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 Market Withdrawal to the Retail level involving EZETIMIBE & SIMVASTATIN TABLETS 10MG/40MG (90's Pack Container).
The Market withdrawal to the retail level of the above identified product batch of EZETIMIBE AND SIMVASTATIN TABLETS 10mg/40 mg has been initiated by Glenmark out of an abundance of precaution because an Out of Specification result reported for Anhydro Simvastatin in the Related Substance test at the 06-month time point during a long-term (25°C/60% RH) stability study. All other parameters of aforementioned batch complied with specification.

As the initial OOS result for Anhydro simvastatin impurity at 6-month stability time point of subjected batch was quite abnormal, this was escalated to R&D for further investigation. Multiple hypothesis testing was carried out at R&D on subjected batch #17240195. In all the experiments, results of Anhydro simvastatin impurity found complying with the specification limit, though in few cases on the borderline. However, the abnormally high result as observed during initial analysis in QC laboratory (OOS result as 0.51%), was not observed in these experiments. Though the Anhydro simvastatin impurity was observed on the higher side, it met specification limit and the results were much lower than the initial OOS result.

Moreover subsequent stability time point samples of 09 Months and 12 months of subjected batch # 17240195 were analysed. The result for Anhydro Simvastatin met the specification limit though on higher side.

Based on the data evaluation and manufacturing investigation, most probable cause for higher result of Anhydro simvastatin impurity in Batch # 17240195 during stability study compared to other batches in stability could be due to higher hold time (cumulative wet mass hold time + cumulative intermittent stoppage time in this batch was 339 minutes) during manufacturing of the batch at drying stage.

As an impact assessment, the highest cumulative hold time of the batches that has successfully completed stability study up to shelf life was reviewed. The highest cumulative hold time in batch # 17222077 that has completed stability study up to 24 months is observed to be 218 minutes with corresponding Anhydro simvastatin impurity level as 0.35% (Specification Limit: NMT 0.4%). Hence, cumulative hold time up to 218 minutes is considered to be acceptable. Further the cumulative hold time of all the batches within the shelf life available in market was reviewed and found to be less than 218 minutes. With this withdrawal, all batches having more than 218 minutes of cumulative hold time at drying stage stands withdrawn from the market.

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

NDC NUMBER: 68462-323-90

BATCH NUMNER: 17240195

EXPIRATION DATE: 01/2026