Label and Approval History

Drug Name(s)	**GATTEX KIT**
FDA Application No.	**(NDA) 203441**
Active Ingredient(s)	**TEDUGLUTIDE RECOMBINANT**
Company	**NPS PHARMS INC**

Go to Approval History

Label Information

What information does a label include?
Note: Not all labels are available in electronic format from FDA.

The supplement type of the 10/05/2015 approval does not usually require new labeling.

View the label approved on 06/26/2014 (PDF) for **NDA no. 203441**

- To see if other previously-approved labels are available on this site, go to the "Approval History" section of this page. **Older labels are for historical information only and should not be used for clinical purposes.**

Approval History
NDA 203441

Note: Not all reviews are available in electronic format from FDA.
Older labels are for historical information only, and should not be used for clinical purposes.
Approval dates can only be verified from 1984 to the present.

Click on a column header to re-sort the table: Download data

Action Date	Supplement Number	Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
10/05/2015	006	Manufacturing Change or Addition		This supplement type does not usually require new labeling.
05/18/2015	005	Manufacturing Change or Addition		This supplement type does not usually require new labeling.
01/05/2015	004	Manufacturing Change or Addition		This supplement type does not usually require new labeling.
06/26/2014	002	Efficacy Supplement with Clinical Data to Support	Label (PDF) Letter (PDF)	
12/21/2012	000	Approval	Label (PDF) Letter (PDF) REMS Review Summary Review (PDF)	

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players

- There are no Therapeutic Equivalents
- Medication Guide
- REMS

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