

# 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      |                      |                    | <a href="#">(show_code.cfm?id=&amp;type=0)</a> |                  |
| 001        | 6322819*PED | Apr 21, 2019      |                      |                    | <a href="#">(show_code.cfm?id=&amp;type=0)</a> |                  |
| 001        | 6605300     | Oct 21, 2018      |                      |                    | <a href="#">(show_code.cfm?id=&amp;type=0)</a> |                  |
| 001        | 6605300*PED | Apr 21, 2019      |                      |                    | <a href="#">(show_code.cfm?id=&amp;type=0)</a> |                  |
| 001        | RE41148     | Oct 21, 2018      |                      | DP                 | <a href="#">(show_code.cfm?id=&amp;type=0)</a> |                  |
| 001        | RE41148*PED | Apr 21, 2019      |                      |                    | <a href="#">(show_code.cfm?id=&amp;type=0)</a> |                  |
| 001        | RE42096     | Oct 21, 2018      |                      | DP                 | <a href="#">(show_code.cfm?id=&amp;type=0)</a> |                  |
| 001        | RE42096*PED | Apr 21, 2019      |                      |                    | <a href="#">(show_code.cfm?id=&amp;type=0)</a> |                  |

### 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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