New Drug Manufacturer Report

Section		Data element	Field type	Drug #1	Please add columns as needed
1.	**Drug identification**	National drug code (11-digit NDC)	Numeric	73606-0020-01	
		Drug name	Text	Syfovre	
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	**Marketing:** SYFOVRE is a FDA approved treatment for Geographic Atophy (GA), secondary to age-related macular degeneration (AMD). SYFOVRE is the first and only FDA-approved therapy indicated for GA. Apellis' Marketing plan consists of items for HCP promotions covering salaries and compensation for promotional field teams calling on HCPs, electronic and print materials for direct promotion to HCPs, HCP focused websites, digital and print HCP media, educational events for HCPs for information about GA and SYFOVRE, and sponsorships and exhibit production costs for HCP congresses. The Marketing plan also includes items to educate consumers on GA and SYFOVRE via TV, magazines, internet and social media advertising, search engine marketing, consumer focused websites, and print materials. **Pricing:** SYFOVRE has been developed for the treatment of patients with Geographic Atrophy (GA), secondary to age-related macular degeneration (AMD). SYFOVRE provides an option to deliver a safe, effective treatment that slows lesion progression. SYFOVRE is priced responsibly. Pricing accounts for development costs, complexity of manufacturing, distribution, and storage. Apellis places a priority on patient access and ensuring all eligible patients with the potential to benefit can receive SYFOVRE. Apellis performed a thorough analysis of the clinical value of SYFOVRE in GA, examined relevant benchmarks, and considered patient access to determine the list price. Pricing Methodology for Syfovre was based on the fact that EMPAVELI demonstrated a clinically meaningful effect on lesion size reduction. Based on market research and analog products within the retinal class, a cross functional team evaluated the clinical value of the product, based on the entirety of the data available, to establish the list price.	
		Estimated volume of patients who may be prescribed the drug	Numeric	The estimated number of patients living with GA is 1,000,000 patients, per *Yates JR, Sepp T, Matharu BK, et al; Genetic Factors in AMD Study Group. Complement C3 variant and the risk of age-related macular degeneration. N Engl J Med. 2007;357(6):553-561.*	
		Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	SYFOVRE was reviewed by the FDA under priority review. SYFOVRE does not have a breakthrough therapy designation.	
		Date and price of acquisition if the drug was not developed by the manufacturer	Text	N/A	