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: N210493

Product 002
FOSNETUPITANT CHLORIDE HYDROCHLORIDE; PALONOSETRON HYDROCHLORIDE (AKYNZEO) SOLUTION EQ 235MG BASE/20ML (EQ 11.75MG BASE/ML);EQ 0.25MG BASE/20ML (EQ 0.0125MG BASE/ML)

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
002	8426450	05/23/2032	DS	DP			06/24/2020
002	8895586	05/23/2032			U-2301		06/24/2020
002	9186357	11/18/2030			U-2301		06/24/2020
002	9403772	05/23/2032	DS		U-2301		06/24/2020
002	9908907	05/23/2032	DS	DP			06/24/2020
002	10208073	05/23/2032			U-2301		06/24/2020
002	10624911	06/02/2037		DP			06/24/2020

HELSINN EXHIBIT 2021
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00947

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
002	10717721	05/23/2032	DS				08/19/2020
002	10828297	12/17/2030			U-2301		12/09/2020
002	11312698	05/23/2032	DS	DP			05/13/2022
002	11529362	06/02/2037		DP			01/17/2023
002	12208109	06/02/2037		DP			02/20/2025

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
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View a list of all exclusivity codes (results_exclusivity.cfm)