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 that Glenmark is initiating a recall at the Retail level involving Abiraterone Acetate Tablets USP 500 mg by Glenmark Pharmaceuticals, Inc. USA.

Abiraterone acetate is a prescription-only antineoplastic agent that is converted in vivo to abiraterone, an androgen biosynthesis inhibitor. Abiraterone inhibits CYP17, an enzyme required for androgen biosynthesis, thereby reducing androgen production. Androgen-sensitive prostatic carcinoma responds to treatment that decreases androgen levels. Abiraterone acetate tablets are indicated, in combination with prednisone, for the treatment of adult patients with metastatic prostate cancer.

Glenmark received a complaint on August 13, 2026, from a pharmacist for batch number 13250135. According to the pharmacist, the outer carton appeared normal; however, upon opening the carton, it was observed that the bottle inside did not have a product label affixed. The pharmacist further confirmed that only one bottle was affected.

A review of complaint history for products manufactured and packaged at the OSD manufacturing facility did not identify similar complaints related to missing bottle labels. Based on the available information, the event is considered an isolated occurrence, with no missing bottle label trend observed across products.

Based on the investigation and simulation study, the most probable cause for the missing label was identified as the label not being applied onto the bottle during manufacturing. The Health Hazard Assessment (HHA) concluded that the complaint is an isolated occurrence. Based on the high detectability of the defect, the absence of patient exposure, and the lack of reported adverse events, the associated product quality defect is considered unlikely to pose a risk to patient health or safety.

This recall should be conducted to the retail level.

PRODUCT: Abiraterone Acetate Tablets USP 500 mg 60's Tablets

NDC NUMBER: 68462-882-60

LOT NUMBER: 13250135

EXPIRATION DATE: Nov. 2027