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*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**

<b>Submit</b>	<b>Received</b>	<b>Review Request</b>	<b>Assigned to Reviewer</b>
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

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## **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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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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BRYAN S RILEY  
03/30/2012

JOHN W METCALFE  
03/30/2012  
I concur.

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