

# 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: N203634

Product 001  
BUDESONIDE (UCERIS) TABLET, EXTENDED RELEASE 9MG

### Patent Data

Product No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
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Exhibit 1060

001	7410651	Jun 9, 2020	DP	<b><u>U-1325</u></b> <b><u>(show code.cfm?id=1325&amp;type=0)</u></b>
001	7431943	Jun 9, 2020	DP	<b><u>(show code.cfm?id=&amp;type=0)</u></b>
001	8293273	Jun 9, 2020	DP	<b><u>(show code.cfm?id=&amp;type=0)</u></b>
001	8784888	Jun 9, 2020	DP	<b><u>(show code.cfm?id=&amp;type=0)</u></b>
001	8895064	Sep 7, 2031	DP	<b><u>(show code.cfm?id=&amp;type=0)</u></b>
001	9132093	Sep 7, 2031	DP	<b><u>(show code.cfm?id=&amp;type=0)</u></b>
001	9192581	Sep 7, 2031	DP	<b><u>U-1325</u></b> <b><u>(show code.cfm?id=1325&amp;type=0)</u></b>
001	9320716	Jun 9, 2020	DP	<b><u>U-1325</u></b> <b><u>(show code.cfm?id=1325&amp;type=0)</u></b>
001	9532954	Jun 9, 2020	DP	<b><u>U-1325</u></b> <b><u>(show code.cfm?id=1325&amp;type=0)</u></b>
001	RE43799	Jun 9, 2020	DP	<b><u>U-1325</u></b> <b><u>(show code.cfm?id=1325&amp;type=0)</u></b>

### 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.