

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

f [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=003&APPL_NO=210563&APPL_TYPE=N\)](HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=003&APPL_NO=210563&APPL_TYPE=N)

t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=003&APPL_NO=210563&APPL_TYPE=N\)](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=003&APPL_NO=210563&APPL_TYPE=N)

+

e [EMAIL \(MAILTO:?SUBJECT=ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/OB/PATENT_INFO.CFM?PRODUCT_NO=003&APPL_NO=210563&APPL_TYPE=N\)](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=003&APPL_NO=210563&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: N210563

Product 003
IBRUTINIB (IMBRUVICA) TABLET 420MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
003	10004746	06/03/2031			U-1684 U-1946 U-2241 U-2242		07/17/2018
003	10010507	03/03/2036		DP			07/17/2018
003	10016435	06/03/2031			U-1650		08/02/2018
003	10106548	06/03/2033	DS	DP			10/26/2018
003	10125140	06/03/2033	DS	DP			11/16/2018
003	7514444	12/28/2026	DS	DP			03/06/2018
003	8008309	12/28/2026	DS	DP			03/06/2018
003	8476284	12/28/2026			U-1456 U-1650 U-1946 U-1947 U-2241		03/06/2018
003	8497277	12/28/2026			U-1456 U-1491 U-1650 U-1946 U-1947 U-2241 U-2242		03/06/2018
003	8563563	04/26/2027			U-1491 U-1650 U-1946 U-2241 U-2242		03/06/2018
003	8697711	12/28/2026	DS	DP			03/06/2018
003	8703780	12/28/2026			U-1491 U-2242		03/06/2018

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
003	8735403	12/28/2026	DS	DP			03/06/2018
003	8754090	06/03/2031			<u>U-1456</u>		03/06/2018
003	8754091	12/28/2026		DP			03/06/2018
003	8952015	12/28/2026			<u>U-1456</u> <u>U-1491</u> <u>U-1650</u> <u>U-1946</u> <u>U-1947</u> <u>U-2241</u> <u>U-2242</u>		03/06/2018
003	8957079	12/28/2026	DS	DP			03/06/2018
003	8999999	06/03/2031			<u>U-1491</u> <u>U-1946</u> <u>U-2241</u> <u>U-2242</u>		03/06/2018
003	9125889	06/03/2031			<u>U-1650</u>		03/06/2018
003	9181257	12/28/2026	DS				03/06/2018
003	9296753	10/30/2033	DS				03/06/2018
003	9655857	03/03/2036		DP			03/06/2018
003	9725455	06/03/2033	DS				03/06/2018
003	9795604	10/24/2034			<u>U-2150</u>		03/06/2018
003	9801881	06/03/2031			<u>U-1491</u> <u>U-2242</u>		03/06/2018
003	9801883	06/03/2031			<u>U-2159</u> <u>U-2243</u>		03/06/2018
003	9814721	06/03/2031			<u>U-1947</u>		03/06/2018

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
------------	------------------	------------------------

There is no unexpired exclusivity for this product in the Orange Book database.

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