



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No: **2017-266**

19 SEP 2017

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Use of Unnotified Toy and Childcare Article (TCCAs) Products (Batch 9)

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

I. TOYS

1. TOY DUCK (IN FOREIGN LANGUAGE)
2. KISS FAMILY PEPPA PIG 6in1 DOLL NO. PP6310
3. LIAN TAI COLLECT ALL DINOSAUR DINO 3+ AGES
4. INTEX BEACH BALL
5. JUSTICE FIGHTER TOY ROBOT
6. SHOOTER FIRES FOAM DARTS
7. SPEED CHAMPIONS JIXA
8. AVENGERS 2 AGE OF ULTRON
9. TOYS TOY CAR
10. MILITARY – COOL MILITARY VEHICLES SERIES

II. CHILDCARE ARTICLES

11. SESAME STREET SESAME BEGINNINGS 2 PACK PACIFIER WITH PACIFIER CASE SB9224
12. DORA THE EXPLORER WATER-FILLED TEETHER RATTLE

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.



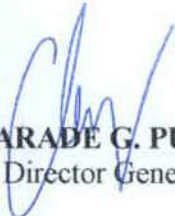
In light of the above, the public is advised not to purchase the aforementioned violative products. Moreover, the public is also advised to be vigilant against TCCA products that might not be duly notified with FDA. Always check if a TCCA product has been notified with FDA before purchasing it by making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

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. 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
FDA Director General





DTN: 20170905153859



ANNEX
Details on the Unnotified TCCA Products

I. TOYS

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
1 TOY DUCK (IN FOREIGN LANGUAGE)	Country of Manufacture: Label is in Foreign Language Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated	
2 KISS FAMILY PEPPA PIG 6in1 DOLL NO. PP6310	Country of Manufacture: China Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated	
3 LIAN TAI COLLECT ALL DINOSAUR DINO 3+ AGES	Country of Manufacture: China Local Company Responsible for Placing the Product in the Market: Not Indicated Address: Not Indicated	
4 INTEX BEACH BALL	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
5 JUSTICE FIGHTER TOY ROBOT	<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>	 <p>The image shows the packaging for a Justice Fighter Toy Robot. It features two robots, one blue and one yellow, standing side-by-side. The packaging has a 'JUSTICE FIGHTER' logo at the top and 'ATTACK HERE' text on the left. The background is a colorful illustration of a battle scene.</p>
6 SHOOTER FIRES FOAM DARTS	<p>Country of Manufacture: Not Indicated</p> <p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p>	 <p>The image shows the packaging for a Shooter Fires Foam Darts toy. It features a large, colorful illustration of a shooter toy with a dartboard. The packaging has 'SHOOTER' and 'FIRES FOAM DARTS' text. There are also some numbers and a 'Cool!!' sticker on the right.</p>
7 SPEED CHAMPIONS JIXA	<p>Country of Manufacture: Not Indicated</p> <p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p>	 <p>The image shows the packaging for a Speed Champions JIXA toy. It features a yellow and black sports car. The packaging has 'SPEED' and 'JIXA' text. There is also a '1:43' scale indicator.</p>
8 AVENGERS 2 AGE OF ULTRON	<p>Country of Manufacture: Not Indicated</p> <p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p>	 <p>The image shows the packaging for an Avengers 2 Age of Ultron toy. It features a Captain America action figure. The packaging has 'AVENGERS 2 AGE OF ULTRON' and 'CAPTAIN AMERICA' text. There is also a 'MARVEL' logo.</p>

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
9 TOYS TOY CAR	<p>Country of Manufacture: Not Indicated</p> <p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p>	
10 MILITARY – COOL MILITARY VEHICLES SERIES	<p>Country of Manufacture: Not Indicated</p> <p>Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Address: Not Indicated</p>	

II. CHILDCARE ARTICLES

PRODUCT NAME	PRODUCT DETAILS	PRODUCT IMAGE/S
11 SESAME STREET SESAME BEGINNINGS 2 PACK PACIFIER WITH PACIFIER CASE SB9224	<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>	
12 DORA THE EXPLORER WATER- FILLED TEETHER RATTLE	<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>	