

New Drug Manufacturer Report

Section		Data element	Field type	Drug #1
1.	Drug identification	National drug code (11-digit NDC)	Numeric	72606-0559-02
		Drug name	Text	Busulfan Injection, 60 mg/10 mL
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. is a new pharmaceutical company and has not yet begun direct-to-consumer marketing activities. We will be working towards increasing awareness of the availability of a new branded generic product to healthcare providers (HCPs) through speaker engagements and seminars, and provide FDA approved medication information through print material, mobile application, and website.
		Estimated volume of patients who may be prescribed the drug	Numeric	33,000
		Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	Not applicable
		Date and price of acquisition if the drug was not developed by the manufacturer	Text	Not applicable