

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.

Teva Pharmaceuticals USA, Inc. (TEVA USA) is initiating a nationwide recall of Tri-Lo-Sprintec® 28 DAY REGIMEN to the **RETAIL LEVEL**. The products in this recall were distributed to TEVA USA direct customers under the Teva Pharmaceuticals USA, Inc. label. The reason for the recall is out-of-specification (OOS) dissolution results have been obtained for these specified lots. A Teva USA Health Hazard Assessment determined that the main health consequence that could arise from this OOS dissolution result is decreased efficacy of the product, possibly leading to an unexpected or unplanned pregnancy. However, because the active substances norgestimate and ethinyl estradiol are rapidly absorbed following oral administration, a slight deviation in dissolution will not have a significant clinical impact on the patients taking this medicine, especially those who have already reached steady-state concentration. Therefore, the exposure to the product of concern is not expected to lead to adverse health consequences outside of the known safety profile of the drug.

Lot	Exp. Date	Size	NDC Carton	NDC Blister Card
100038111	07 2024	3 Blister Cards, 28 Tablets Each	0093-2140-62	0093-2140-28
100039678	04 2024	3 Blister Cards, 28 Tablets Each	0093-2140-62	0093-2140-28
100042277	07 2024	3 Blister Cards, 28 Tablets Each	0093-2140-62	0093-2140-28