Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 JUL 2015

FDA Advisory
No. 2015-061

SUBJECT: TERMINATION OF PRODUCT RECALL ORDER ISSUED ON SPECIFIC BATCHES OF TETRAHYDROZOLINE HCl (EYE-MO RED EYES FORMULA) 0.05% OPHTHALMIC SOLUTION (EYE DROPS)

This is to inform the public that the Product Recall Order (PRO) issued on affected batches of Tetrahydrozoline HCl (Eye-Mo Red Eyes Formula) 0.05% Ophthalmic Solution (Eye Drops) is hereby terminated by the Food and Drug Administration (FDA). This product with registration number DRHR-431 was manufactured by GlaxoSmithKline (Tianjin) Co. Ltd. in China and imported by GlaxoSmithKline Philippines, Inc. The impacted batches are as follows:

Batch No.	Expiry Date	Batch No.	Expiry Date
12045175	March 2015	12085219	August 2015
12045176	March 2015	13015274	January 2016
12045253	April 2015	13035142	February 2016
12045252	April 2015	13035143	February 2016
12055036	April 2015	13035144	February 2016
12055037	April 2015	13035179	February 2016
12055038	April 2015	13035180	February 2016
12055211	May 2015	13045131	March 2016
12055212	May 2015	13045132	March 2016
12075012	June 2015	13045183	April 2016
12075013	June 2015	13045184	April 2016
12075171	July 2015	13055078	April 2016
12075172	July 2015	13055079	April 2016
12075206	July 2015	13055080	April 2016
12075207	July 2015	13055230	May 2016
12085215	August 2015	13055231	May 2016
12085216	August 2015	13055232	May 2016
12085217	August 2015	13055233	May 2016
12085218	August 2015	13065053	May 2016
12095099	August 2015	13065054	May 2016
12095100	August 2015	13075013	June 2016
12095198	September 2015	13075014	June 2016
12095235	September 2015	13075015	June 2016
12105060	September 2015	13075016	June 2016
12115148	October 2015	13085027	July 2016
12115216	November 2015	13085028	July 2016
12115217	November 2015	13095061	August 2016
12115218	November 2015	13095062	September 2016

13015108	December 2015	13105002	September 2016
13015107	December 2015	13105001	September 2016
13015109	December 2015	13105223	October 2016
13015224	January 2016	13105224	October 2016
13025035	January 2016		

As stated in the FDA Advisory No. 2014-066 dated 12 August 2014, FDA informed the public of the recall of the above-mentioned affected batches of Tetrahydrozoline HCl (Eye-Mo Red Eyes Formula) 0.05% Ophthalmic Solution (Eye Drops) 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, GlaxoSmithKline 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.

All Field Regulatory Operations Office (FROO) Officers are ordered to appropriately seal discovered stocks of the affected batches of the product, and instruct the concerned establishment to give back the sealed stocks to the MAH for proper destruction to be witnessed by an appropriate FDA representative.

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.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General[1]

DTN: 20150713110145
[1]Pursuant to DPO 2015-1845