Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

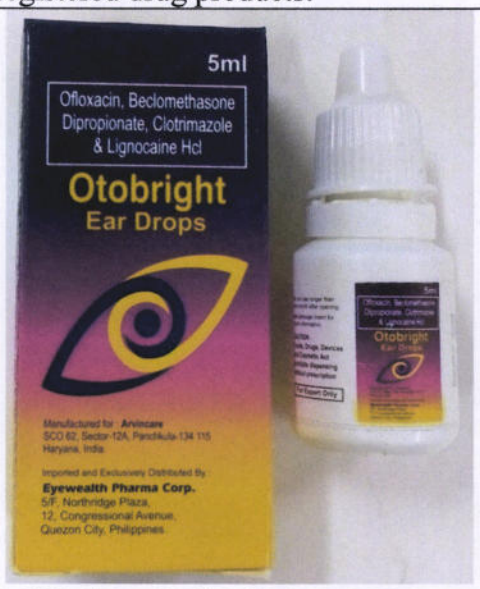
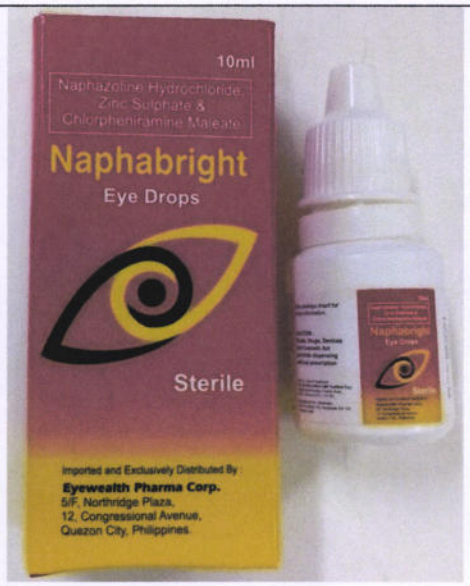
30 JUL 2015

FDA ADVISORY
No. 2015-052

SUBJECT: **Public Health Warning Against the Use of the Following Unregistered Drug Products:**

1. **Ofloxacin + Beclomethasone Dipropionate + Clotrimazole + Lignocaine Hcl (Otobright) Ear Drops 5 mL**
2. **Naphazoline Hydrochloride + Zinc Sulphate + Chlorpheniramine Maleate (Naphabright) Eye Drops 10 mL**
3. **Potassium Iodide + Calcium Chloride (Catabright Plus) Eye Drops 5 mL**
4. **Olopatadine Hydrochloride (Patabright) Eye Drops 5 mL**
5. **Latanoprost Ophthalmic Solution (Latanobright) Eye Drops 2.5 mL**

The Food and Drug Administration advises the public against the use of the following unregistered drug products:

 **OFLOXACIN + BECLOMETHASONE DIPROPIONATE + CLOTRIMAZOLE + LIGNOCAINE Hcl (OTOBRIGHT) EAR DROPS 5 mL** Manufactured for: Arvincare – SCO 62, Sector-12A, Panchkula-134 115 Haryana, India	 **NAPHAZOLINE HYDROCHLORIDE + ZINC SULPHATE + CHLORPHENIRAMINE MALEATE (NAPHABRIGHT) EYE DROPS 10 mL** Manufactured by: Sunvet Healthcare – Village Shambhuwala, Paonta Road, Distt. – Sirmour (H.P.) – 173 001

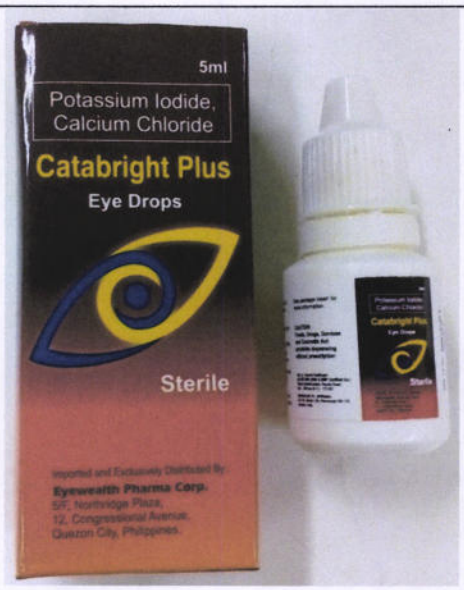
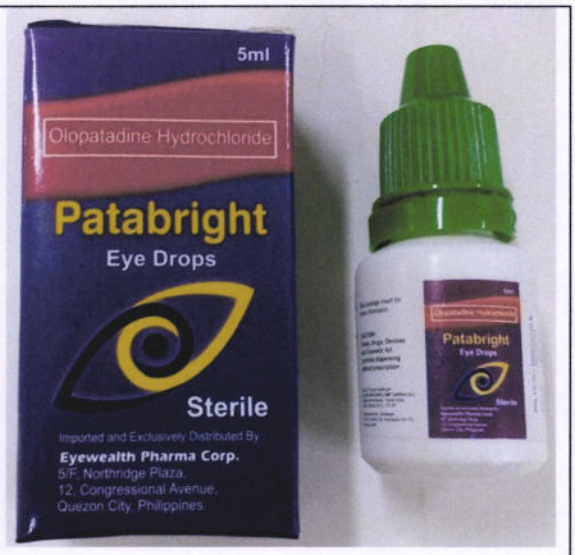
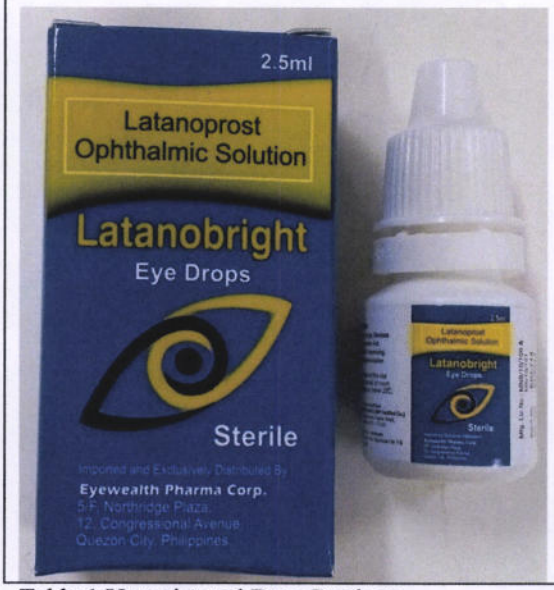
 **POTASSIUM IODIDE + CALCIUM CHLORIDE (CATABRIGHT PLUS) EYE DROPS 5 mL** Manufactured by: Sunvet Healthcare – Village Shambhuwala, Paonta Road, Distt. – Sirmour (H.P.) – 173 001	 **OLOPATADINE HYDROCHLORIDE (PATABRIGHT) EYE DROPS 5 mL** Manufactured by: Sunvet Healthcare – Village Shambhuwala, Paonta Road, Distt. – Sirmour (H.P.) – 173 001
	**LATANOPROST OPHTHALMIC SOLUTION (LATANOBRIGHT) EYE DROPS 2.5 mL** Manufactured by: Sunvet Healthcare – Village Shambhuwala, Paonta Road, Distt. – Sirmour (H.P.) – 173 001

Table 1.Unregistered Drug Products

The abovementioned drug products pose potential danger or injury to the consuming public and the importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.

In the interest of protecting public health and safety, and pursuant to Section 12 of R.A. No. 9711, the Field Regulatory Operations Office (FROO) Officers are hereby ordered to seize the aforementioned unregistered drug products found in the market.

All establishments and outlets are hereby warned against selling and/or dispensing the above identified products. Anyone found selling the said products will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that these products are not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that, in addition to inspection of establishments, product evaluation, registration and testing are measures that the government undertakes to ensure the quality, safety and efficacy of health products. Please look for the FDA Registration number on the product label. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

For more information and inquiries, please email us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly email us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

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Secretary of Health
Acting Director General[1]

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[1] Pursuant to DPO 2015-1845