

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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- 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: N209090

Product 001
 LEVOCETIRIZINE DIHYDROCHLORIDE (XYZAL ALLERGY 24HR) SOLUTION 2.5MG/5ML
 (0.5MG/ML)

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	8633194	10/16/2027		DP			02/28/2017

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
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