

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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- 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: N210922

Product 001

PATISIRAN SODIUM (ONPATTRO) SOLUTION EQ 10MG BASE/5ML (EQ 2MG BASE/ML)

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submissic Date
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PROTIVA - EXHIBIT 2027

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8058069	04/15/2029		DP			09/06/2018
001	8158601	11/10/2030		DP	<u>U-2378</u>		09/06/2018
001	8168775	10/20/2029	DS	DP	<u>U-2378</u>		09/06/2018
001	8334373	05/27/2025	DS	DP			09/06/2018
001	8362231	03/30/2021	DS	DP			09/06/2018
001	8372968	03/30/2021	DS	DP			09/06/2018
001	8492359	04/15/2029		DP			09/06/2018
001	8552171	03/30/2021	DS	DP			09/06/2018
001	8642076	10/03/2027		DP			09/06/2018
001	8741866	10/20/2029			<u>U-2378</u>		09/06/2018
001	8778902	03/30/2021			<u>U-2378</u>		09/06/2018
001	8802644	10/21/2030		DP	<u>U-2378</u>		09/06/2018
001	8822668	04/15/2029		DP	<u>U-2378</u>		09/06/2018
001	8895718	03/30/2021	DS	DP			09/06/2018
001	8895721	03/30/2021	DS	DP			09/06/2018
001	9193753	03/30/2021			<u>U-2378</u>		09/06/2018
001	9234196	10/20/2029		DP	<u>U-2378</u>		09/06/2018
001	9364435	04/15/2029		DP	<u>U-2378</u>		09/06/2018
001	9567582	03/30/2021	DS	DP			09/06/2018
001	9943538	11/04/2023		DP			09/06/2018
001	9943539	11/04/2023		DP			09/06/2018

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	NCE	08/10/2023
001	ODE-197	08/10/2025

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