# 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: N207154

Product 001 DAPSONE (ACZONE) GEL 7.5%

#### **Patent Data**

Product	Patent	Patent	Drug	Drug		Delist	Submis
No	No	Expiration	Substance	Product	Patent Use Code	Requested	Date

ProductPatentDrugDrugDelistSubmisNoNoExpirationSubstanceProductPatent Use CodeRequestedDate



001	9161926	11/18/2033	DP	(show_code.cfm? id=&type=0)	03/01/2
001	9517219	11/18/2033		<u>U-1033</u> (show_code.cfm? id=1136&type=0)	12/16/2

### **Exclusivity Data**

Product No	Exclusivity Code	<b>Exclusivity Expiration</b>
001	NS (show_code.cfm?id=1160&type=1)	02/24/2019

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