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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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Patent and Exclusivity for: N204410

Product 001
MACITENTAN (OPSUMIT) TABLET 10MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	7094781	12/05/2025	DS	DP			11/06/2013
001	7094781*PED	06/05/2026					
001	8268847	04/18/2029			U-1446		11/06/2013
001	8268847*PED	10/18/2029					
001	8367685	10/04/2028		DP	U-1445		11/06/2013
001	8367685*PED	04/04/2029					
001	9265762	05/29/2027		DP	U-1820		03/16/2016
001	9265762*PED	11/29/2027					
001	10946015	09/11/2026		DP	U-1445		04/08/2021
001	10946015*PED	03/11/2027					

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	M-187	02/28/2028
001	M-187 *PED	08/28/2028

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