Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 20201077

15 JUN 2020

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Following Unregistered Medical Device Products:**

1. **BELLAST ULTRA PLUS CROSS-LINKED HYALURONIC ACID 24MG WITH LIDOCAINE**
2. **STYLAGE IPN – LIKE TECHNOLOGY XXL LIDOCAINE BI-SOFT INJECTION TECHNOLOGY**
3. **STYLAGE IPN – LIKE TECHNOLOGY M LIDOCAINE**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the unregistered medical device products:

Figure 1. Unregistered Bellast Ultra Plus Cross-Linked Hyaluronic Acid 24mg with Lidocaine

Figure 2. Unregistered Stylage IPN – Like Technology XXL Lidocaine Bi-SOFT Injection Technology

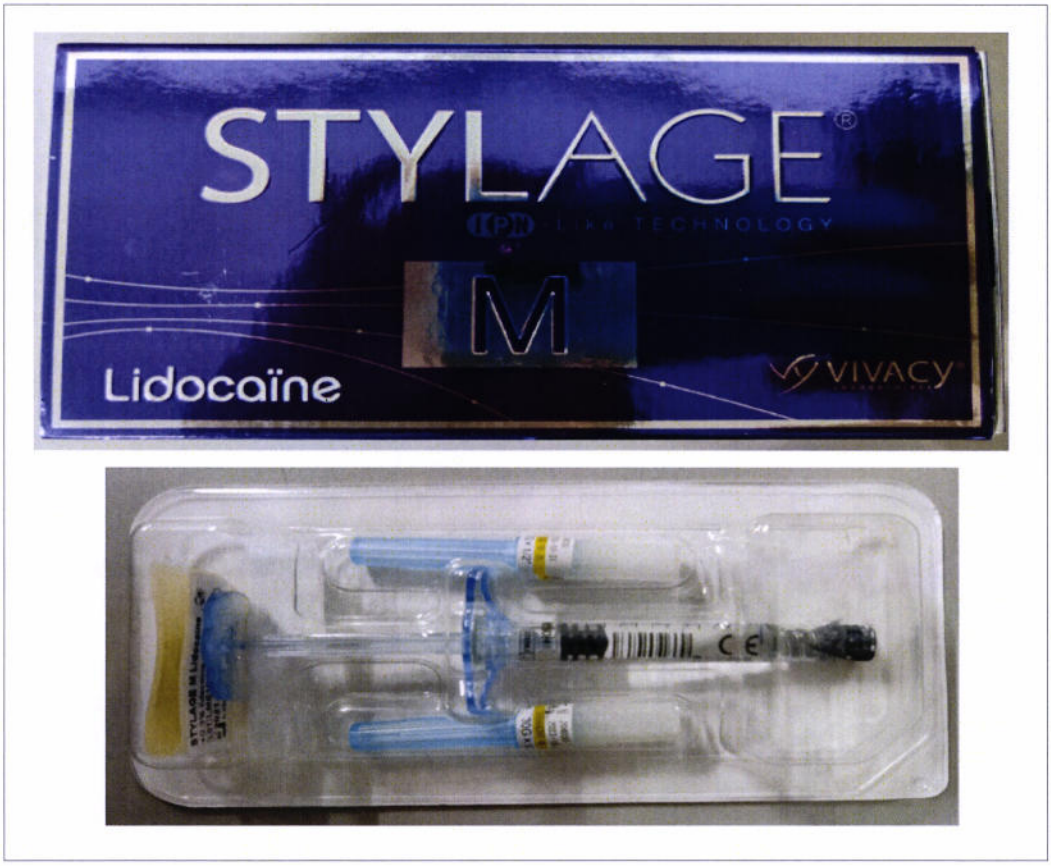

Figure 3. Unregistered Stylage IPN – Like Technology M Lidocaine

The FDA verified through post-marketing surveillance that the abovementioned medical device products are not registered and no corresponding Certificate of Product Registration has been issued. Pursuant to the Republic Act No. 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 is prohibited.

Since these unregistered medical device products have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device products until CPRs are issued, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product has been registered with the FDA before purchasing it by making use of the embedded Search feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label.

All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that these products are not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of these unregistered products.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr-prsdd@fda.gov.ph**, or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unregistered medical device product, 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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Director General

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