



FDA ADVISORY
No. **2019-286**

06 SEP 2019

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the following Unnotified Toys and Child Care Articles (TCCAs):

1. **KOMIKU BABY SHOWER GOOD PARTNER**
2. **BABYJOY SILICONE NIPPLE (X)**
3. **BABYJOY SILICONE NIPPLE (M)**
4. **BABYJOY SILICONE NIPPLE (S)**

The Food and Drug Administration (FDA) warns the public from purchasing and using the following Unnotified TCCAs:



Figure 1. Unnotified Komiku Baby Shower Good Partner





Figure 2. Unnotified Babyjoy Silicone Nipple (X)



Figure 3. Unnotified Babyjoy Silicone Nipple (M)



Figure 4. Unnotified Babyjoy Silicone Nipple (S)

The FDA verified through post-marketing surveillance that the abovementioned TCCA products are not authorized and the Certificates of Product Notification (CPN) have not 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 unnotified TCCA products have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety. The use of such violative products may pose health risks to consumers.

Potential hazards may come from ingredients that are restricted or not allowed to be part of a TCCA product such as Phthalate and Bisphenol A. The use of substandard and possibly adulterated TCCA products may result to health risks including but not limited to endocrine disruption and reproductive or developmental effects in relation to exposure to these compounds.

In light of the foregoing, the public is advised not to purchase the aforementioned violative products. Moreover, the public is advised to always check if a TCCA is notified with the FDA. The FDA website (www.fda.gov.ph) has a *Search* feature which may be used by typing in the name of the product before purchasing.

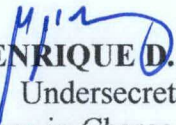
All concerned establishments are warned not to distribute violative TCCAs until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a CPN for the TCCA products.

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

Kindly contact the FDA Center for Cosmetics Regulation and Research through e-mail at crr@fda.gov.ph, or call (02) 857-1900 loc. 8113 or 8107.

To report any sale or distribution of unnotified TCCAs, 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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