN S RILEY
08/26/2014
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 206030 **Applicant:** Lundbeck **Letter Date:** 20 December 2013

Drug Name: Carbella™ **NDA Type:** Standard **Stamp Date:** 23 December 2013

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		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		Sections P.3.3 and P.3.5
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		Section P.3.5
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		The drug product is not preserved. Integrity testing was provided in section P.2.5.
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		Section P.5.1
7	Has the applicant submitted the results of analytical method verification studies?	X		Section P.5.3
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?		X	No such studies were requested.
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The application is arranged in eCTD format.

16 January 2014

Stephen E. Langille Ph.D.
Reviewing Microbiologist Date

16 January 2014

John Metcalfe, Ph.D.
Microbiology Secondary Reviewer/Team Leader Date

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/s/

STEPHEN E LANGILLE
01/16/2014

JOHN W METCALFE
01/16/2014
I concur.