



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2019-200**

15 JUL 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. BESTWAY DOLPHIN ARMBANDS
2. SWIMMING AID/ARMBAND (HELLO KITTY DESIGN)
3. WEI BRAND SWIM SET MASK/SNORKEL/DIVE STICK
4. MIAOFENG TOY SWIM RING
5. SAINTEVE® SWIM VEST

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



Figure 1. Unnotified Bestway Dolphin Armbands





Figure 2. Unnotified Swimming Aid/Armband (Hello Kitty Design)

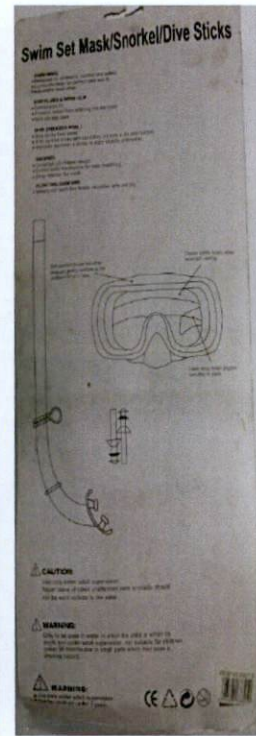


Figure 3. Unnotified Wei brand Swim set Mask/ Snorkel / Dive Sticks



Figure 4. Unnotified Miaofeng Toy Swim Ring



Figure 5. Unnotified Sainteve® Swim Vest

The FDA verified through post-marketing surveillance that the abovementioned TCCAs 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 TCCAs 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 product is notified/registered 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 TCCA product until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a CPN for the TCCA product.

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 ccrr@fda.gov.ph, or call (02) 857-1900 loc. 8113 or 8107.

To report any sale or distribution of unnotified TCCA, the online reporting facility, **eReport** can be accessed at www.fda.gov.ph/ereport.

Dissemination of this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health
Officer-in-Charge, Director General

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