

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2018-168 0 3 MAY 2018

TO:

GENERAL CONSUMING PUBLIC

SUBJECT:

Public Health Warning Against the Use of Unnotified Toy

and Childcare Article (TCCA) Products (Batch 4)

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

I. TOYS

- 1. ZAINI MARVEL ULTIMATE SPIDER-MAN (TOY SURPRISE INSIDE EACH EGG)
- 2. DISNEY JUNIOR MICKEY MOUSE CLUBHOUSE HAMMER FUN

II. CHILDCARE ARTICLE

3. GERBER (FIRST ESSENTIALS BOTTLES)

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 product notification. Pursuant to Book II, Article I, Section 1 (a) of the Rules and Regulations Implementing Republic Act (RA) 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 any health product 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 product. 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.



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 the above products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at <u>info@fda.gov.ph</u>. To report continuous sale or distribution of the above unnotified TCCA products, utilize our online reporting facility, **eReport**, at <u>www.fda.gov.ph/ereport</u>, or e-mail us via <u>report@fda.gov.ph</u>, 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: 20180427140929

ANNEX Details on the Unnotified TCCA Products

	I. TOYS		
	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1	ZAINI MARVEL ULTIMATE SPIDER- MAN (TOY SURPRISE INSIDE EACH EGG)	Country of Manufacture: Italy Local Company Responsible for Placing the Product in the Market: Resourceful International Marketing Inc. Address: 82 Nicanor Roxas St., Brgy. Sto. Domingo, Quezon City	Splder-Han surprise Inside each egg Surprise Spider-Han dans chaque stur! 3 out of 3 Zaint 3 xxx g = 60 g C
2	DISNEY JUNIOR MICKEY MOUSE CLUBHOUSE HAMMER FUN	Country of Manufacture: Not Indicated Local Company Responsible for Placing the Product in the Market: JS Philippines Global Corp Address: Not Indicated	BAS HAMMER FUN

	PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
3	GERBER (FIRST ESSENTIALS	Country of Manufacture: U.S.A.	[[] [] [] [] [] [] [] [] [] [] [] [] []
	BOTTLES)	Local Company Responsible for Placing	17
		the Product in the Market: Not Indicated	
		Address: Not Indicated	First Sentials Section 1997 Sec