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.

Marksans Pharma Limited, India is voluntarily recalling Metformin Hydrochloride Extended-Release Tablets, USP 500mg, lot # XP9004, to the consumer level. FDA analysis has found the product to contain N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit (ADI) of 96ng/day.

Risk Statement: NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant found in water and foods, including meats, dairy products and vegetables. Marksans Pharma Limited has not received any reports of adverse events related to this recall to date.

Metformin Hydrochloride Extended-Release Tablets, USP 500mg is indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus and is packaged in 100 count bottles with NDC code 49483-623-01. The affected Metformin Hydrochloride Extended-Release Tablets, USP 500mg, are white to off white, capsule shaped, biconvex tablets, debossed with '101' on one side and plain on the other side.

Product name: Metformin Hydrochloride Extended Release Tablets USP, 500 mg

Lot #: XP9004

Expiry Date (MM/YYYY): 12/2020

The product can be identified by lot # XP9004 and expiration date 12/2020. Metformin Hydrochloride Extended-Release Tablets, USP 500mg, lot # XP9004 was distributed by Time-Cap Labs, Inc. (located at 7 Michael Avenue, Farmingdale, New York 11735) nationwide in the USA to wholesalers who further distributed to pharmacies.

Marksans Pharma Limited is notifying its distributors and customers by issuing notification letter and press release and is arranging for return/replacement etc. of recalled product lot. Distributors/retailers that have Metformin Hydrochloride Extended-Release Tablets, USP 500mg, lot # XP9004 which is being recalled should return to place of purchase.

Consumers with questions regarding this recall and return can contact Ms. Irene McGregor (Vice President, Regulatory Affairs) of Time-Cap Labs, Inc., located at 7 Michael Avenue, Farmingdale, New York 11735, by phone number 631-753-9090; ext. 160, [Monday to Friday 8am-5pm EST] or e-mail address imcgregor@timecaplabs.com.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online.
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 or call **Time-Cap Labs**, Inc. at 1-877-376-4271 or Fax at 631-753-2220.

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