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.

This is to inform you of a product recall involving one (1) lot of LIBTAYO® (cemiplimab-rwlc) injection for intravenous use, 350 mg/7 mL solution in a single dose vial by Regeneron Healthcare.

The recall has been initiated due to the potential for incomplete crimping for 350 mg/7 mL LIBTAYO® vials in the subject lot. Therefore, container closure integrity of the impacted vials and the sterility of the drug product may not be guaranteed.

To date, Regeneron has not received reports of any adverse events associated with this issue. The probability of occurrence of this defect is minimized by a 100% manual visual inspection process conducted by the manufacturer. However, there may be a risk of this defect being present on the market. Therefore, this limited recall is being conducted as a precautionary risk-mitigation measure and is not anticipated to have any adverse impact to product supply.

No other lots of LIBTAYO® distributed in the United States are included in this recall.

The recall of the below referenced lot of 350 mg/7 mL LIBTAYO® is being conducted to the Wholesaler/Pharmacy/Hospital level with the knowledge of the Food and Drug Administration.

PRODUCT: LIBTAYO® (cemiplimab-rwlc) injection for intravenous use, 350 mg/7 mL solution in a single dose vial

NDC NUMBER: 61755-008-01

LOT NUMBER: 8494000002

EXPIRATION DATE: Jul-28

DISTRIBUTION DATES: 4/27/26 - 7/1/26