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

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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

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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).
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