CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

200656Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

REV-QUALITYMICRO-02 (Review Noted (NAI))
NDA-200656
ORIG-1
Supporting Document 27
Proprietary Name/Request for Review
Resubmission/Class 2
Submit Date: 11/22/2013 - FDA Received Date: 11/22/2013

Resubmission: Quality microbiology review not required, original application was recommended for approval on 09/21/2011.

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/s/

DENISE A MILLER
04/28/2014

Product Quality Microbiology Review

21 September 2011

NDA: 200-656/N000

Drug Product Name
Proprietary: Kabiven and [redacted] (b) (4)
Non-proprietary: Total Parenteral Nutrition in three chamber bag

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
28 Jan 2011	28 Jan 2011	28 Jan 2011	28 Jan 2011
25 Apr 2011 (SD 004)	26 Apr 2011	NA	NA
27 July 2011 (SD 008)	27 July 2011	NA	NA

Submission History (for amendments only) – NA

Applicant/Sponsor
Name: APP Pharaceuticals, LLC
Address: 1501 East Woodfield Rd
Suite 300E
Schaumbery Illinois 60173
Representative: Aparna Dagar Ph.D.
Sr. Regulatory Scientist
Telephone: (847) 969-2706

Name of Reviewer: Denise A. Miller

Conclusion: Approve

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA application

2. SUBMISSION PROVIDES FOR: The manufacture of an intravenous total parenteral nutrition product

3. MANUFACTURING SITE:
Fresenius Kabi AB
(b) (4)
Uppsala Sweden

CFN (b) (4)

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

- Dosage Form: (b) (4)
- Route of Administration: Intravenous
- Strength/Potency: (b) (4) kcal/liter and (b) (4) kcal/liter

Kabiven (b) (4) to be administered in a central vein via an (b) (4) and is (b) (4) kcal/liter. (b) (4) is to be administered in a peripheral or central vein and is (b) (4) kcal/liter.

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

6. PHARMACOLOGICAL CATEGORY: Parenteral nutrition

B. SUPPORTING/RELATED DOCUMENTS: NA

C. REMARKS:
1) Application is in e-CTD format
2) This product is presented in a 3 chamber bag in which each chamber contains a separate nutrition formula, dextrose, 20% Intralipid and (b) (4) The contents of the chambers are mixed prior to administration.
3) The 74 day letter requested method suitability for the endotoxin test and the sterility test. This was submitted in the amendment received 26 Apr 2011 (supporting document 004).
4) An information request was sent to the sponsor on 12 July 2011 for which a response was received on 27 July 2011 (supporting document 008).

filename: N200656N000R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability - Recommend to approve from a quality microbiology standpoint.

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 – (b) (4)

B. Brief Description of Microbiology Deficiencies – None

C. Assessment of Risk Due to Microbiology Deficiencies - NA

III. Administrative

A. Reviewer's Signature _____

Denise A. Miller
Microbiologist, NDMS

B. Endorsement Block _____

James L. McVey
Team Leader, NDMS

C. CC Block

N/A

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/s/

DENISE A MILLER
09/21/2011

JAMES L MCVEY
09/21/2011
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 200-656 **Applicant:** APP Pharmaceuticals **Letter Date:** 28 JAN 2011

Drug Name: Kabiven and (b) (4) **NDA Type:** 505(b)(2) **Stamp Date:** 28 JAN 2011

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?	√		(b) (4) Hold times provided.
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	√		(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?	√		No preservatives Container closure studies submitted
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?		√	B&F were not found E&I were not found
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	NA		
9	Is this NDA fileable? If not, then describe why.	√		

Additional Comments:

Provide method suitability studies for the sterility test.
Provide method suitability studies for the endotoxin test.

Denise A. Miller, Quality Microbiology Reviewer Date

James L. McVey, Quality Microbiology Team Leader Date

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/s/

DENISE A MILLER
03/08/2011

JAMES L MCVEY
03/08/2011
I concur.