

[FDA Circular No. 2015-002, February 20, 2015]

GUIDELINES ON THE ELECTRONIC NOTIFICATION OF TOYS AND CHILDCARE ARTICLES (TCCAS)

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I. RATIONALE/ BACKGROUND

The Food and Drug Administration recognizes the need to keep its standards, rules and regulations at par with the rest of the regulatory agencies across the globe. Complex regulations and requirements may potentially pose as barriers to trade and innovative technology. To support the country's economic progress, a more simplified regulatory scheme is needed. Industries should be allowed to meet the fast changing needs and demands of consumers for safer products. Notification encourages innovations and technological advancement as well as national competitiveness of the manufacturing, import and export industries, paving the way for accelerated economic growth.

In this light, the FDA outlines the guidelines for the application of toys and childcare articles (TCCAs) through the Notification Scheme. This simplified approach places the responsibility primarily in ensuring the safety and quality of the products on the companies. However, the FDA shall strengthen post- marketing surveillance (PMS) to ensure continuous compliance of the companies to FDA safety and quality standards.

Section 10 of the Republic Act No. 9711 considers a prohibited act "the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertisement, or sponsorship of any health product which, although requiring registration, is not registered with the FDA pursuant to this Act".

FDA aims to simplify and provide fast, efficient service without compromising public health, thus, it will be implementing the Electronic Notification System of Toys and Childcare Articles (E-notification of Toys and CCA's)

II. SCOPE AND COVERAGE

The following products covered are: a) Toys intended for children below 14 years of age; b) Toys for exemption such as (i) toys for children 14 years of age and above (ii) toys for display or exhibit purposes and/ or those that are not intended to be marketed in the Philippines, and (iii) toys for personal or adult collector's use and (iv) toys for donation/missions c) Swings, slides and similar activity toys for indoor and outdoor family domestic use; and d) Childcare Articles such as but not limited to feeding bottles, sippy cups, pacifiers/soothers, teething aids, bottle teats/nipples,

toothbrushes for babies and baby feeding set.

III. GUIDELINES

1. License to Operate (LTO)

The company or person responsible for placing the product in the market must be a holder of valid FDA License to Operate (LTO) as HUHS Manufacturer, Trader, Distributor (Importer/Wholesaler/Exporter) before applying for e- notification. Applications of companies with expired LTOs will automatically be disapproved. Companies must apply for the renewal of their LTOs three (3) months prior to the expiration date of the LTO.

For those companies who have applied for LTO renewal that are under processing, their previous LTO No. and last validity date shall be reflected in sections on Local Company Responsible for Placing the Product in the Market and Establishment Information. Apart from these, the scanned copies of the Official Receipt (OR) for payment of LTO renewal fee and old LTO shall be uploaded in the Document Requirements part. The acknowledged notifications will be cancelled immediately if the LTO renewal application is disapproved.

The following are the needed documentary requirements for an individual/company applying for toy exemption:

Categories of Toys for Exemption	Requirements
1. Toys for children 14 years of age and above	<ul style="list-style-type: none">• Letter of Intent• Laboratory test report showing age grading 14+ years• Pictures showing packaging and labeling requirements stated in Section 7 of this circular.• Notarized affidavit of undertaking stating reason of exemption
2. Toys for display or exhibit purposes and/or those that are not intended to be marketed in the Philippines	<ul style="list-style-type: none">• Letter of Intent• Notarized affidavit of undertaking stating (1) details of the event and company responsible, (2) reason for exemption, (3) items are only intended for display or exhibit purposes and are not intended to be marketed in the Philippines, (4) items are not to be given as promotional items/ samples and (5) after the exhibit/expo the same number of items with corresponding description in the packing list would be shipped out of the country.• Bill of lading/ airway bill• Invoice• Packing list• Pictures showing packaging and labeling requirements stated in Section 7 of this circular.
3. Toys for personal use	<ul style="list-style-type: none">• Letter of Intent• Notarized affidavit of undertaking stating (1) reason for exemption, (2) number of items and description, (3) Declaration of value/ cost, (4) these items are not intended to

	be marketed in the Philippines, and (5) items are not to be given as promotional items/samples. <ul style="list-style-type: none"> • Bill of lading/ airway bill • Invoice • Packing list • Pictures showing packaging and labeling requirements stated in Section 7 of this circular.
4. Toys for adult collector's use	<ul style="list-style-type: none"> • Letter of Intent • Notarized affidavit of undertaking stating (1) reason for exemption, (2) items are only intended for personal display/collection items, (3) items are not to be given as promotional items/ samples. • Bill of lading/airway bill • Invoice • Packing list • Pictures showing packaging and labeling requirements stated in Section 7 of this circular.
5. Toys for donation/ charity/ missionary work	<ul style="list-style-type: none"> • Letter of Intent stating general information of the event. • Program of the charity activity/ mission where the donation will be given • Notarized affidavit of undertaking stating (1) details and company/ institution/organization responsible for the charity activity/mission, (2) reason for exemption, (3) items are only intended for donation/missionary work, (4) items are not to be sold, and (5) both the consignor and the consignee are liable for the safety and quality of the toys and childcare articles specially during the occurrence of adverse events and need for product recall/ disposal. • Laboratory Test Reports ISO 8124 Parts I-III and Phthalate testing, if applicable • Bill of lading/airway bill • Invoice • Packing list • Pictures showing packaging and labeling requirements stated in Section 7 of this circular.

For those applying for toy exemption falling under the sub-categories (1) toys for display or exhibit purposes and/or those that are not intended to be marketed in the Philippines and (2) toys for donation/charity/missionary work, the applicant (individual/company/organization) must apply for the Certificate of Exemption in Securing an LTO. Based on the net worth of the toys for exemption, the following exemption fees shall apply:

Exemption Fee	Net Worth of Shipment
PhP1,000.00	< P500,000
PhP2,000.00	P500,000 - P999,999
PhP3,000.00	> or equal to P1,000,000

2. Marketing Authorization

For the release of shipments from the Bureau of Customs (BOC), the companies must present their copy of a valid FDA LTO and acknowledged notification since

CCRR shall no longer issue Clearance for Conditional Release (CondR) and Clearance for Customs Release (CustR).

The acknowledged notification shall serve as proof of product registration with FDA in lieu of the Certificate of Conformity (COC) and companies may freely sell their TCCAs in the market. However, these TCCAs are subject to post-market surveillance which include toy product audit (review of laboratory test reports and representative/retention sample TCCA for compliance to labeling and packaging requirements), post-evaluation of acknowledged notification, market sampling for quality monitoring, laboratory testing, product recall and seizure/ confiscation.

Upon acknowledgment of the notification, the notified products are immediately posted in the FDA website. In case of non-compliance specially in the submission of pictures of labeling and packaging requirements, the system automatically issues a "Letter of Cancellation" (see Annex G) to TCCA account and removes the notified products in the list of notified TCCAs at the FDA website.

3. Applicability

The company shall notify the FDA of their intent to distribute/market/sell a particular product by (1) securing FDA TCCAs E-Notification Account and (2) filling up the information needed in the on-line notification application for TCCAs. The information needed are (1) Product Information such as brand name, item name, model/SKU number, age grading and product type; (2) Source of the Product such as name of the manufacturer, importer, and the local company responsible for placing the product in the market; and (3) Declaration stating among others the full responsibility over the quality and safety of the product(s) sold in the market, reports of adverse events and full cooperation on post-market surveillance activities.

Any company may apply for a notification prior to the arrival of shipment in the Philippines. One (1) notification application can accommodate a maximum of five (5) item/model/SKU numbers from the same toy/CCA product category and same source/supplier/manufacturer.

A separate notification application must be applied for (1) toys for exemption, (2) swings, slides and similar activity toys for indoor and outdoor family domestic use and (3) childcare articles. The aforementioned product classifications must not be mixed in 1 application along with toys intended for children below 14 years of age. Otherwise, the application shall be disapproved.

An individual/company applying for toy exemption falling under the sub-categories (1) toys for display or exhibit purposes and/or those that are not intended to be marketed in the Philippines, and (2) toys for donation/charity/ missionary work must apply for "Certificate of Exemption from Securing an LTO" before importing TCCAs and applying for e-notification. Non-functional, incomplete, worn-out, broken or unsanitary imported donated products/ TCCAs shall be restricted to enter the Philippines and be re-shipped to the country of origin by the company/institution/organization responsible for the shipment.

4. Grounds for Disapproval/ Cancellation of Notification

The following shall serve as a basis for the disapproval of TCCA e-notification

application:

- a. Companies with history of non-compliance e.g. company only applying for CondR and CustR but fails to apply for a COC, non-submission of compliance documents to issued Notice of Deficiencies (NODS).
- b. Companies that does not submit pictures of compliance to labeling and packaging requirement following RA 10620 and its IRR
- c. Companies that submit pictures of compliance to labeling and packaging requirement following RA 10620 and its IRR beyond the allotted 30 calendar days upon acknowledgement of notification
- d. Companies submitted pictures showing labeling and packaging that are non-compliant to RA 10620 and its IRR
- e. Non-submission, incomplete and/or altered laboratory test report
- f. Non-submission of phthalates test, if applicable
- g. If toys and CCAs product categories are mixed up in one (1) notification application ex. 2 item/model/SKU number are toys intended for children below 14 years of age, 2 item/model/SKU number are toys for exemption; application has dolls, swings, cars, puzzle mats and pull toys
- h. If the toy/CCA poses health hazard/risk specially based on health alerts/advisories on adverse events from other countries national regulatory authorities, WHO, sponsoring organizations and the like.

5. For Changes of Information

Any change of information or amendment to previously acknowledged TCCA's E-Notification will require application of new notification

6. Laboratory Test Reports

The scanned copy of the complete laboratory test report per Item/ Model/ SKU No. in .pdf or .png format shall be submitted/ uploaded individually. The Item/ Model/ SKU No. of the item followed by the words "LAB REPORT" shall be reflected as the filename of the laboratory test report ex. 12345 LAB REPORT.

The laboratory test reports shall come from accredited laboratories by International Laboratory Accreditation Cooperation (ILAC), Asia Pacific Laboratory Accreditation Cooperation (APLAC) or its accepted equivalent.

7. Labeling and Packaging

All companies must submit the (scanned) copy of the pictures of the labeling and packaging of representative toy/ childcare article sample in .pdf or .png format per Item/ Model/ SKU No. shall be submitted] uploaded individually. The Item/ Model/ SKU No. of the item followed by the words "PICS" shall be reflected as the filename ex. 12345 PICS. For a smaller file size, the product details and pictures per Item/ Model/ SKU No. can be placed in MS Word and saved in .pdf or .png format.

The packaging and labeling of the representative sample TCCA must show compliance to the labeling and packaging requirements as per RA 10620 "Toy and Game Safety Labeling Act of 2013" and its implementing rules and regulations