

New Drug Manufacturer Report

Section	Data element	Field type	Drug #1	Drug #2
1. Drug identification	National drug code (11-digit NDC)	Numeric	72606-0566-01	72606-0573-01
	Drug name	Text	Abiraterone Acetate Oral Tablet 250 MG	Abiraterone Acetate Oral Tablet 500 MG
2. Drug Launch Information	Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	Text	Celltrion USA Inc. launched a new oncology drug over the specialty threshold. This product was licensed to Celltrion. This oncology product has a dedicated production line, and this oncology drug has an expensive active pharmaceutical ingredient ('API'), this product is a generic equivalent of an existing innovator product. Celltrion USA, Inc. does not engage in direct-to-consumer marketing and paid advertising to consumers, physicians, or other healthcare professionals for its generic products.	Celltrion USA Inc. launched a new oncology drug over the specialty threshold. This product was licensed to Celltrion. This oncology product has a dedicated production line, and this oncology drug has an expensive active pharmaceutical ingredient ('API'), this product is a generic equivalent of an existing innovator product. Celltrion USA, Inc. does not engage in direct-to-consumer marketing and paid advertising to consumers, physicians, or other healthcare professionals for its generic products.
	Estimated volume of patients who may be prescribed the drug	Numeric	4500	4500
	Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	Not applicable	Not applicable
	Date and price of acquisition if the drug was not developed by the manufacturer	Text	Not applicable	Not applicable