New Drug Manufacturer Report

Section	Data element	Field type	OPZELURA
1. Drug identification	National drug code (11-digit NDC)	Numeric	50881-0007-05
	Drug name	Text	OPZELURA (ruxolitinib) cream 1.5% 60gm tube
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	To market OPZELURA, Incyte designed activities to increase awareness and understanding with healthcare providers about OPZELURA. Marketing activities will include education and training provided by our sales force and by contracted speakers to health care providers. Consumer-directed communications to educate patients on the disease state and OPZELURA are planned. At Incyte, we are driven by rigorous science and committed to ensuring patients have access to our innovative medicines. We responsibly price our drugs by balancing the value of the outcomes and innovation they bring to patients and the health care system within market and societal expectations. OPZELURA is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Use of OPZELURA in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.
	Estimated volume of patients who may be prescribed the drug	Numeric	Estimated 5.5 million patients in the US 12 years of age and older with mild to severe AD are drug-treated annually
	Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	Yes priority review No breakthrough therapy
	Date and price of acquisition if the drug was not developed by the manufacturer	Text	NA - product not acquired