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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
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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>U-3820</u>		03/04/2024
001	8497258	11/09/2026			<u>U-3820</u>		03/04/2024
001	8679545	11/09/2026		DP			03/04/2024
001	8975243	11/09/2026			<u>U-3820</u>		03/04/2024
001	9050368	08/01/2029		DP			03/04/2024
001	9119863	11/09/2026			<u>U-3820</u>		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

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

Exclusivity Data

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

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