New Drug Manufacturer Report

Section		Data element	Drug #1	Drug #2	Drug #3	Drug #4	Drug #5
1.	**Drug identification**	National drug code (11-digit NDC)	10094030502	10094030702	10094031002	10094031202	10094031502
		Drug name	Libervant (diazepam) Buccal Film, 5 MG, 2 Each, Unit-of-Use, Box	Libervant (diazepam) Buccal Film, 7.5 MG, 2 Each, Unit-of-Use, Box	Libervant (diazepam) Buccal Film, 10 MG, 2 Each, Unit-of-Use, Box	Libervant (diazepam) Buccal Film, 12.5 MG, 2 Each, Unit-of-Use, Box	Libervant (diazepam) Buccal Film, 15 MG, 2 Each, Unit-of-Use, Box
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	Libervant will be marketed to key pediatric neurologists across the US. There will be no drug samples or other promotional materials provided during marketing. The product is priced in accordance with other branded products in its therapeutic class.	Libervant will be marketed to key pediatric neurologists across the US. There will be no drug samples or other promotional materials provided during marketing. The product is priced in accordance with other branded products in its therapeutic class.	Libervant will be marketed to key pediatric neurologists across the US. There will be no drug samples or other promotional materials provided during marketing. The product is priced in accordance with other branded products in its therapeutic class.	Libervant will be marketed to key pediatric neurologists across the US. There will be no drug samples or other promotional materials provided during marketing. The product is priced in accordance with other branded products in its therapeutic class.	Libervant will be marketed to key pediatric neurologists across the US. There will be no drug samples or other promotional materials provided during marketing. The product is priced in accordance with other branded products in its therapeutic class.
		Estimated volume of patients who may be prescribed the drug	100	100	150	500	100
		Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	No	No	No	No	No
		Date and price of acquisition if the drug was not developed by the manufacturer	N/A	N/A	N/A	N/A	N/A