

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: N021303

Product 001
AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE (ADDERALL XR 10) CAPSULE, EXTENDED RELEASE 2.5MG;2.5MG;2.5MG;2.5MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
001	6322819	Oct 21, 2018			(show_code.cfm?id=&type=0)	
001	6322819*PED	Apr 21, 2019			(show_code.cfm?id=&type=0)	
001	6605300	Oct 21, 2018			(show_code.cfm?id=&type=0)	
001	6605300*PED	Apr 21, 2019			(show_code.cfm?id=&type=0)	
001	RE41148	Oct 21, 2018		DP	(show_code.cfm?id=&type=0)	
001	RE41148*PED	Apr 21, 2019			(show_code.cfm?id=&type=0)	
001	RE42096	Oct 21, 2018		DP	(show_code.cfm?id=&type=0)	
001	RE42096*PED	Apr 21, 2019			(show_code.cfm?id=&type=0)	

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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