Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-1051

08 JUN 2020

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the following Unregistered Medical Devices in Foreign Characters:**

1. **Medical Infusion Paste**
2. **Donless Natural Rubber Latex Male Condom**
3. **Disposable Vaginal Speculum**
4. **Infusion Set for Single Use with Needle**

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

Figure 1. Unregistered Medical Infusion Paste

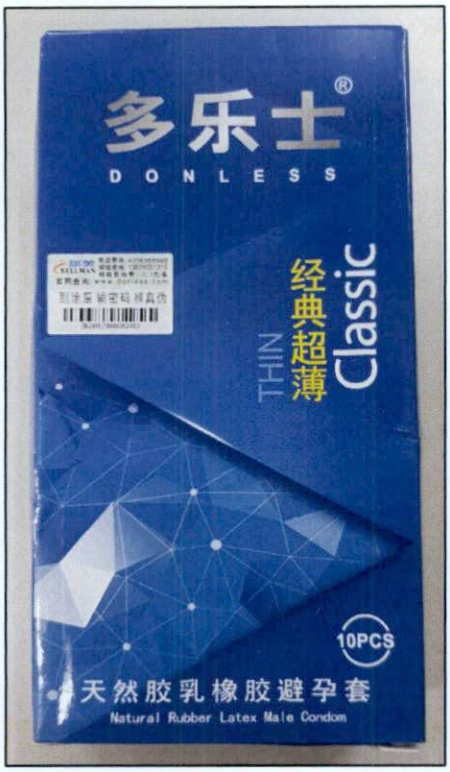

Figure 2. Unregistered Donless Natural Rubber Latex Male Condom

Figure 3. Unregistered Disposable Vaginal Speculum

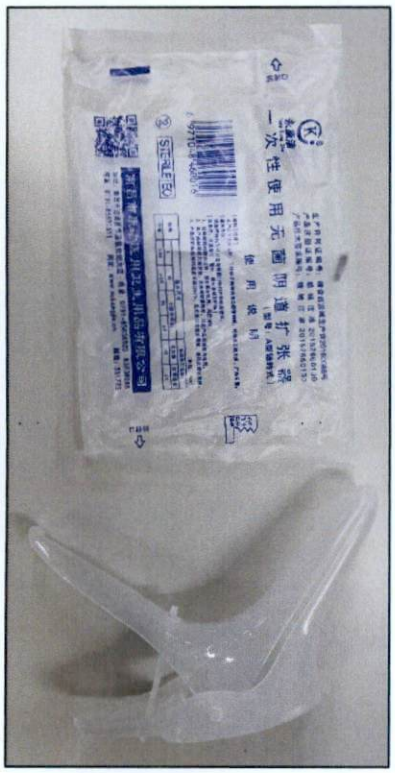

Figure 4. Unregistered Disposable Vaginal Speculum

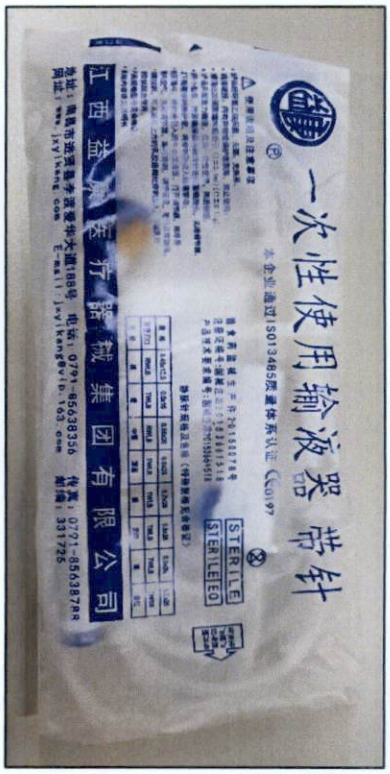

Figure 5. Unregistered Infusion Set for Single Use with Needle

The FDA verified through post-marketing surveillance conducted on 26 May 2020 that the above mentioned medical device is not registered and no Certificate of Product Registration (CPR) 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 this unregistered medical device product has not gone through the evaluation process of the FDA, the agency cannot assure its quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device product until CPR is 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 Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) are requested to ensure that this product is not sold or made available in the market or areas of jurisdiction.

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

For more information and inquiries about this advisory, kindly contact the FDA CDRRHR through e-mail at **cdrrhr-prsdd@fda.gov.ph**, or call **(02) 857-1900 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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