CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203441Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

29 MARCH 2012

NDA: 203441/N-001

Drug Product Name
Proprietary: GATTEX
Non-proprietary: Teduglutide [rDNA origin] powder for sc injection

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
16 August 2011	16 August 2011	28 December 2011	5 January 2012
30 November 2011	30 November 2011	28 December 2011	5 January 2012

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: NPS Pharmaceuticals
Address: 550 Hills Drive, 3rd Floor, Bedminster, NJ 07921
Representative: Sandra C. Cottrell, MA, Ph.D.
Telephone: 908-450-5300

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: 505(b)(1) original NDA

2. SUBMISSION PROVIDES FOR: A sterile parenteral drug product

3. MANUFACTURING SITE: Hospira, Inc.
1776 N. Centennial Drive
McPherson, KS 67460

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile lyophilized powder in a glass vial for subcutaneous injection, 10 mg/mL.

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

6. PHARMACOLOGICAL CATEGORY: Treatment of Adults with Short Bowel Syndrome (SBS)

B. SUPPORTING/RELATED DOCUMENTS: DMF (b) (4)

C. REMARKS: This was an eCTD submission.

filename: N203441R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – This submission is recommended for approval on the basis of product quality microbiology.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The drug product is sterile (b) (4) and lyophilized.

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature _____

Bryan S. Riley, Ph.D.
Senior Review Microbiologist, OPS/NDMS

B. Endorsement Block _____

John W. Metcalfe, Ph.D.
Senior Review Microbiologist, OPS/NDMS

C. CC Block

N/A

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/s/

BRYAN S RILEY
03/30/2012

JOHN W METCALFE
03/30/2012
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 203441 **Applicant:** NPS Pharmaceuticals, Inc. **Letter Date:** 30 NOV 2011 and 16 AUG 2011

Drug Name: GATTEX **NDA Type:** 505(b)(1) **Stamp Date:** 30 NOV 2011 and 16 AUG 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?	X		The submission is in the eCTD format.
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	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		
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		CCI studies were provided; AME test N/A
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		
7	Has the applicant submitted the results of analytical method verification studies?	X		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	X		
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: This is a rolling submission. The CMC section was submitted on 16 August 2011 and the remainder of the NDA was submitted on 30 November 2011.

10 January 2012

Bryan S. Riley, Ph.D. Date
Senior Review Microbiologist

John W. Metcalfe, Ph.D. Date
Senior Review Microbiologist

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/s/

BRYAN S RILEY
01/11/2012

JOHN W METCALFE
01/11/2012
I concur.