

FDA Home³ Drug Databases⁴ Orange Book⁵
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 Page⁶](#)

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 March 2016
Patent and Generic Drug Product Data Last Updated April 15, 2016

Links on this page:

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

CFAD Exhibit 1076

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:

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, 2020	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 Page⁶

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 March 2016
 Patent and Generic Drug Product Data Last Updated April 15, 2016

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
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



Links on this page: