

# 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).
- 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: N021880

Product 004  
LENALIDOMIDE (REVLIMID) CAPSULE 25MG

### Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
004	5635517	10/04/2019	DS				
004	6045501	08/28/2018			<u>U-1210</u>		
004	6315720	10/23/2020			<u>U-1210</u>		
004	6561976	08/28/2018			<u>U-1210</u>		
004	6561977	10/23/2020			<u>U-1210</u>		
004	6755784	10/23/2020			<u>U-1210</u>		
004	6908432	08/28/2018			<u>U-1210</u>		
004	7189740	04/11/2023			<u>U-1215</u>		
004	7465800	04/27/2027	DS	DP			
004	7468363	10/07/2023			<u>U-1414</u>		
004	7855217	11/24/2024	DS	DP			
004	7968569	10/07/2023			<u>U-1216</u>		07/14/2011
004	8204763	08/28/2018			<u>U-1249</u>		
004	8315886	10/23/2020			<u>U-1249</u>		
004	8404717	04/11/2023			<u>U-1215</u>		
004	8530498	05/15/2023			<u>U-1216</u>		09/26/2013
004	8589188	08/28/2018			<u>U-1210</u>		
004	8626531	10/23/2020			<u>U-1210</u>		02/05/2014
004	8648095	05/15/2023			<u>U-1216</u>		
004	8741929	03/08/2028			<u>U-1414</u>		06/17/2014
004	9056120	04/11/2023			<u>U-1215</u>		07/09/2015
004	9101621	05/15/2023			<u>U-1216</u>		08/26/2015

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
004	9101622	05/15/2023			<u>U-1216</u>		08/26/2015

### Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
004	<u>I-706</u>	02/17/2018
004	<u>ODE-49</u>	06/05/2020
004	<u>ODE-88</u>	02/17/2022
004	<u>ODE-131</u>	02/22/2024

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