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 Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/ 0.02 mg and Ethinyl Estradiol Tablets USP 0.01 mg (Brand Name – Viorele).

The recall to the retail level of the above-identified Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/ 0.02 mg and Ethinyl Estradiol Tablets USP 0.01 mg (Viorele) batch have been initiated due to failure results were reported for the Related Substances (By HPLC) test for commercial annual stability batch # 20230733 at the long-term (25°C/60% RH) 18 month time stability interval, wherein the Impurity D, Specified Impurity at RRT 0.70, Any unknown impurity and Total impurities results are found to be OOS in Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/ 0.02 mg against the specification of Not more than 1.0%, Not more than 1.00%, Not more than 1.00%, and Not more than 3.50% respectively.

To date, Glenmark has not received any reports of adverse events related to this recall. The health hazard assessment concluded that the observed OOS results in related substance test are not considered a clinically significant risk to patient health and safety.

PRODUCT: Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/ 0.02 mg and Ethinyl Estradiol Tablets USP 0.01 mg (Brand Name – Viorele), 3 X 28 tablet pack

NDC NUMBER: 68462-318-29

BATCH NUMBER: 20230733

EXPIRATION DATE: October 2025