Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

26 September 2014

FDA CIRCULAR
No. 2014-023

SUBJECT: **Guidelines on the Manual Notification of Toys and Childcare Articles (CCAs)**

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 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.

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 those that are not intended to be

marketed in the Philippines (iii) toys for personal or adult collector's use; c) Swings, slides and similar activity toys for indoor and outdoor family domestic use; d) Childcare articles such as but not limited to feeding bottles, sippy cups, pacifiers/soothers, teething aids, bottle teats/nipples, toothbrushes for babies, baby feeding set. **Notification of Toys and CCAs is applicable per product per Stock Keeping Unit (SKU)/ model number/ item number.**

III. GUIDELINES

1. Applicability

One (1) notification application per product per SKU/ model number/ item number is required.

2. For New Products

A notification scheme for the above products shall be implemented. Prior to the notification, the company must be a holder of valid FDA License to Operate (LTO) as HUHS Manufacturer, Trader, Distributor (Importer/Wholesaler/Exporter).

The company or person responsible for placing the product in the market shall notify the FDA their intent to distribute/market/sell a particular product by filling out the Notification Template for Toys and Childcare Articles (see Annex II), including the following details:

A. Product Information includes brand name, item name, SKU/model number/ item number, product type, age grading, and if applicable, particulars for activity toys,
B. Description of the toy or CCAs (e.g. blue remote controlled race car, doll in pink dress, shoes and bags),
C. Source of the product and all other pertinent information as to the name of the manufacturer, importer, and the local company responsible for placing the product in the market,
D. Declaration stating among others: the full responsibility over the product, reports of adverse events and full cooperation on post-marketing activities.

Note: All particulars of the notification template shall be completely filled-out and must be in upper case. If such particular is not applicable, mark with the term *NA or NOT APPLICABLE.*

3. **For Products with Existing Registration**

All toys and CCAs with existing Certificate of Conformity (COC) shall file for a new notification application in the event that the company re-orders the said products. Upon expiration of the notification, the company shall apply for a new notification if the products are still being sold in the market.

4. **For Changes of Information**

Any change of information in the product notification shall constitute a new notification application.

5. **Laboratory Test Reports**

The soft copy of the complete laboratory test report(s) per SKU/Model/Item No. placed in a USB flash drive shall be submitted together with all the other pertinent documents needed. The test report shall be in .pdf format with the SKU/Model/Item No. reflected as the file name (e.g. 1234A, 1234B, ABCD). 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.

6. **Labeling and Packaging**

The companies will be given thirty (30) working days upon arrival of the shipment to submit the printed copy of pictures to 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 (IRR).

The following shall appear on, embossed, directly printed, or affixed to the package, container, wrapper or protective covering of the covered product/s: (1) LTO number issued by FDA, (2) age grading, (3) cautionary statements/ warnings, (4) instructional literature and (5) manufacturer's marking wherein the name and address of the manufacturer or the distributor is reflected or a trademark and/or mark which clearly identifies the manufacturer/distributor is used.

For small toy/ childcare article, pictures of the leaflets/ tags, carton box holding the individual units prior to retail and other labelling materials that can aide evaluation must be submitted.

Before submission, the company must download from the FDA website and completely fill out the Blank Template for the Submission of Labeling and

Packaging of Representative Toys and/ or Childcare Articles (see Annex III) then printed using the company's letterhead.

IV. FEES AND PAYMENT

Notifications shall be charged PHP 100.00 per product per SKU/ model number/ item number. Payments shall be made at the FDA Cashier.

V. TRANSITORY PERIOD

1. Starting 15 October 2014, applications for Clearance for Conditional Release, Clearance Customs Release, Certificate of Conformity and Certificate of Exemption will no longer be received and processed by the Center for Cosmetics Regulation and Research (CCRR).
2. Companies may opt to request for the cancellation of their previous application for COCs and avail of the new Notification scheme. (Note: Previous payments made are non-refundable and non-transferrable)
3. Existing COCs of toys and CCAs shall be replaced by the Notification in the event that the company re-orders the said products.
4. All applications received prior to the implementation of this Notification scheme shall be processed as per procedure prior to Notification, including compliances to Notice of Deficiencies (NODs).

VI. REQUIREMENTS

1. Accomplished assessment form (see Annex I);
2. Two (2) original and colored copies of the accomplished Notification Template for Toys and Childcare Articles (Annex II);
3. Proof of payment (official receipt issued by the FDA Cashier);
4. Photocopy of the valid LTO;
5. Soft copy in .pdf format placed in a USB flash drive of the complete laboratory test reports
   (a) *For toys intended for children below 14 years of age*: Parts 1 to 3 of the PNS/ISO 8124 or its accepted equivalent and reports for Phthalate testing, if applicable specially those containing Polyvinyl Chloride (PVC);
   (b) *For swings, slides and similar activity toys:* Requirements listed in (a) and Part 4 of the PNS/ISO 8124 or its accepted equivalent.
   (c) *For childcare articles:* Laboratory reports for Migration of Certain Elements (e.g. antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium) and for Phthalate testing.

Note: Use the SKU/Model/Item No. of the item as the filename of the laboratory report

6. FOR CANCELLATION OF EXISTING COC APPLICATION- a letter requesting for cancellation.

VII. PROCEDURES

1. All Toy and CCA establishments are required to comply with the following procedure:

    i. Download and accomplish the assessment form (see Annex I) at http://www.fda.gov.ph
    ii. Secure the notification template which may also be downloaded at the FDA website.
    iii. Completely fill out the fields in the template with the necessary information and print as is on A4 size paper. All entries should be in upper case. If such is not applicable to you, mark with *NA* or *NOT APPLICABLE.*
    iv. Two (2) copies of the accomplished templates in original form shall be submitted- first copy to be retained by FDA and the second copy to be returned to the applicant company after appropriate acknowledgement. Each application shall be stamped as received upon the submission of the applicant of the required documents. A claim stub with TCCA number shall be issued upon submission.
    v. Submit other requirements, such as the photocopy of the valid LTO and the USB flash drive containing the laboratory test reports, together with the assessment form and accomplished notification template.
2. Arrange the documents in clear book filler enclosed in a RED folder or binder (for large volume printed copies of pictures).
3. Proceed to the FDA staff assigned to receive the applications and have the applications assessed.
4. Pay the corresponding fees at the FDA cashier.
5. After payment, present the official receipt to the FDA staff and submit the paid assessment form together with the application documents.
6. All Toys and CCA applications shall be received every day between 8:30 AM – 11:30 AM at the Public Assistance Information and Receiving (FDA-PAIR). Applications received beyond 11:30 AM shall not be accommodated.
7. Incomplete applications, as well as those with inconsistencies are subject to evaluation and can be a basis for disapproval.

8. The FDA reserves the right to issue a letter/ notice to the company in case of clarifications. The agency is not precluded in determining and imposing remedial actions and legal penalties in a situation when the product subject of the application failed to conform to any of the existing standards or specifications set by FDA.
9. Acknowledged notification applications or Letter of Disapproval (LOD) shall be released at the Releasing Section from Mondays to Fridays within office hours.
10. Submission of the pictures for labeling and packaging of representative toys and/ or childcare articles with accomplished cover letter (see Annex III) shall also follow the schedule for receiving of applications for toys and CCAs set above.
11. All submitted pictures for labeling and packaging of representative toys and/ or childcare articles shall be arranged according to the TCCA No. in ascending order and placed in a red folder or binder (for large volume printed copies of pictures).

VIII. APPLICATION LEADTIME

All applications shall be processed and completed within twenty-two (22) working days provided the application complies with requirements.

IX. NOTIFICATION VALIDITY

The Notification of Toys and Childcare Articles shall be valid for a period of one (1) year.

X. SEPARABILITY CLAUSE

If any provision of this issuance is declared unauthorized or rendered invalid by court of law or competent authority, those provisions not affected thereby shall remain valid and effective.

XI. EFFECTIVITY

This Order shall take effect on 15 October 2014.

KENNETH Y. HARTIGAN-GO, MD
Acting Director General

CCRR's Copy

Food and Drug Administration

ASSESSMENT SLIP

HOUSEHOLD HAZARDOUS SUBSTANCES (TOYS & CHILDCARE ARTICLES)

Date: _____ DTN: _____

APPLICATION DETAILS (Tick where applicable)

TYPE OF PRODUCT:	TYPE OF ESTABLISHMENT:	TYPE OF APPLICATION:
☐ Toys	☐ Manufacturer	☐ Notification
		☐ License to Operate (LTO)
☐ Childcare Articles	☐ Distributor (Importer/Exporter/ Wholesaler)	☐ Initial
		☐ Renewal
		☐ Amendment

Product Name:	
SKU/Model No./Item No.:	
Applicant Company's Name and Address:	
Distributor(s):	
Retailer(s):	
Broker(s):	
Bill of Lading:	
Invoice/ Packing List No.:	
Container Number(s):	

PAYMENT DETAILS (To be filled by FDA Personnel)

EVALUATOR		*CASHIER*	
Fee	: _____	Amount	: _____
Surcharge	: _____	OR Number	: _____
TOTAL	: _____	Date Issued	: _____
Evaluated by	: _____	Received by	: _____

RECEIPT DETAILS

Name : _____

Signature : _____

Accounting Section's Copy

Food and Drug Administration

ASSESSMENT SLIP

HOUSEHOLD HAZARDOUS SUBSTANCES (TOYS & CHILDCARE ARTICLES)

Date: _____ DTN: _____

APPLICATION DETAILS (Tick where applicable)

TYPE OF PRODUCT:	TYPE OF ESTABLISHMENT:	TYPE OF APPLICATION:
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		☐ License to Operate (LTO)
☐ Childcare Articles	☐ Distributor (Importer/Exporter/ Wholesaler)	☐ Initial
		☐ Renewal
		☐ Amendment

Product Name:	
SKU/Model No./Item No.:	
Applicant Company's Name and Address:	
Distributor(s):	
Retailer(s):	
Broker(s):	
Bill of Lading:	
Invoice/ Packing List No.:	
Container Number(s):	

PAYMENT DETAILS (To be filled by FDA Personnel)

EVALUATOR		*CASHIER*	
Fee	: _____	Amount	: _____
Surcharge	: _____	OR Number	: _____
TOTAL	: _____	Date Issued	: _____
Evaluated by	: _____	Received by	: _____

RECEIPT DETAILS

Name : _____

Signature : _____

Republic of the Philippines
Department of Health
Food and Drug Administration
Alabang, Muntinlupa City

FDA Food and Drug Administration PHILIPPINES

ANNEX II
NOTIFICATION OF TOYS AND CHILDCARE ARTICLES

FOR FDA USE
Date Received:
Product Notification no: TCCA –
Valid until:

☑Tick where applicable

PARTICULARS OF PRODUCT

MARIA THERESA M. GUTIERREZ, RPh, MSc
Officer-In-Charge, Center for Cosmetics Regulation and Research

1. Product Details
   1.1 Brand

   1.2 Item Name

   1.3 SKU/Model number/ Item number

2. Product Type (Tick only one)
   - ☐ Toys intended for children below fourteen (14) years of age
   - ☐ Swings, slides and similar activity toys for indoor and outdoor family domestic use
   - ☐ Childcare articles such as but not limited to feeding bottles, sippy cups, pacifiers/soothers, teething aids, bottle teats/nipples, toothbrushes for babies, baby feeding set
   - ☐ Toys for exemption such as (i) toys for children 14 years of age and above (ii) toys for display or exhibit purposes and those that are not intended to be marketed in the Philippines (iii) toys for personal or adult collector's use

3. Age Grading printed on the final packaging

4. For swings, slides and similar activity toys for indoor and outdoor family domestic use (if applicable)
   - ☐ For indoor use
   - ☐ For outdoor use

   Mass (in kilograms) of the child for whom the toy is intended:

If appropriate, the maximum number of children that may safely use the equipment simultaneously:

5. For toys subject to exemption

   Exemption for the reason that:

   - ☐ The toy is intended for children fourteen (14) years and above
   - ☐ The toy is for display or exhibit purposes and is not to be marketed in the Philippines
   - ☐ The toy is for personal or adult collector's use

6. Product Description (e.g. blue remote controlled race car, doll in pink dress, shoes and bags)

PARTICULARS OF FOREIGN SOURCE(S)/ SUPPLIER (S)/ MANUFACTURER(S)[1]

[Please attach in a separate sheet if there are more than foreign source/ supplier/ manufacturer]

7. Name of Foreign Source(s)/ Supplier(s)/ Manufacturer(s):

   Complete Address of Foreign Source(s)/ Supplier(s)/ Manufacturer(s):

   Tel: _____ Fax: _____ E-mail Address:_____

PARTICULARS OF LOCAL COMPANY RESPONSIBLE FOR PLACING THE PRODUCT IN THE MARKET

8. Name of Company:

   License to Operate (LTO) Number | Validity

   Complete Address of Company:

   Tel: _____ Fax: _____ E-mail Address:_____

PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY

9. Name of Person:

   Tel: _____Fax: _____ E-mail Address:_____

[1] "**Manufacturer**", in relation to a health product, means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packaging, repackaging, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.

Position/ Designation in the Company

PARTICULARS OF DISTRIBUTOR/ IMPORTER/ RETAILER[2]

[Please attach in a separate sheet if there are more than one distributor/ importer/retailer]

10. Name of Distributor/ Importer/ Retailer:

Address of Distributor/ Importer/ Retailer:

Tel: _____ Fax: _____ E-mail Address:_____

DECLARATION

□ I undertake to respond to and cooperate fully with the regulatory authority with regard to any subsequent post-marketing activity initiated by the authority.

□ I undertake to ensure that the product's technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of the products for product recall purposes.

□ I undertake to notify the Authority of fatal or life threatening serious adverse event as soon as possible by telephone, facsimile transmission, e-mail or in writing, and in any case, not later than 7 calendar upon knowledge of the adverse event.

□ I declare that the particulars given in this notification are true and correct.

□ I undertake to ensure that if and when directed by the regulatory authority I will recall the product from the market, and discontinue selling/ supplying the product

□ I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.

□ I declare that our product does not contain any restricted or banned substances that can be harmful/ hazardous/ life threatening to children and infants.

□ I understand that I cannot place reliance on the acceptance of my product notification by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

[Name and Signature of person representing the local company]
[Company Stamp] [Date]

[2] **"Distributor/Importer** means any establishment that imports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets.

Day – Month - Year

MARIA THERESA M. GUTIERREZ, RPh, MSc
Officer-In-Charge
Center for Cosmetics Regulation and Research
Food and Drug Administration

Subject: **SUBMISSION OF LABELLING AND PACKAGING OF REPRESENTATIVE TOYS AND/ OR CHILDCARE ARTICLES (TCCAs)**

Dear Ms. Gutierrez:

We are submitting the printed copy of pictures of representative TCCAs for your evaluation to show our 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 (IRR).

Document Tracking No.	Notification No.	SKU / Model No./ Item No.	Product Information

Very truly yours,

NAME OF THE COMPANY OWNER / AUTHORIZED REPRESENTATIVE
Official Designation (ex. Owner, Authorize Representative, Marketing Manager, etc.)

Office Telephone No./ Fax No. _____
Mobile Phone Nos. _____
E-mail Address: _____