

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: N022044

Product 001
METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE (JANUMET) TABLET 500MG;EQ
50MG BASE

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
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Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	6699871	07/26/2022	DS	DP	<u>U-802</u>		
001	6890898	02/02/2019			<u>U-1996</u>		
001	7078381	02/02/2019			<u>U-1996</u>		
001	7125873	07/26/2022		DP	<u>U-803</u> <u>U-1036</u> <u>U-1038</u>		
001	7326708	11/24/2026	DS	DP	<u>U-802</u>		
001	7459428	02/02/2019			<u>U-1996</u>		
001	8414921	07/21/2028		DP	<u>U-1036</u>		04/09/2013

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
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There is no unexpired exclusivity for this product in the Orange Book database.

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