Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/)

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Home (index.cfm?resetfields=1) | Back to Product Details

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: N213976

Product 001
BUDESONIDE (EOHILIA) SUSPENSION 2MG/10ML

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	8324192	08/03/2029			U-3820		03/04/2024
001	8497258	11/09/2026			U-3820		03/04/2024
001	8679545	11/09/2026		DP			03/04/2024
001	8975243	11/09/2026			U-3820		03/04/2024
001	9050368	08/01/2029		DP			03/04/2024
001	9119863	11/09/2026			U-3820		03/04/2024
001	10293052	11/22/2028		DP			03/04/2024
001	11197822	11/09/2026		DP			03/04/2024
001	11260064	01/10/2039		DP			03/04/2024

Ellodi's Exhibit 2022
Falk v. Ellodi
IPR2025-00052 - Page 001

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	11357859	11/12/2028			U-3820		03/04/2024
001	11413296	11/09/2026		DP			03/04/2024
001	11564934	01/10/2039			U-3820		03/04/2024

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	NP	02/09/2027
001	ODE-466	02/09/2031

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Ellodi's Exhibit 2022
Falk v. Ellodi
IPR2025-00052 - Page 002