



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



14 November 2013

FDA Memorandum Circular
№ 013-045

**SUBJECT: GUIDELINES ON NOTIFICATION OF SELECTED HOUSEHOLD/
URBAN HAZARDOUS SUBSTANCES (HUHS) PRODUCTS**

I. RATIONALE/BACKGROUND

The Food and Drug Administration (FDA) 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 and export industries, paving the way for accelerated economic growth.

In this light, the FDA outlines the guidelines for the application of selected HUHS 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 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) Paints, lacquers, varnish; b) Solvent paint, lacquer thinner, mineral spirits; c) Adhesives (contact cement); d) Polishes and Waxes (metal polish, wood polish, shoe polish); e) Bleaches; f) Cleaners; g) Disinfectant sprays; h) Detergents (bar, liquid and powder); i) Dishwashing (liquid and paste); j) Glues/Paste; k) Fabric (dyes, softeners, conditioners); l) Educational set and miscellaneous chemistry set (paste, crayons, pencils, water colors, glue stick/glues, correction fluid/rubber eraser, crayons, oil pastels, art paints, chalk, moulding clays); m) Stationeries/ Art paper (colored and/or scented); n) Air Fresheners (deodorizer, fabric freshener, aromatherapy product, scented candles, gels, oil, spray); and the like. **Product notification is applicable per formulation per packaging presentation.**



FOOD AND DRUG ADMINISTRATION

III. GUIDELINES

1. Applicability

One (1) notification application per product formulation per packaging presentation is required.

Example 1) A product with five different packaging presentations with the same formulation will need five separate notification applications, one each per packaging presentation.

Example 2) A product with two or three different packaging sizes but of the same packaging presentation and same formulation will need only one notification.

2. Product Information File

A Product Information File (PIF) shall be prepared and kept by the company following the format as specified in Annex II upon receipt of the acknowledged notification. Upon audit, a complete PIF shall be readily available in a suitable paper format, convenient and easily consulted by the Authorities. The PIF shall be retained for a minimum of three (3) years after the product is last placed in the market.

3. 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 or Distributor.

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 HUHS Notification Template (Annex I), including the following details:

- A. Product Information (brand name and variants, product format),
- B. Source of the product and all other pertinent information as to the name of the importer/distributor/trader and manufacturer of the product,
- C. Full Ingredient Listing in exact amount or percentage (%) and function of each ingredient,
- D. Technical Specifications of the finished product and;
- E. Declaration stating among others: the full responsibility over the product, the availability of product information file, reports of adverse events and full cooperation on post-marketing activities.

4. For Products with Existing Registration

All existing Certificate of Product Registration (CPR) due for renewal or seeking amendments shall file for new notification application. This will be treated as initial application.

5. For Changes of Information

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

6. LTO Requirement

A valid LTO shall be required for notification application.



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



IV. FEES & PAYMENT COLLECTION

Applications shall be charged according to current issuances on fees and charges.

V. TRANSITORY PERIOD

1. Companies may opt to request for the cancellation of their previous application and existing valid CPRs, and avail of the new Notification scheme. (Note: Previous payments made are non-refundable and non-transferable)
2. Existing CPR shall remain valid and recognized until expiration or replacement by Notification.
3. 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. HUHS Notification Template (Annex I);
2. Proof of payment (official receipt issued by the FDA Cashier);
3. FOR CANCELLATION OF EXISTING REGISTRATION OR APPLICATION - a letter requesting for cancellation;
4. FOR THOSE WITH EXISTING CPRs – the original CPR.

VII. NOTIFICATION PROCEDURE

1. All HUHS establishments are required to comply with the following procedure:
 - A. For New Products
 - i. Secure the proper HUHS notification template which may be downloaded at <http://www.fda.gov.ph>.
 - ii. Completely fill out the fields in the template with the necessary information and print as is on A4 size paper. A separate sheet may be attached for the formulation of products exceeding the designated space provided (Product Ingredient List table under item number 5).
 - iii. Two (2) copies of notification template in original form shall be submitted - first copy to be retained by FDA and second copy to be returned to the applicant company after appropriate acknowledgement. Each notification application shall be stamped as received upon the submission of the applicant of the required documents. A claim stub with a notification number shall be issued upon submission.
 - B. For Existing Products (where the validity of CPR is about to expire)
 - i. Follow the Notification Procedure for New Products;
 - ii. Surrender the original copy of the CPR.
2. Arrange the documents in clear book filler enclosed in red folder.
3. Each company may submit a maximum of five (5) HUHS notification application per day.



FOOD AND DRUG ADMINISTRATION

4. All HUHS notification applications shall only be received every Thursdays between 8:00 AM - 3:00 PM at the Public Assistance Information and Receiving (FDA – PAIR). Application received beyond 3:00 PM shall not be accommodated.
5. A claim stub or document tacking log for each HUHS notification application will be issued bearing the notification number.
6. Any inconsistencies found within the notification application are subject to evaluation and can be a basis for disapproval.
7. The FDA reserves the right to issue a letter/notice to the company in case of clarification. 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.
8. Acknowledged notifications and letters of disapproval shall be released at the FDA – PAIR from Mondays to Fridays from 8:00 A.M.-4:00PM

XII. NOTIFICATION LEADTIME

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

XII. NOTIFICATION VALIDITY

The HUHS notification shall be valid for a period of one (1) year.

XIII. 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.

XIV. EFFECTIVITY

This Order shall take effect immediately.



KENNETH Y. HARTIGAN-GO, MD
Acting Director General



Republic of the Philippines
 Department of Health
FOOD AND DRUG ADMINISTRATION
ANNEX I



NOTIFICATION OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES

FOR FDA USE

Date Received: _____

Product Notification no: **III -** _____

Valid until: _____

Tick where applicable

PARTICULARS OF PRODUCT

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

1. Name of brand & product
 1.1 Brand

- 1.2 Product Name (include scent or fragrance, if applicable)

2. Product type (Tick only one)

- | | |
|--|---|
| <input type="checkbox"/> Paints, lacquers, varnish | <input type="checkbox"/> Glues/Paste |
| <input type="checkbox"/> Solvent paint, lacquer thinner, mineral spirits | <input type="checkbox"/> Fabric (Dyes, softeners, conditioners) |
| <input type="checkbox"/> Adhesives (contact cement) | <input type="checkbox"/> Educational set and miscellaneous chemistry set (paste, crayons, pencils, water colors, glue stick/glues, correction fluid/rubber eraser, crayons, Oil Pastels, Art Paints, chalk, moulding clays) |
| <input type="checkbox"/> Polishes and Waxes (metal polish, wood polish, shoe polish) | <input type="checkbox"/> Stationeries/ Art paper (colored and scented) |
| <input type="checkbox"/> Bleaches | <input type="checkbox"/> Air Fresheners (deodorizer, fabric freshener, aromatherapy product, scented candles, gels, oil, spray) |
| <input type="checkbox"/> Cleaners | |
| <input type="checkbox"/> Disinfectant sprays | |
| <input type="checkbox"/> Detergents (bar, liquid and powder) | |
| <input type="checkbox"/> Dishwashing (liquid and paste) | |

3. Product presentation (Tick only one)

- | | | |
|---|---|---|
| <input type="checkbox"/> Sachet | <input type="checkbox"/> Glass bottle | <input type="checkbox"/> Canister |
| <input type="checkbox"/> Pouch | <input type="checkbox"/> Spray bottle | <input type="checkbox"/> Others [Specify] _____ |
| <input type="checkbox"/> Doy pack | <input type="checkbox"/> Carbuoy | _____ |
| <input type="checkbox"/> Plastic bottle | <input type="checkbox"/> Plastic gallon | _____ |

4. Product description (including color, odor, etc)



PRODUCT INGREDIENT LIST

5. Fill-up the full ingredient listing in the provided table
[Please use a separate sheet in the following format]

| Full ingredient name (use appropriate acceptable common name or approved nomenclature in standard references, include CAS# if available) | Function | Amount, Percentage (%) |
|--|----------|------------------------|
| | | |
| | | |
| | | |
| | | |
| | | |

PARTICULARS OF MANUFACTURER (S)¹

[Please attach in a separate sheet if there are more than one manufacturer/assembler]

6. Name of manufacturer:

Address of manufacturer (include country):

Tel: _____ Fax: _____

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

7. Name of company:

Address of company:

Tel: _____ Fax: _____

License to Operate Number

PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY

8. Name of Person:

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, formulation, filling, packaging, repackaging, alteration, ornamentation, finishing and labeling with the end in view of its storage, sale or distribution.



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



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

Designation in the company

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PARTICULARS OF IMPORTER²

9. Name of Importer

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|--|

Address of Importer:

| |
|--|
| |
|--|

Tel: _____ Fax: _____

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, email or in writing, and in any case, no later than 7 calendar days after first knowledge.
- I declare that the particulars given in this notification are true, all data, and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.
- 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 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.



ANNEX II
PRODUCT INFORMATION FILE

The company shall present upon audit the hereunder information as part of the product information file of each notified product. The company responsible for placing the product in the market shall keep a Product Information File (PIF) as part of the undertaking "to ensure the product's technical information to be readily available to the regulatory authority concerned".

The product information required is listed hereunder:

- I. Table of Contents
- II. Administrative Documents
 1. Copy of the Acknowledged Product Notification
 2. Valid License to Operate (LTO) with the following supporting documents:
 - i. For Manufacturers
 1. List of HUHS Distributor/s
 2. List of product lines
 - ii. For Distributor (Importer/ Exporter/Wholesaler)
 1. List of Product Source/s, including manufacturer and distributors of the product from where the applicant distributor sources its product
 2. List of product lines
 3. FOR IMPORTED HOUSEHOLD PRODUCTS ONLY; the following documents must be duly authenticated and notarized by the Philippine embassy in the country of origin of the product
 - a. Certificate of Free Sale issued by a government authority, OR
 - b. Certificate of Good Manufacturing Practice, OR
 - c. Manufacturing License
- III. Technical Information
 1. Formulation (in exact amount or percent, and function of each ingredient used)
 2. Technical specification of raw materials used as component of the product (Safety Data Sheet)
 3. Technical specifications of the Finished Product
 4. Certificate of Analysis of the Finished Product
 5. Complete Test Methods done on the Finished Product
 6. Substantiation to support special product claims
 7. Labeling Materials
- IV. Representative Sample (for each packaging size and packaging presentation, with the commercial packaging/label consistent with the declared information in the product notification, and is in accordance to Department of Health Administrative Order no. 311 series of 1977, or the current guidelines set by the department)