



FDA ADVISORY  
No. **2017-055**

28 FEB 2017

**TO: GENERAL CONSUMING PUBLIC**

**SUBJECT: Public Health Warning Against the Use of Unnotified Toy and Childcare Article (TCCAs) Products (Batch 2)**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unnotified TCCA products whose particulars/details are provided in the attached annex:

1. **BABYFLO SILICONE NIPPLE SMALL HOLE**
2. **BABYFLO PACIFIER JELLY-FILLED**
3. **BON BON NIPPLE SILICONE**

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned TCCA products have not gone through the verification process of the agency and have not been issued the proper authorization in the form of acknowledged TCCA notifications. Pursuant to 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 from FDA is prohibited.

Accordingly, because unnotified TCCA products have not gone through the verification process of the FDA, the agency cannot guarantee their quality and safety. The use of such violative products may pose potential health hazards to the consuming public. Potential hazards may come from materials that are not allowed to be part of a TCCA product or being exposed to chemicals that can leach out from the product such as phthalates and nitrosamines. Based on some international studies, these chemicals may cause allergy and cancer.

In light of the above, the public is advised not to purchase the aforementioned violative products. Moreover, the public is also advised to be vigilant against TCCA products that might not be duly notified with FDA. Always check if a TCCA product has been notified with FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at [www.fda.gov.ph](http://www.fda.gov.ph).


All concerned establishments are warned not to distribute the above-identified violative TCCA products until they have already been covered by the appropriate authorization (TCCA notification), otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (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 e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph). To report continuous sale or distribution of the above unnotified TCCA products, utilize our online reporting facility, **eReport**, at [www.fda.gov.ph/ereport](http://www.fda.gov.ph/ereport), or e-mail us via [report@fda.gov.ph](mailto:report@fda.gov.ph), or call us at the Center for Cosmetics Regulation and Research (CCRR) hotline (02) 857-1979 or (02) 857-1984.



Dissemination of the information to all concerned is requested.

  
NELA CHARADE G. PUNO, RPh  
FDA Director General

DTN: 20170124101408



**ANNEX**  
 Details on the Unnotified TCCA Products

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
<b>1 BABYFLO            SILICONE NIPPLE            SMALL HOLE</b>	Country of Manufacture: Not Indicated Local Company Responsible for Placing the Product in the Market: Philusa Corporation Address: 28 Shaw Boulevard, Pasig City	
<b>2 BABYFLO            PACIFIER JELLY-            FILLED</b>	Country of Manufacture: Not Indicated Local Company Responsible for Placing the Product in the Market: Philusa Corporation Address: Not Indicated	
<b>3 BON BON NIPPLE            SILICONE</b>	Country of Manufacture: Not Indicated Local Company Responsible for Placing the Product in the Market: Pagoda Philippines Address: Not Indicated	