

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: N021897

Product 001
NALTREXONE (VIVITROL) FOR SUSPENSION, EXTENDED RELEASE 380MG/VIAL

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	6194006	12/30/2018		DP			
001	6264987	05/19/2020		DP			
001	6331317	11/12/2019		DP			
001	6379703	12/30/2018		DP			
001	6379704	05/19/2020		DP			
001	6395304	11/12/2019		DP			
001	6495164	05/25/2020		DP			
001	6495166	11/12/2019		DP			
001	6534092	05/19/2020		DP			
001	6537586	11/12/2019		DP			
001	6596316	12/30/2018		DP			
001	6667061	05/25/2020		DP			
001	6713090	11/12/2019		DP			
001	6939033	11/12/2019		DP			
001	7799345	05/25/2020		DP			10/28/2010
001	7919499	10/15/2029			<u>U-1123</u> <u>U-1124</u>		05/16/2011

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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