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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: N203284

Product 001
GLYCEROL PHENYLBUTYRATE (RAVICTI) LIQUID 1.1GM/ML

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	5968979	07/28/2018	DS	DP	U-1378		04/22/2013
001	8404215	03/09/2032			U-1383		04/25/2013
001	8642012	09/22/2030			U-1383		02/27/2014
001	9095559	03/09/2032			U-1383		09/03/2015
001	9254278	03/09/2032			U-1816		02/29/2016
001	9326966	03/09/2032			U-1816		05/25/2016
001	9561197	09/22/2030			U-1383		07/06/2017
001	9962359	09/22/2030			U-1816		06/07/2018

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	<u>ODE-42</u>	02/01/2020
001	NPP	04/28/2020
001	ODE-157	04/28/2024

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