

## Label and Approval History

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

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### 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.**

NPS EX. 2138  
CFAD v. NPS  
IPR2015-01093

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.

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| 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 | <a href="#">Label (PDF)</a><br><a href="#">Letter (PDF)</a>   |   |
| 12/21/2012  | 000               | Approval  | <a href="#">Label (PDF)</a><br><a href="#">Letter (PDF)</a><br><a href="#">REMS Review Summary Review (PDF)</a> |   |

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- There are no Therapeutic Equivalents
- [Medication Guide](#)
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