Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

22 SEP 2015

FDA ADVISORY
No. 2015-065

SUBJECT: Health Warning on the Use of Unregistered Intraocular Lens (IOL)

The public is warned against using intraocular lenses (IOL) that are not registered with the Food and Drug Administration (FDA). An intraocular lens is a synthetic, artificial lens placed inside the eye that replaces the focusing power of a natural lens that is surgically removed, usually as part of cataract surgery.

Only a licensed ophthalmologist performs IOL surgeries. The following are the common risks associated with IOL implantation:

1. Minor Infection
2. Corneal Edema (Swelling)
3. Intraocular Pressure Spikes
4. Wound Leaks
5. IOL Decentration
6. IOL Power Miscalculation
7. Retinal Detachment

IOL risks increase for patients with certain medical conditions and health-related issues, and other issues such as use of unregistered products.

All ophthalmologists are required to use only registered products. The list of registered intraocular lens, brands and models can be downloaded from www.fda.gov.ph.

To report unregistered IOL in the market, please email us via report.fda.gov.ph. For inquiries and more information, kindly email us at info.fda.gov.ph.

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[1] Pursuant to DPO 2015-1845