CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

203441Orig1s000

Trade Name: GATTEX for injection, for subcutaneous use, 5 mg.

Generic Name: teduglutide [rDNA origin]

Sponsor: NPS Pharmaceuticals, Inc.

Approval Date: December 20, 2012

Indications: Provides for the use of GATTEX (teduglutide [rDNA origin]) for injection, for subcutaneous use for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203441

NDA APPROVAL

NPS Pharmaceuticals, Inc.
Attention: Sandra Cottrell, MA, PhD
Vice President, Regulatory Affairs and Drug Safety
550 Hills Drive 3rd Floor
Bedminster, NJ 07921

Dear Dr. Cottrell:

Please refer to your New Drug Application (NDA), dated and received November 30, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), for GATTEX (teduglutide [rDNA origin]) for injection, for subcutaneous use, 5 mg.

We acknowledge receipt of your amendments dated December 22 & 23, 2011; January 12 & 13, 2012; February 7, 9, 16, 21, 23 & 24, 2012; March 7, 12, 23(2) & 29, 2012; April 11 & 20, 2012; May 7, 2012; June 12, 18, 20, 28 & 29, 2012; July 10 & 20, 2012; August 3, 10 & 15, 2012; September 5, 6, 10, 12(2) , 18, 19 & 27, 2012; October 2, 18, 24, & 31, 2012; November 8, 9, 20, 26 & 30, 2012; December 6, 7, 10, 12(3), 13(2), 17, 18(2), 19, & 20(2), 2012.

This new drug application provides for the use of GATTEX (teduglutide [rDNA origin]) for injection, for subcutaneous use for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. In the medication guide, remove the extra bullet point under the list of most common side effects.
2. On the vial label, revise the storage temperature range to read, “Prior to dispensing, store at 2°C to 8°C (36°F to 46°F). Do not freeze.”
3. For all carton and container labels, revise the room temperature storage conditions to be consistent with those listed in Section 16 HOW SUPPLIED/STORAGE AND HANDLING section of the package insert.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA

automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert and Medication Guide. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND IMMEDIATE-CONTAINER LABELS

Submit final printed carton and immediate-container labels that are identical to the submitted carton and immediate-container labels, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 203441."** Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

MARKET PACKAGE

Please submit one market package of the drug product when it is available to the following address:

Matthew Scherer
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5139
10903 New Hampshire Avenue
Silver Spring, Maryland
Use zip code **20903** *if shipping via United States Postal Service (USPS).*
Use zip code **20993** *if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

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