Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

03 JUL 2019

FDA ADVISORY
No. 2019-174

TO: **THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Consumption of the Unregistered Medical Device Hydroxypropyl Methylcellulose Ophthalmic Solution USP 2% w/v**

The Food and Drug Administration (FDA) advises the general public and all healthcare professionals against the purchase and use of the unregistered medical device:

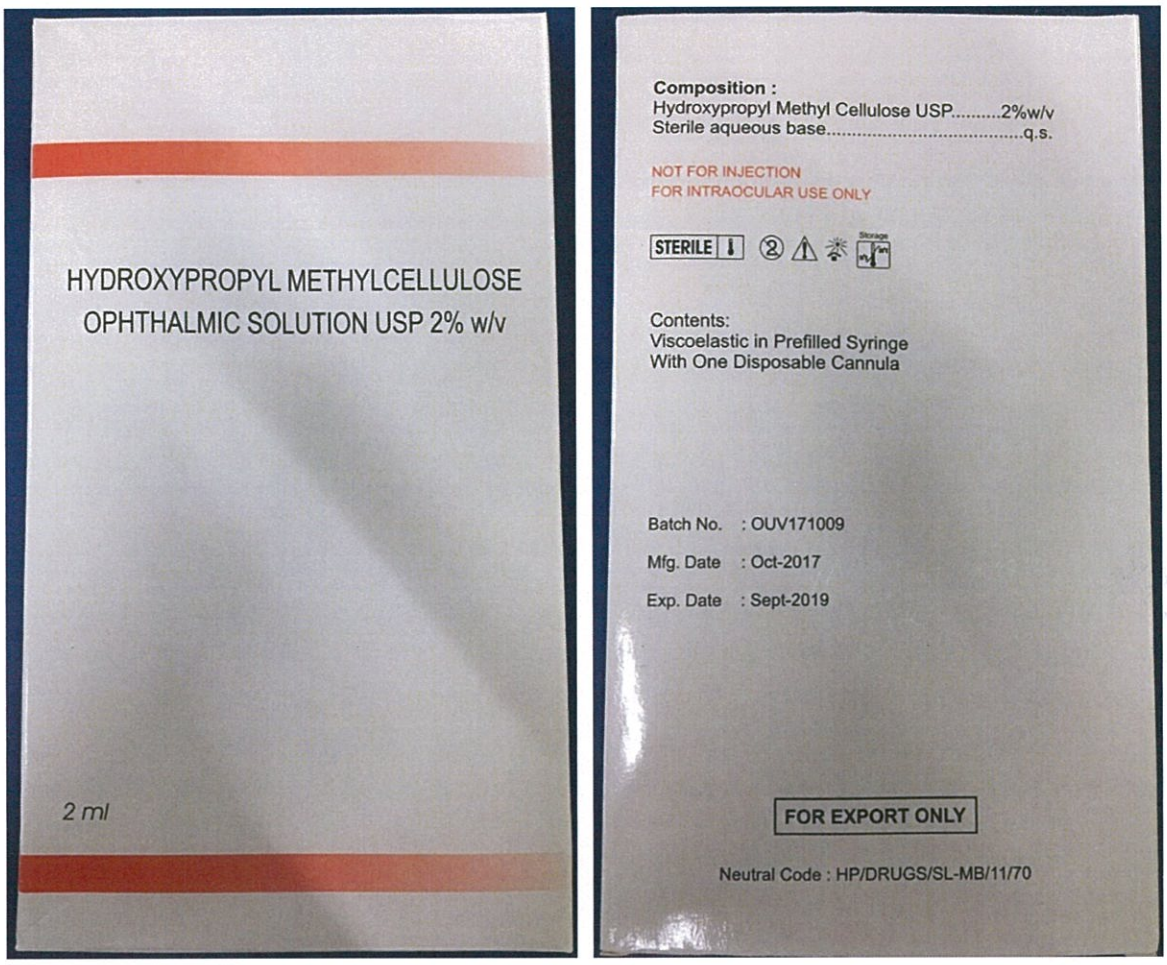

Figure 1. Unregistered Hydroxypropyl Methylcellulose Ophthalmic Solution USP 2% w/v

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The FDA verified through post-marketing surveillance that the abovementioned medical device is not registered and the Certificate of Product Registration (CPR) has not yet been issued. Pursuant to the 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 health products without the proper authorization from FDA are prohibited.

Since this unregistered medical device has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety. The use of such violative product may pose potential health hazard to the consuming public.

In light of the above, the public is advised not to purchase this product in the market. Moreover, the public is advised to always check if a medical device is registered with the FDA. The FDA website (www.fda.gov.ph) has a *Search* feature which may be used by typing-in the name of the product before purchasing.

All concerned establishments are warned not to distribute violative medical device until it has been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a CPR for the medical device.

All FDA Field Officers and Regulatory Enforcement Unit (REU) in coordination with the law enforcement agencies and Local Government Units (LGUs) are requested to ensure that violative products are not sold or made available in the market or areas of jurisdiction.

Kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at **cdrrhr@fda.gov.ph,** or call **(02) 857-1900 local 8301**.

To report any sale or distribution of unregistered 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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Undersecretary of Health
Officer-in-Charge, Director General

DTN: 20190416141216