Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2019-176

03 JUL 2019

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of Unregistered Medical Devices:**

1. **Add Gray Contact Lens**
2. **GBT Contact Lens**
3. **G&G SI Soft Contact Lens**
4. **G&G SII Soft Contact Lens**
5. **CQ Plus Soft Contact Lens**
6. **K-Luv Soft Contact Lens**
7. **Skinny Magic-eye Premium Contact Lens**

The Food and Drug Administration (FDA) warns all concerned healthcare professionals and the public against the purchase and use of these unregistered medical devices (see photos below):

Figure 1. ADD Gray Contact Lens

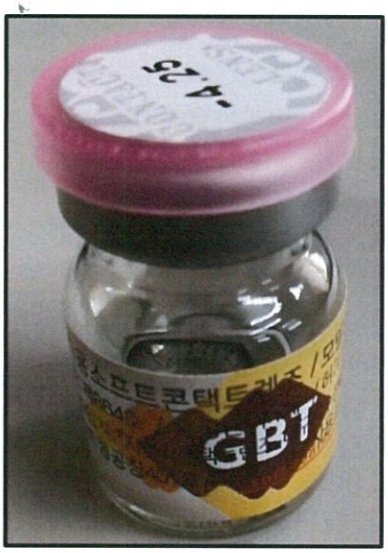

Figure 2. GBT Contact Lens

Figure 3. G&G SI Contact Lens

Figure 4. G&G SII Contact Lens

Figure 5. CQ Plus Contact Lens

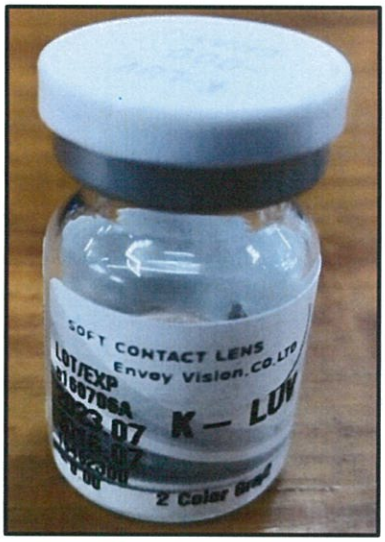

Figure 6. K-Luv Soft Contact Lens

Figure 7. Skinny Magic-Eye Premium Contact Lens

The FDA verified through post-marketing surveillance that the abovementioned medical device is not registered and the Certificate of Product Registration (CPR) has not been issued. Pursuant to Republic Act 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product without the proper authorization is prohibited.

Since this unregistered medical device has not gone through the evaluation process of the FDA, the agency cannot guarantee its quality and safety.

In light of the foregoing, the public is hereby advised not to purchase this violative product in the market.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device until the Certificate of Product Registration is issued, otherwise, regulatory actions and sanctions shall be strictly pursued.

All FDA Field Officers and Regulatory Enforcement Unit in coordination with the law enforcement agencies and Local Government Units are requested to ensure that this product is not sold or made available in their localities or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this unregistered product.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through email at **cdrrhr@fda.gov.ph** or call (02) 857-1900 local 8301.

To report any sale or distribution of the above medical device, the online reporting facility, **eReport**, can be accessed at **www.fda.gov.ph/ereport**.

Dissemination of this advisory to all concerned is hereby requested.

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