Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

29 MAY 2018

FDA ADVISORY
No. 2018-190

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Product Recall of Lot No. SJN077 of Allopurinol 300 mg Tablet (Allujen)**

All healthcare professionals and the general public are hereby warned by the Food and Drug Administration (FDA) that a specific lot of the subject product is being recalled from the market. The details of the product are as follows:

DRUG PRODUCT	**ALLOPURINOL 300 MG TABLET (ALLUJEN)**
REGISTRATION NUMBER	**DRP-2173-01**
LOT NUMBER / EXPIRY DATE	**SJN077 / SEPTEMBER 2018**
MANUFACTURER	**NEW MYREX LABORATORIES, INC. - BO. CATMON, STA. MARIA, BULACAN**
DISTRIBUTOR (Marketing Authorization Holder [MAH])	**SKPD JEN INC. - 3RD FLR. 44-A ANNAPOLIS ST., BRGY. E. RODRIGUEZ, CUBAO, QUEZON CITY**

Based on the results of the laboratory analyses conducted by the FDA, it was found that the affected lot did not conform to the set specifications of hardness test. The hardness of an immediate-release tablet should be such that the tablet will be able to withstand the rigors of manufacturing, packaging, shipping, and distribution of the drug product. The stated lot presents quality concerns since it failed to meet the specifications set by the manufacturer.

Allopurinol is indicated in the management of patients with signs and symptoms of primary or secondary gout (acute attacks, tophi, joint destruction, uric acid lithiasis, and/or nephropathy), in the management of patients with leukemia, lymphoma and malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels, and in the management of patients with recurrent calcium oxalate calculi whose daily uric acid secretion exceeds 800 mg/day in male patients and 750 mg/day in female patients. Allopurinol 300 mg Tablet (Allujen) is packed in aluminum-clear PVC blister pack x 10's (box of 100's).

Therefore, distributors, hospitals, retailers, pharmacies or clinics that have the affected lot of the drug product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lot and

may contact New Myrex Laboratories or SKPD Jen, Inc. at telephone numbers +632 912 8034 / +632 400 8224 / +632 9134718 / +63922 8608151 or e-mail us at cdrr_prsdd@fda.gov.ph for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product lot is not sold or made available in their localities or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the aforementioned product lot should be reported immediately to FDA through this link: ww2.fda.gov.ph/adr-report-new and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
Director General

DTN: 20180503163547