

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.

Out of an abundance of caution, a recall to the Retail level for Ezetimibe and Simvastatin Tablets 10 mg / 40mg has been initiated by Glenmark due to an out-of-specification result that was confirmed for the anhydro-simvastatin (Impurity C) in the related substance test at the 6 month time point during a long-term (25°C/60% RH) stability study. However, this same impurity was found within the specification at the 9 month and 12month stability study time points.

In accordance with ICH M7 (R2), an in-silico assessment of the mutagenic potential of “anhydro simvastatin” was confirmed not to be mutagenic. Therefore, a marginal increase above the specification limit for anhydro-simvastatin in ezetimibe/simvastatin tablets at the 6 month time point is unlikely to have any impact on patient health and safety.

PRODUCT: EZETIMIBE and SIMVASTATIN TABLETS 10 MG/40 MG (90's Pack Container)

NDC NUMBER: 68462-323-90

LOT NUMBER: 17240195

EXPIRATION DATE: 01/2026