

NDA 203441/S-018

SUPPLEMENT APPROVAL

Shire-NPS Pharmaceuticals, Inc.
Attention: Denzel Ngoma
Senior Manager, Global Regulatory Affairs Development, GI
40 Landsdowne Street
Cambridge, MA 02139

Dear Mr. Ngoma:

Please refer to your supplemental new drug application (sNDA), dated and received on February 24, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Gattex (teduglutide) for Injection.

This Prior Approval sNDA provides updates to the human exposure margins in the Prescribing Information in Section 8.1 Pregnancy, 8.4 Pediatric Use, and 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility, based upon data from animal toxicity studies.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

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 [FDA.gov](http://www.fda.gov).¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Medication Guide, and Instructions for Use), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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*.² The SPL will be accessible from publicly available labeling repositories. Also, within 14 days, amend all

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft (MS) Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean MS Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.³

If you have any questions, contact Anum Shami, Regulatory Project Manager, at 301-837-7103 or at anum.shami@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling:
Prescribing Information
Medication Guide
Instructions for Use

³ <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOYCE A KORVICK
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