

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Bausch Health US, LLC is conducting a market withdrawal for Diastat® (diazepam rectal gel)/Diastat® AcuDial™ (diazepam rectal gel) Rectal Delivery System 10 mg and 20 mg (NDC: 68682-652-20 and 68682-655- 20). This market withdrawal is being made with the knowledge of the Food and Drug Administration.

This market withdrawal is being initiated because the lubricating jelly packet supplied with the Diastat® (Diazepam) Rectal Gel Delivery System has an expiry date that is earlier than the drug product expiry date. There is no issue related to the quality of the drug product up to the assigned expiry date except with the expiry date of the lubricating jelly packet. The issue with the expiry date on the lubricating jelly packets is detectable as it is printed on the packets.

Bausch Health intends to carry out a phased approach for market withdrawal at the pharmacy level based on the expiry date of the lubricating jelly packets. This letter serves as a notification that the finished product lots listed in Table 1 below are included within the scope.

Product Name	NDC#	Lot#	Product Exp Date	Jelly Pack Exp Date	Distribution Dates
Diazepam Rectal Gel, 10mg	68682-652-20	SKCH	10/31/2026	11/30/2025	2022 - 2025
		SKCG	9/30/2026	11/30/2025	2022 - 2025
Diazepam Rectal Gel, 20mg	68682-655-20	SKCR	9/30/2026	11/30/2025	2022 - 2025