

The Board of Pharmacy has received notice of the following product market withdrawal:

Carton NDC - 0591-3508-04

Carton Lot # - 1369117B

TDS (Patch) NDC - 0591-3508-54

TDS (Patch) Lot Number – 1369117

Exp Date – 11/2021

Size - 4 Patches / Carton

Teva Pharmaceuticals USA, Inc. is voluntarily recalling one lot of Clonidine Transdermal System, USP 0.1 mg/day to the Retail Level. The lot in this recall was distributed under the Actavis Pharma Inc., label. This recall is being initiated because Lot # 1369117B exceeded the stability specification limit for related substances. Teva's Toxicological Analysis of this Clonidine related substance determined it to be non-mutagenic and does not pose any health risks to the patient. In addition, Teva's Health Hazard Assessment concluded exposure to the related substance is unlikely to result in any adverse health consequences or impact the efficacy of the drug. As such, the overall risk of harm is considered to be low. This recall is being made with the knowledge of the Food and Drug Administration.

The Board of Pharmacy strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.