

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: N022527

Product 001
FINGOLIMOD (GILENYA) CAPSULE 0.5MG

Patent Data

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

001	5604229	Feb 18, 2019	DS	<u>U-1086</u> <u>(show_code.cfm?id=1189&type=0)</u>
001	6004565	Sep 23, 2017		<u>U-1086</u> <u>(show_code.cfm?id=1189&type=0)</u>
001	8324283	Mar 29, 2026		<u>(show_code.cfm?id=&type=0)</u>
001	9187405	Jun 25, 2027		<u>U-1086</u> <u>(show_code.cfm?id=1189&type=0)</u>

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	<u>NCE (show_code.cfm?id=1103&type=1)</u>	Sep 21, 2015

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