Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 MAY 2017

FDA ADVISORY
No. 2017-138

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 (CPR)**

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

A. Unregistered Condoms

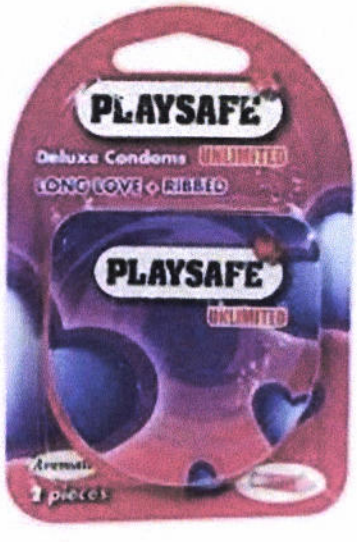

Figure 1. PlaySafe Condom Easy Pack Long Love + Ribbed

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B. Condoms with Expired Certificate of Product Registration

Figure 4. PlaySafe Condom Fix-Tex 002

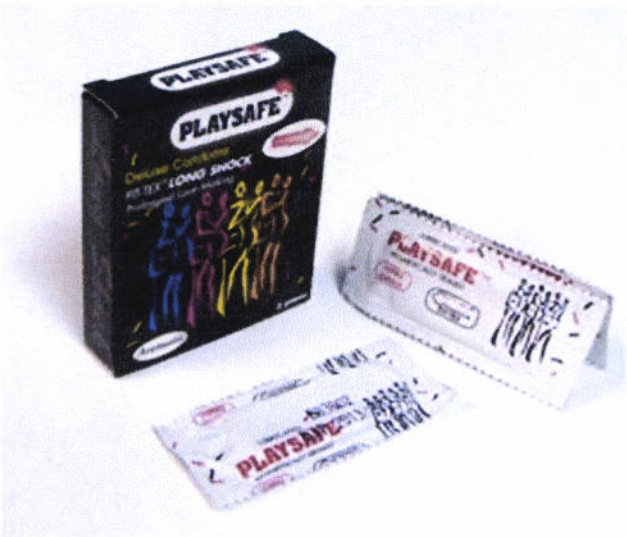

Figure 5. PlaySafe Condom Fix-Tex Long Shock

Figure 2. PlaySafe Condom Extrasafe

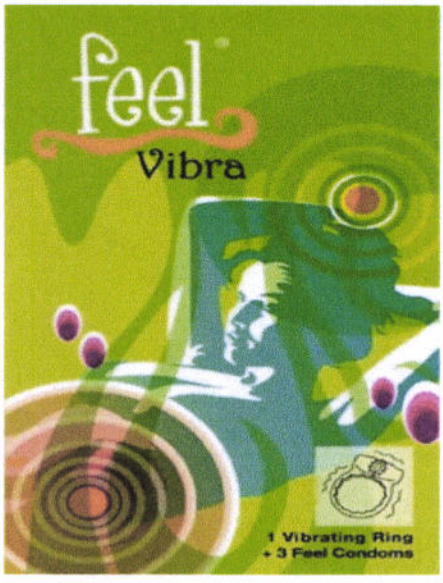

Figure 3. Feel Condom Vibra

Figure 6. Feel Condom 4 in 1

Post-marketing surveillance activities conducted by the FDA have verified that PlaySafe Condom Easy Pack Long Love + Ribbed (see Figure 1), PlaySafe Condom Extrasafe (see Figure 2) and Feel Condom Vibra (see Figure 3) have not gone through the registration process of the agency and have not been issued with Certificate of Product Registration (CPR). Furthermore, it was found out that the CPRs of PlaySafe Condom Fix-Tex 002 (see Figure 4), PlaySafe Condom Fix-Tex Long Shock (see Figure 5) and Feel Condom 4 in 1 (see Figure 6) are 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 cdrrhr_prsdd@fda.gov.ph or call the Product Research and Standards Development Division of the FDA - Center for Device Regulation, Radiation Health and Research at 857-1900 local 8301.

Dissemination of the information to all concerned is requested.

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FDA Director General

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