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) is initiating a nationwide recall of one (1) lot of Trazodone Hydrochloride Tablets USP, 50mg to the RETAIL LEVEL. The product in this recall is distributed under the Teva Pharmaceuticals USA, Inc. label. This lot is being recalled as a safety precaution because, to date, a single Buspirone Hydrochloride Tablet, USP (15 mg) was discovered in each of two individual sealed bottles of Trazodone Hydrochloride Tablets USP, 50mg lot 1394026. The clinical concern regarding use of the recalled lot is lack of effect or lack of efficacy and/or potential for an adverse event(s). To date, TEVA has received no relevant complaints for drug ineffectiveness, lack of effect or lack of efficacy. Teva's health hazard assessment concluded that use of the subject product lot of concern may result in, at most, mild and transient self-limiting effects following administration of a product other than that prescribed. However, because hypersensitivity to the mixed-up drug cannot be excluded, the potential severity was assessed as severe. The likelihood of harm is considered negligible, as there is a low probability that the product would reach the patient, and even if it did, the defect could be readily identified visually by the patient or healthcare professional. Consequently, the overall risk of harm to the patient population is considered low.

This recall is being conducted to the retail level. This recall is being made with the knowledge of the U.S. Food and Drug Administration.

PRODUCT: Trazodone Hydrochloride Tablets, USP 50mg, 100 count bottle

NDC NUMBER: 50111-560-01

LOT NUMBER: 1394026

EXPIRATION DATE: 02/2028