Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

27 MAR 2018

FDA ADVISORY
No. 2018-115

TO: **THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Use of Medical Devices (Condoms) that are Unregistered and with Expired Certificate of Product Registration**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following medical device products:

A. Unregistered Condom

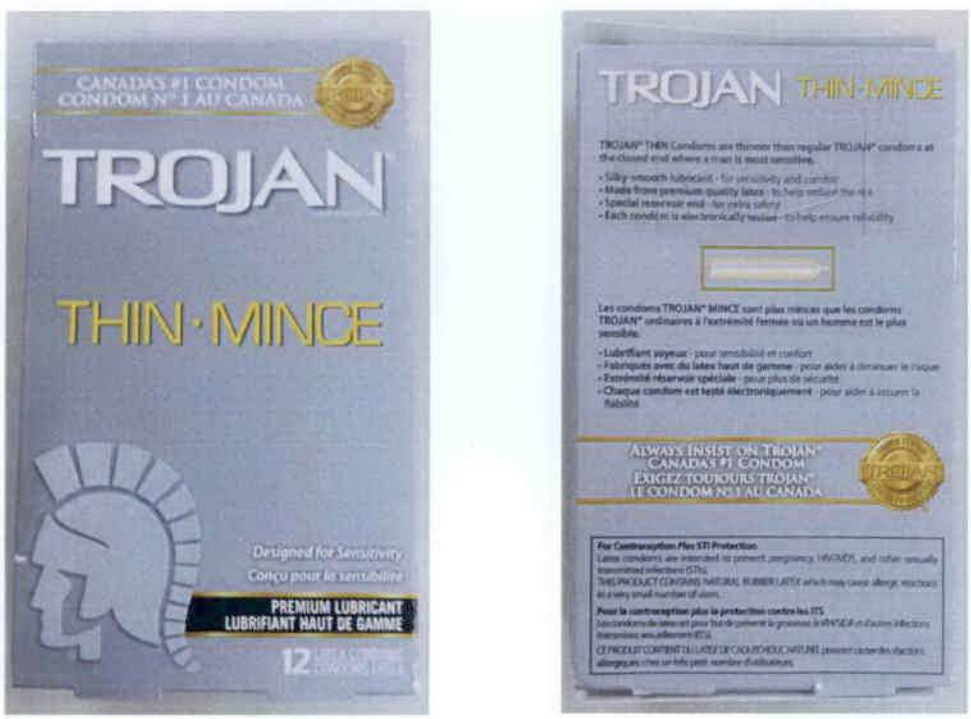

Figure 1. Trojan Latex Condom (Thin Mince)

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900
Website: www.fda.gov.ph
Fax +63 2 807 0751
Email: info@fda.gov.ph

B. Condom with Expired Certificate of Product Registration

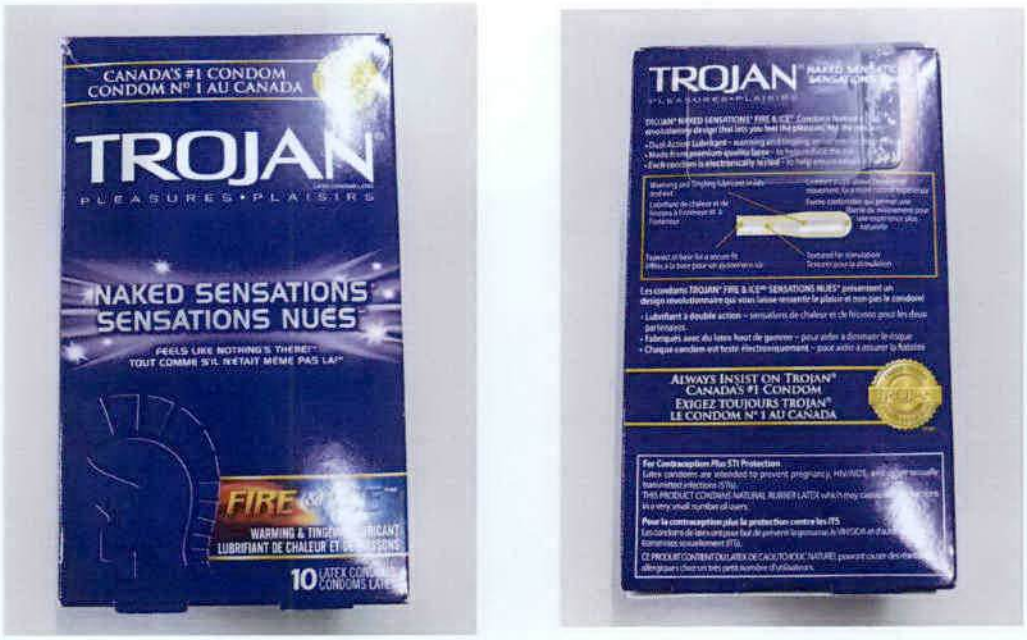

Figure 2. Trojan Latex Condom (Naked Sensations - Fire & Ice)

Post-marketing surveillance activities conducted by the FDA have verified that Trojan Latex Condom - Thin Mince (see Figure 1) has not gone through the registration process of the agency and has not been issued with Certificate of Product Registration (CPR). Furthermore, it was found out that the CPR of Trojan Latex Condom - Naked Sensations Fire & Ice (see Figure 2) was already expired.

Pursuant to the provisions of 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 are prohibited.

Since the abovementioned products did not undergo the evaluation process of the FDA, the agency cannot guarantee their quality and safety.

In this regard, the public is hereby advised not to purchase the above-mentioned violative products. All concerned establishments are warned not to advertise, sell or distribute the said products until such have been issued with the corresponding Cerificate of Product Registration, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agenies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please email us at **info@fda.gov.ph.** To report continuous sale or distribution of the above medical devices, utilize our online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**, or email us via **report@fda.gov.ph**, or call us at the Center for Device Regulation, Radiation Health and Research hotline 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
FDA Director General

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