



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



25 APR 2019

FDA ADVISORY
No: 2019-102

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Unnotified Toy and Child Care Article (TCCA) Products (Batch 1)

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unnotified Toy and Child Care Article (TCCA) products:

1. **J.H. Toy Lasting Friend Space Balloon**
2. **Magic Balloon**
3. **Zestar Plastic Balloom size 11**
4. **Zestar Plastic Balloon Size 7**

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned TCCA products have not gone through the notification process of the agency and have not been issued the proper marketing authorization (MA). 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.

The TCCA products, prior to being placed into the local market, must be duly notified with the FDA by a licensed TCCA distributor and/or manufacturer pursuant to the Implementing Rules and Regulations (IRR) of R.A. 9711 sec. 5ii. If a TCCA product has not been evaluated by FDA, as in the case of these unnotified products, the use of such products may pose potential health hazards to the consuming public.

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 are unnotified 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.

Consumers are further reminded to:

- Buy TCCA products from reputable stores or dealers;
- Read the label. Check that the TCCA product has FDA notification number indicated in the label.
- Never buy TCCAs that do not have instructions written in Filipino or English. Strictly follow the instructions for use of the product.

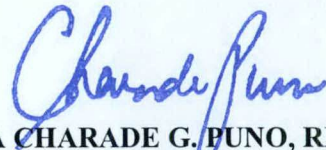


All concerned establishments are warned not to distribute the above-identified violative TCCA products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

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. To report continuous sale or distribution of the above unnotified TCCA products, utilize our online reporting facility, **eReport**, at www.fda.gov.ph/ereport, or e-mail us via 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.
Director General

DTN: 20190321154959



ANNEX
Details on the Unnotified TCCA Products

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1 J.H. TOY LASTING FRIEND SPACE BALLOON	Manufacturer's Name: Not indicated Country of Manufacture: Not Indicated Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated	

PRODUCT NAME

PRODUCT DETAILS

PRODUCT IMAGE/S

2 MAGIC BALLOON

Manufacturer's Name:
In foreign language

Country of Manufacture:
China

Local Company Responsible for Placing the Product in the Market:
Not indicated

Address: Not indicated



PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
3 ZESTAR PLASTIC BALLOON SIZE 11	<p>Manufacturer's Name: In foreign language</p> <p>Country of Manufacture: China</p> <p>Local Company Responsible for Placing the Product in the Market: Not indicated</p> <p>Address: Not indicated</p>	

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
4. ZESTAR PLASTIC BALLOON SIZE 7	<p>Manufacturer's Name: In foreign language</p> <p>Country of Manufacture: China</p> <p>Local Company Responsible for Placing the Product in the Market: Not indicated</p> <p>Address: Not indicated</p>	