Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/)

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N205718

Product 001
NETUPITANT; PALONOSETRON HYDROCHLORIDE (AKYNZEO) CAPSULE 300MG;EQ 0.5MG BASE

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8623826	11/18/2030			U-2293		11/06/2014
001	8951969	11/18/2030		DP			03/06/2015
001	9186357	11/18/2030			U-2293		12/02/2015
001	9271975	09/09/2031			U-2293		07/14/2016
001	9943515	11/18/2030			U-2293		05/16/2018
001	9951016	09/25/2035	DS	DP			05/16/2018
001	10233154	09/25/2035	DS				03/28/2019
001	10676440	09/25/2035	DS	DP			07/08/2020

HELSINN EXHIBIT 2034
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00945

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	10828297	12/17/2030			U-2293		12/04/2020
001	10961195	09/25/2035	DS	DP			04/15/2021
001	11559523	11/18/2030		DP	U-3522		02/22/2023
001	12042494	11/18/2030		DP	U-3522		08/07/2024

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
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