

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.

ANI Pharmaceuticals, Inc. would like to inform you of a product recall involving Estradiol Gel 0.1%, 0.25mg, NDC 70954-531-20, 30 packets per carton, Lot Number M251109.

This recall has been initiated due to a developing customer complaint trend for empty/partially filled packets of Estradiol Gel 0.1%, 0.25mg, Batch number M251109. As a precautionary measure, ANI Pharmaceuticals, Inc. has elected to recall this batch. Based on a Health Hazard Evaluation, partially filled or empty packets could provide a subtherapeutic dose. This could cause a lack of control of vasomotor symptoms, such as hot flashes and night sweats. The drug product was distributed from January 14, 2026, to January 15, 2026.

This recall is being carried out to the retail level.

PRODUCT: Estradiol Gel 0.1%, 0.25mg

NDC NUMBER: 70954-531-20

LOT NUMBER: M251109

EXPIRY DATE: Nov. 2027