



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



22 AUG 2016

**FDA ADVISORY**  
No. **2016-106**

**TO : GENERAL CONSUMING PUBLIC, FIELD REGULATORY OPERATIONS OFFICE OF THE FOOD AND DRUG ADMINISTRATION, LAW ENFORCEMENT AGENCIES, LOCAL GOVERNMENT UNITS AND TOY AND CHILDCARE ARTICLES (TCCA) DISTRIBUTORS AND RETAILERS**

**SUBJECT : Public Health Warning Against the Use of Cartoon Electronic Organ Toys which have No FDA Certificate of Product Notification**

Article II, Section 15 of the 1987 Constitution of the Republic of the Philippines provided that "*The State shall protect and promote the right to health of the people and instill health consciousness among them*". In line with this, Republic Act (RA) No. 3720 otherwise known as "Foods, Drugs and Devices, and Cosmetics Act", as amended by RA No. 9711, otherwise known as "Food and Drug Administration (FDA) Act of 2009" have mandated FDA to ensure the safety, quality and efficacy of health products under its jurisdiction.

FDA, being the national regulatory authority covering Toys and Childcare Articles (TCCA) products, requires companies intending to manufacture, import, export, distribute, sell, offer for sale, transfer, promote and advertise TCCA products to apply with the aforementioned agency, prior to carrying out said activities, for the following market authorizations, specifically, (1) License to Operate (LTO) as Household Urban Hazardous Substance (HUHS) Establishments and (2) TCCA Product Notification.

Toy products intended to be placed in the Philippine market are required by law to have the following information namely:

- a. LTO number issued by FDA;
- b. Age grade;
- c. Cautionary statements/ warnings;
- d. Instructional literature;
- e. Item/ Model/ SKU No. of the product
- f. Manufacturer's marking wherein the complete name and address of the manufacturer or distributor is reflected.

These information must be displayed prominently on the label attached to the immediate container which is in direct contact with the product. In addition, labels shall appear in English and/or national language and/or a language understood by the consumer where the toy product is marketed.

Thus, FDA hereby advises the general public not to purchase/use the following TCCA products that have been collected from Shoppers Mart- 657-663 Ongpin St., Binondo, Manila which have not passed through the verification process of FDA thus have no valid TCCA product notification:

1. Product Name: **CARTOON ELECTRONIC ORGAN TOYS**
2. Brand Name: **Frozen**
3. Manufacturer: **Xinrenheng Toys - China**
4. Distributor/ Retailer: **Shoppers Mart - 657-663 Ongpin St., Binondo, Manila**



Figure 1. Principal Display Panel



Figure 2. Side Panel



Figure 3. Actual Product




Figure 4. Back Panel



The FDA Field Regulatory Operations Office (FROO) is ordered to monitor the market for the manufacture, importation, exportation, distribution, sale, offer for sale, transportation, promotion and/or advertisement of the abovementioned TCCA products. FROO is further ordered to inventory and seal all unnotified TCCA products and to effect/ conduct seizure of the same in accordance with existing laws, rules and regulations.

All consumers are advised to buy toy products only if these items have the corresponding FDA market authorization, and to buy the same only from legitimate establishments. Consumers are further encouraged to access the FDA website (<http://www.fda.gov.ph>) to check if a particular toy product has FDA registration by simply typing the name of the product on the SEARCH bar. For more information and clarification, kindly email us at [info@fda.gov.ph](mailto:info@fda.gov.ph).

  
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