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.

Bristol-Myers Squibb Company is initiating a recall of one lot of Opdualag™ (nivolumalb and relatimab-rmbw) Injection 240mg and 80mg/20 mL; the impacted LOT is 033A23B. This recall is being conducted at the retail level, with the knowledge of the US Food and Drug Administration (FDA).

During a routine inspection, FDA determined that a vendor led investigation record, specifically for a case of atypical extrinsic particle contaminant was incomplete. This recall is a precaution based on the Company's investigation of an atypical extrinsic particle found during the manufacturing of the Opdualag drug product lot 033A23B. A thorough assessment of safety database was carried out for the affected lot of Opdualag. There were no new safety concerns or trends identified pertaining to Opdualag Batch 033A23. BMS through health risk assessment determined the probability of a particle, if present, entering the systemic circulation through the in-line filter, causing patient harm, is low.

PRODUCT: Opdualag 240MG/80MG (1VLX20ML), US

NDC NUMBER: 0003-7125-11

LOT NUMBER: 033A23B

EXPIRATION DATE: APR2026