



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2021-1179**

03 JUN 2021,

TO:

**ALL HEALTHCARE PROFESSIONALS AND THE
GENERAL PUBLIC**

SUBJECT:

**Public Health Warning Against the Purchase and Use of the
Unregistered Condoms in Foreign Characters:**

1. **OKAMOTO® SKINLESS SKIN (IN BLUE AND IN
WHITE BOX IN FOREIGN CHARACTERS)**
2. **OKAMOTO® ZERO ONE (IN FOREIGN
CHARACTERS)**
3. **NOX™ NOT ONLY SEX (IN FOREIGN
CHARACTERS)**
4. **DUREX® FETHERLITE FEEL IN FOREIGN
CHARACTERS)**
5. **DUREX® PLEASUREMAX IN FOREIGN
CHARACTERS)**
6. **DUREX® LOVE SEX HUG CLOSE IN FOREIGN
CHARACTERS)**
7. **DUREX® LOVE SEX JEANS IN FOREIGN
CHARACTERS)**

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public **NOT TO PURCHASE AND USE** the following unregistered condoms in foreign characters:



Figure 1. Unregistered Okamoto® Skinless Skin (Blue box in foreign characters)



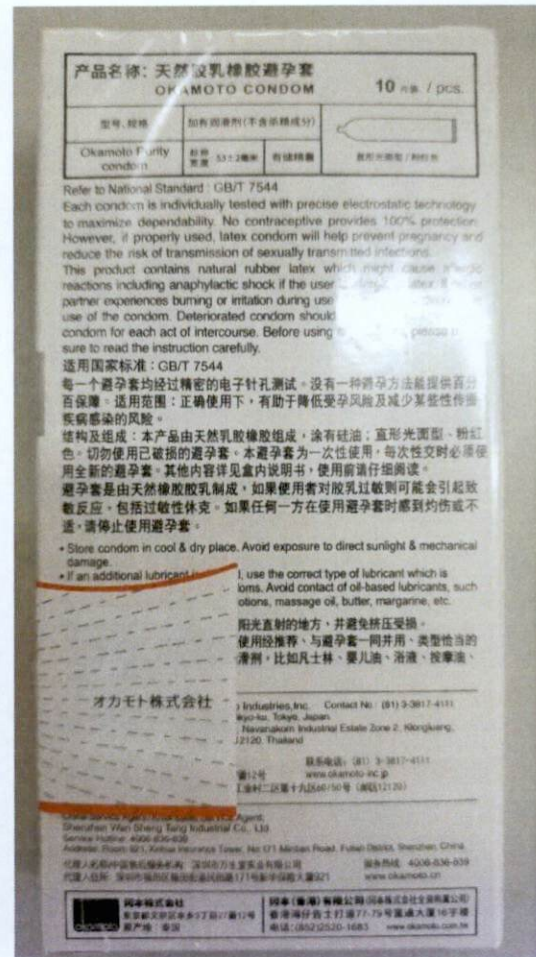


Figure 2. Unregistered Okamoto® Skinless Skin (White box in foreign characters)

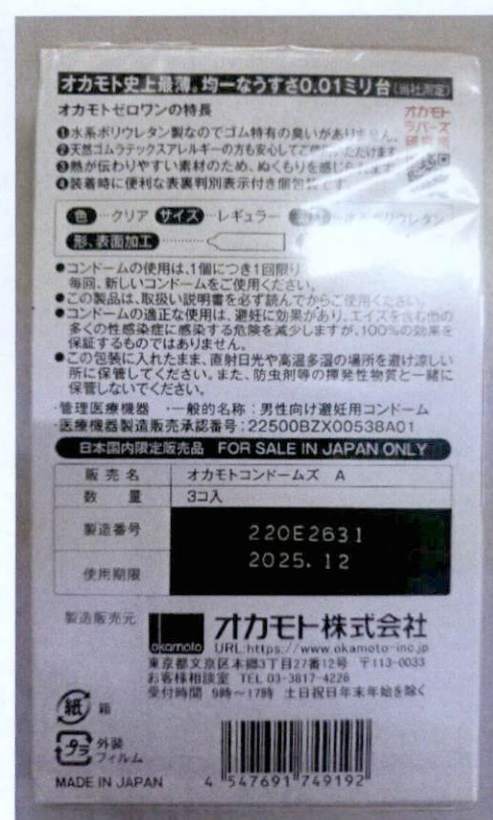


Figure 3. Unregistered Okamoto® Zero One (in foreign characters)



Figure 4. Unregistered Nox™ Not Only Sex (in foreign characters)



Figure 5. Durex® Fetherlite Feel (in foreign characters)



Figure 6. Durex® Pleasuremax (in foreign characters)



Figure 7. Durex® Love Sex Hug Close (in foreign characters)



Figure 8. Durex[®] Love Sex Jeans (in foreign characters)

The FDA verified through post-marketing surveillance that the above-mentioned medical device products are not registered and no corresponding Product Registration Certificates have 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 its quality and safety.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device products until the Product Registration Certificates 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 in the form of either DVR-xxx or MDR-xxx.


All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs) 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 about this advisory, kindly contact the FDA CDRRHR through e-mail at cdrhr@fda.gov.ph indicating on the subject the concerned Advisory, or call (02) 8857-1900 loc. 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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Director General

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20210421152948, 20210421153021, 20210421153038, 20210421153055