Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 JUL 2015

FDA Advisory
No. 2015-056

SUBJECT: **TERMINATION OF PRODUCT RECALL ORDER ISSUED ON SPECIFIC BATCHES OF TETRAHYDROZOLINE HYDROCHLORIDE (VISINE) 500 mcg/mL (0.05%) OPHTHALMIC SOLUTION (EYE DROPS)**

This is to inform the public that the Product Recall Order (PRO) issued on affected batches (329-67013, 329-67026, 329-67038 & 429-67018) of Tetrahydrozoline Hydrochloride (Visine) 0.5 mg/mL (0.05%) Ophthalmic Solution (Eye Drops) is hereby terminated by the Food and Drug Administration (FDA). This product with registration number DR-XY37227 was manufactured by PT Pfizer Indonesia and imported by Johnson & Johnson (Philippines), Inc.

As stated in the FDA Advisory No. 2014-074 dated 09 September 2014, FDA informed the public of the recall of the impacted batches of the subject product due to the non-compliance with Good Manufacturing Practice (GMP) issued by the Italian Medicines Agency (AIFA) to the manufacturer, Societa Italiana Medicinali Scandicci, srl (SIMS), of the Active Pharmaceutical Ingredient (API), Tetrahydrozoline HCl.

After due and thorough evaluation of the submitted documents by the Marketing Authorization Holder (MAH), FDA has determined that reasonable efforts had been made by the MAH, Johnson & Johnson (Philippines), Inc., to recall and properly destroy the impacted product batches in accordance with Bureau Circular No. 8, s. 2001, known as the Guidelines to be Observed on the Implementation of Product Recall System.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of existing laws, rules and regulations.

Consumers may contact FDA at telephone number +632 857-1900 or via e-mail at info@fda.gov.ph for any questions or additional information regarding this recalled product.

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Secretary of Health
Acting Director General[1]

DTN: 20150715155324
[1]Pursuant to DPO 2015-1845