



[FDA Home](#)³ [Drug Databases](#)⁴ [Orange Book](#)⁵

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "203441."

Active Ingredient:	TEDUGLUTIDE RECOMBINANT
Dosage Form;Route:	POWDER;SUBCUTANEOUS
Proprietary Name:	GATTEX KIT
Applicant:	NPS PHARMS INC
Strength:	5MG/VIAL
Application Number:	N203441
Product Number:	001
Approval Date:	Dec 21, 2012
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	
Patent and Exclusivity Info for this product:	View

[Return to Electronic Orange Book Home Page](#)⁶

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through December 2015

Patent and Generic Drug Product Data Last Updated January 15, 2016

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
5. [../default.cfm](#)
6. [../default.cfm](#)

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA No Fear Act](#) [Site Map](#) [Transparency](#)
[Website Policies](#)



NPS EX. 2058

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
[Contact FDA](#)



[For Government](#) [For Press](#)

[Combination Products](#) [Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#)
[Emergency Preparedness](#) [International Programs](#) [News & Events](#) [Training and Continuing](#)
[Education](#) [Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry](#) [Health](#)
[Professionals](#) [FDA Archive](#)



Links on this page:

[FDA Home](#)³ [Drug Databases](#)⁴ [Orange Book](#)⁵

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Patent and Exclusivity Search Results from query on Appl No 203441 Product 001 in the OB_Rx list.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N203441	001	5789379	Apr 14, 2016	Y	Y	U - 1320	
N203441	001	7056886	Sep 18, 2022		Y	U - 1320	
N203441	001	7847061	Nov 1, 2025			U - 1320	
N203441	001	9060992	Nov 1, 2025			U - 1320	

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N203441	001	NCE	Dec 21, 2017
N203441	001	ODE	Dec 21, 2019

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.

[View a list of all patent use codes](#)

[View a list of all exclusivity codes](#)

[Return to Electronic Orange Book Home Page](#)⁶

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through December 2015

Patent and Generic Drug Product Data Last Updated January 15, 2016

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>
5. [../default.cfm](#)
6. [../default.cfm](#)

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA No Fear Act](#) [Site Map](#) [Transparency](#) [Website Policies](#)

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
[Contact FDA](#)



For Government For Press

[Combination Products Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety Emergency Preparedness](#) [International Programs](#) [News & Events](#)
[Training and Continuing Education](#) [Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry Health Professionals](#) [FDA Archive](#)

U.S. Department of **Health & Human Services**

Links on this page: