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.

Sun Pharmaceutical Industries, Inc. has initiated a recall for Mesalamine Extended-Release Capsules, USP 500 mg. This recall has been initiated in response to Out of Specification (OOS) dissolution test results observed during retention sample testing.

On 04/25/2024, one (1) additional batch (MHD1162A) was identified as an impacted batch for potential dissolution failure that was additionally identified as an impacted batch during the Mesalamine Extended-Release Capsules, USP Recall (0-0350-2024, RES 93909) initiated on 02/05/2024 which included 23 batches.

Sun Pharmaceutical Industries, Inc. initiated shipment of this product on February 16, 2023.

PRODUCT: Mesalamine Extended-Release Capsules, USP 500 mg

NDC NUMBER: 63304-089-13

LOT NUMBER: MHD1162A

EXPIRATION DATE: 10/31/2024