

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

f [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=001&APPL_NO=022387&APPL_TYPE=N\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?product_no=001&appl_no=022387&appl_type=N)

t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=001&APPL_NO=022387&APPL_TYPE=N\)](https://twitter.com/intent/tweet?text=Orange%20Book:%20Approved%20Drug%20Products%20with%20Therapeutic%20Equivalence%20Evaluations&url=https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?product_no=001&appl_no=022387&appl_type=N)

±

e [EMAIL \(MAILTO:?SUBJECT=ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=001&APPL_NO=022387&APPL_TYPE=N\)](mailto:?subject=Orange%20Book:%20Approved%20Drug%20Products%20with%20Therapeutic%20Equivalence%20Evaluations&body=https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?product_no=001&appl_no=022387&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: N022387

Product 001
TREPASTINIL (TYVASO) SOLUTION 0.6MG/ML

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8497393	12/15/2028	DS			Y	08/20/2013
001	9339507	03/10/2028		DP			05/17/2016

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	9358240	05/05/2028			U-1849		06/08/2016
001	9593066	12/15/2028	DS				03/14/2017
001	9604901	12/15/2028	DS				03/28/2017
001	10376525	05/14/2027			U-1849		04/29/2020
001	10716793	05/14/2027			U-1849		07/21/2020

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	I-856	03/31/2024

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

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