

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204508Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

05 June 2013

NDA: 204-508/N000

Drug Product Name

Proprietary: Clinolipid

Non-proprietary: 20% Lipid Injectable Emulsion, USP

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
02 January 2013	03 January 2013	07 February 2013	07 February 2013

Submission History (for 2nd Reviews or higher) – NA

Applicant/Sponsor

Name: Baxter Healthcare Corporation

Address: 25212 W. Illinois Route 120
Round Lake Illinois

Representative: Kathleen O’Neill
Director of Global Regulatory Affairs

Telephone: (224) 270-4196

Name of Reviewer: Denise A. Miller

Conclusion: Recommended for approval from a quality microbiology perspective.

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original Application
 - 2. SUBMISSION PROVIDES FOR:** The manufacture of a large volume parenteral product.
 - 3. MANUFACTURING SITE:**
Baxter S.A.
Boulevard René Branquart, 80
Lessines, Belgium 7860
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Dosage Form: Sterile Emulsion, 1000 mL in CLARITY (b) (4)
(b) (4) Container Closure System.
 - Route of Administration: Intravenous
 - Strength/Potency: 20% (0.20 gram/mL)
 - 5. METHOD(S) OF STERILIZATION:** (b) (4)
 - 6. PHARMACOLOGICAL CATEGORY:** Parenteral nutrition
- B. SUPPORTING/RELATED DOCUMENTS:**

Baxter DMF (b) (4): Type III, Clarity Container Closure System as Manufactured in (b) (4) was cross referenced in this application. As the NDA applicant holds this DMF, an LOA was not provided. The DMF was reviewed by quality microbiology on 03 June 2013 and deemed adequate in support of this subject NDA,

C. REMARKS:

1) The application was in e-CTD format.

2) (b) (4)

filename: N204508N000R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability** - Recommended for approval from a quality microbiology perspective.
- 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** – This product is filled into (b) (4) (b) (4) bags and (b) (4).
- B. Brief Description of Microbiology Deficiencies** – There were no deficiencies identified from a quality microbiology perspective.
- C. Assessment of Risk Due to Microbiology Deficiencies** – NA
- D. Contains Potential Precedent Decision(s)**- Yes No

III. Administrative

- A. Reviewer's Signature** _____
Denise A. Miller
Microbiologist, OPS/NDMS
- B. Endorsement Block** _____
Bryan S. Riley, Ph.D.
Senior Microbiologist, OPS/NDMS
- C. CC Block**
N/A

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/s/

DENISE A MILLER
06/11/2013

BRYAN S RILEY
06/11/2013
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 204-508 **Applicant:** Baxter Healthcare **Letter Date:** 02 January 2013

Drug Name: 20% Lipid Emulsion **NDA Type:** 505 (b)(2) **Stamp Date:** 03 January 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?	√		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	√		
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	√		Cited DMF (b) (4)
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?		√	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?		√	P.E. NA CCI: DMF (b) (4)
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	√		
7	Has the applicant submitted the results of analytical method verification studies?	√		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	NA		
9	If sterile, are extended post-constitution and/or post-dilution hold time in the draft labeling supported by microbiological data?	NA		Use immediately. Do not add supplemental medications.
10	Is this NDA fileable? If not, then describe why.	√		

Additional Comments: terminally sterilized by moist heat.

Denise A. Miller, Microbiologist

Date

John W. Metcalfe, Ph.D.

Date

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/s/

DENISE A MILLER
03/04/2013

JOHN W METCALFE
03/04/2013
I concur.