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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).
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Patent and Exclusivity for: N216665

Product 001
DIAZOXIDE CHOLINE (VYKAT XR) TABLET, EXTENDED RELEASE 25MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	7572789	12/20/2026	DS	DP			04/23/2025
001	7799777	03/05/2029	DS				04/23/2025
001	9757384	11/12/2035			U-4167		04/23/2025
001	12178823	11/12/2035			U-4167		04/23/2025
001	12343348	11/12/2035			U-4211		07/03/2025
001	12419895	11/12/2035			U-4275		10/06/2025

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	NP	03/26/2028
001	ODE-532	05/26/2032

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Soleno Therapeutics, Inc.
Exhibit 2017
Apotex v. Soleno
PGR2026-00034
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