Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

9 September 2014

FDA Advisory
No. 2014-071

SUBJECT: VOLUNTARY RECALL OF BATCH SPECIFIC ANTAZOLINE HYDROCHLORIDE / TETRYZOLINE HYDROCHLORIDE (SPERSALLERG) 500mcg/400mcg PER mL OPHTHALMIC SOLUTION (DROPS)

This is to inform the public that Novartis Healthcare Philippines, Inc. is initiating a product recall of specific batch of Antazoline Hydrochloride/Tetryzoline Hydrochloride (Spersallerg) 500mcg/400mcg/ per mL Ophthalmic Solution (Drops) in response to the statement of non-compliance with Good Manufacturing Practice (GMP) issued by the Italian Medicines Agency (AIFA) to Societa Italiana Medicinali Scandicci, srl. (SIMS), the manufacturer of the active pharmaceutical ingredient, Tetryzoline Hydrochloride.

The active pharmaceutical ingredient Tetryzoline Hydrochloride was used in the manufacture of the specific batch of Spersallerg Ophthalmic Solution (Drops) by Excelvision AG - Switzerland. The details of the affected batch are as follows:

REGISTRATION NUMBER	**DR-X473**
BATCH NUMBER	**420548**
MANUFACTURER NAME AND ADDRESS	**EXCELVISION AG – RIETHOFSTRASSE 1 CH-8442 HETTLINGEN, SWITZERLAND**
IMPORTER	**NOVARTIS HEALTHCARE PHILS., INC. – 5/F ASIAN REINSURANCE BLDG., COR. GAMBOA & SALCEDO STS., LEGASPI VILLAGE, MAKATI CITY**

Antazoline Hydrochloride/Tetryzoline Hydrochloride (Spersallerg) 500mcg/400mcg per mL Ophthalmic Solution (Drops) is used for the treatment of irritant conjunctivitis, allergic inflammatory conditions of the conjunctiva particularly hay fever conjunctivitis and vernal conjunctivitis. This product is packed in a LDPE Transparent Bottle containing 10 mL solution (box of 1's).

The affected product presents safety risk and potential adverse health consequences. Therefore, distributors, retailers, hospitals, pharmacies, or clinics that have the

affected batches of Antazoline Hydrochloride/Tetryzoline Hydrochloride (Spersallerg) 500mcg/400mcg/ per mL Ophthalmic Solution (Drops) are instructed to discontinue further distribution, sale and use.

All the field Food and Drug Regulation Officers are ordered to monitor the availability of the product batches in the market.

Consumers may contact Novartis Healthcare Philippines, Inc. at telephone number +632 368-7742 or e-mail us at info@fda.gov.ph for any questions or additional information regarding the recall.

Any adverse reaction experienced from the use of the aforementioned product batches should be reported immediately to FDA by visiting www.fda.gov.ph. Look for the ADR Report tab and proceed to fill-out all of the required fields.

KENNETH Y. HARTIGAN-GO, MD
Acting Director General