

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

f [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=001&APPL_NO=210922&APPL_TYPE=N\)](HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=001&APPL_NO=210922&APPL_TYPE=N)

t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=001&APPL_NO=210922&APPL_TYPE=N\)](HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=001&APPL_NO=210922&APPL_TYPE=N)

+

e [EMAIL \(MAILTO:?SUBJECT=ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=001&APPL_NO=210922&APPL_TYPE=N\)](MAILTO:?SUBJECT=ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=001&APPL_NO=210922&APPL_TYPE=N)

[Home \(index.cfm?resetfields=1\)](#) | [Back to Product Details](#)

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: 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 |
|------------|-----------|-------------------|----------------|--------------|-----------------|------------------|----------------|
| | | | | | | | |

ARBUTUS - EXHIBIT 2025

| 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 |

[View a list of all patent use codes \(results_patent.cfm\)](#)

[View a list of all exclusivity codes \(results_exclusivity.cfm\)](#)