

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



29 April 2014

FDA MEMORANDUM CIRCULAR No. 2014-008

SUBJECT: GUIDELINES ON THE ELECTRONIC NOTIFICATION of SELECTED HOUSEHOLD / URBAN HAZARDOUS SUBSTANCES (HUHS E-NOTIFICATION) SYSTEM

Food and Drug Administration (FDA) - Center for Cosmetics Regulation and Research (CCRR) aims to simplify regulatory scheme without compromising public health. With this, the FDA will be implementing the Electronic Notification System of selected Household / Urban Hazardous Substances (E-Notification of HUHS) and hereby updates FDA Memorandum Circular 2013-045 entitled "Guidelines on Notification of Selected Household/Urban Hazardous Substances (HUHS) Products".

I. PROCEDURE

 Secure an HUHS E-Notification Username and Password by sending an e-mail containing the following information to <u>ccrr@fda.gov.ph</u>:

Subject (of the E-mail): Request for HUHS E-Notification Account

Data required on the e-mail of the authorized representative are the following:

Name:

Email Address:

Company Name

Company Address:

Position:

Contact No.:

- 2. Log in at https://www.fda.gov.ph.
- 3. Accomplish the HUHS E-Notification form.
- 4. Download and print two (2) copies of the accomplished assessment slip.
- 5. Present the assessment slips at the FDA Cashier or any Landbank branch and pay the required fee. (for Landbank transaction, see FDA Memorandum Circular No. 2013-046 for the CCRR Account Number)
- 6. Log in again at https://www.fda.gov.ph to select payment mode.
- 7. HUHS E-Notification application can either be acknowledged for those compliant or be disapproved for non-compliant to standards. Either Notice of Acknowledgement or Letter of Disapproval will be sent through the account of the authorized representative for their perusal. See Annex A for more details.
- 8. Status of the E-Notification application can be checked by clicking "Participated."
- 9. Any amendment of previously acknowledged HUHS E-Notification will require application of new notification.





II. GUIDE IN FILLING UP THE HUHS E-NOTIFICATION FORM:

- 1. Fill in the necessary information in **All CAPS**, except for Trademark, Corporate De Facto (e.g. GmbH), and e-mail address, for uniformity.
- 2. Assessment slip will be valid for five (5) days. Applications which have not been paid within the allotted time will automatically be cancelled and deleted from our database.
- 3. One (1) HUHS E-Notification application per formulation per packaging type.
- 4. Coloring materials such as crayons, colored pens/pencils, water colors and the like, that contain pigments and coloring agents in a single pack requires one (1) E-Notification application and shall cover all colors sold in a single packaging presentation.
 - a. The full ingredient listing for all colors must be provided and;
 - b. The number of colors must be indicated in the "Product Name" (i.e. Kulay Coloring Pens 25's).
- Prior to applying for HUHS E-Notification, ensure that your LTO is valid and the source/supplier/product is reflected. In case of expiring/expired LTO, apply for LTO renewal before submitting your E-Notification application.
- 6. Product must not contain any banned ingredients as per the Stockholm Convention on Persistent Organic Pollutants (POPs)
 - (http://chm.pops.int/TheConvention/ThePOPs/tabid/673/Default.aspx), nor should it contain any regulated chemicals without certification issued by appropriate agencies. See Annex B for the list.

III. VALIDITY

The validity of the acknowledged HUHS E- Notification application will be for a period of one (1) year.

IV. PROCESSING TIME

Timeline for the processing of HUHS E-Notification from the time the client has assigned the next step to FDA Accounting to the sending of result to the client's account is within ten (10) working days.

V. FEES

The FDA shall charge a fee based on the current FDA issuance.

VI. EFFECTIVITY

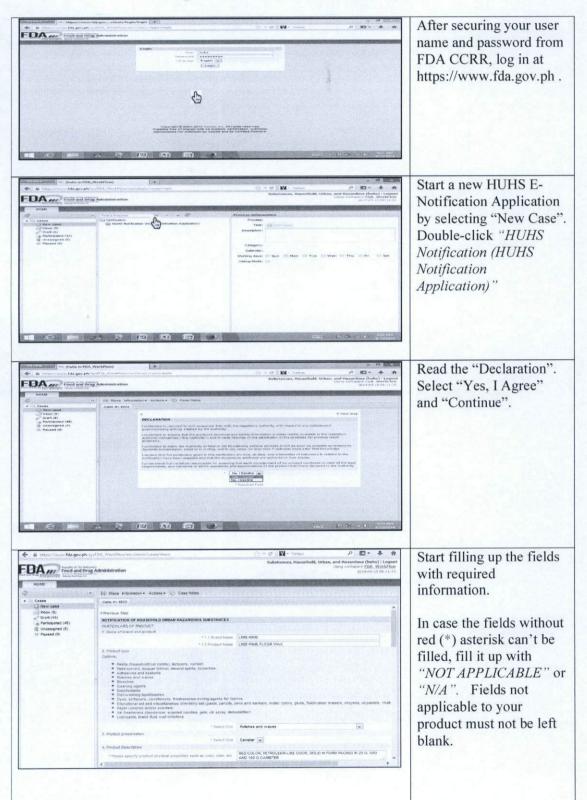
Full implementation of the HUHS E-Notification System will be on 15 May 2014. CCRR will no longer receive any HUHS notification filed manually on said date.

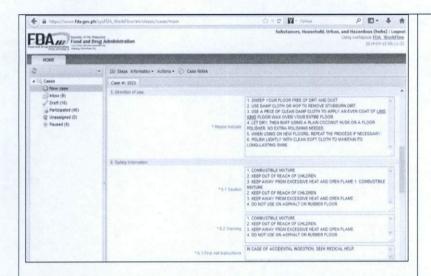
This Order shall take effect.

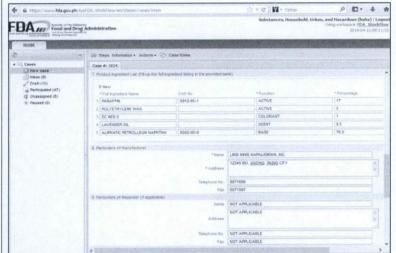
ENNETH Y HARTIGAN-GO, MD

Acting Director IV

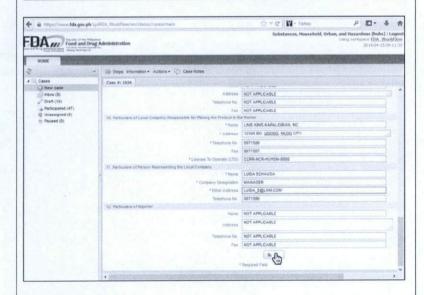
Annex A Using the FDA HUHS e-Notification System





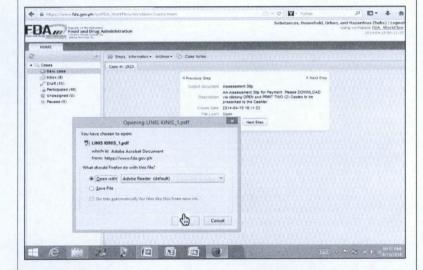


After filling-up the required fields, click "Submit."





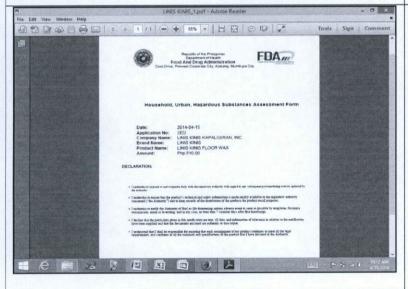
Download the assessment slip by clicking "Open."

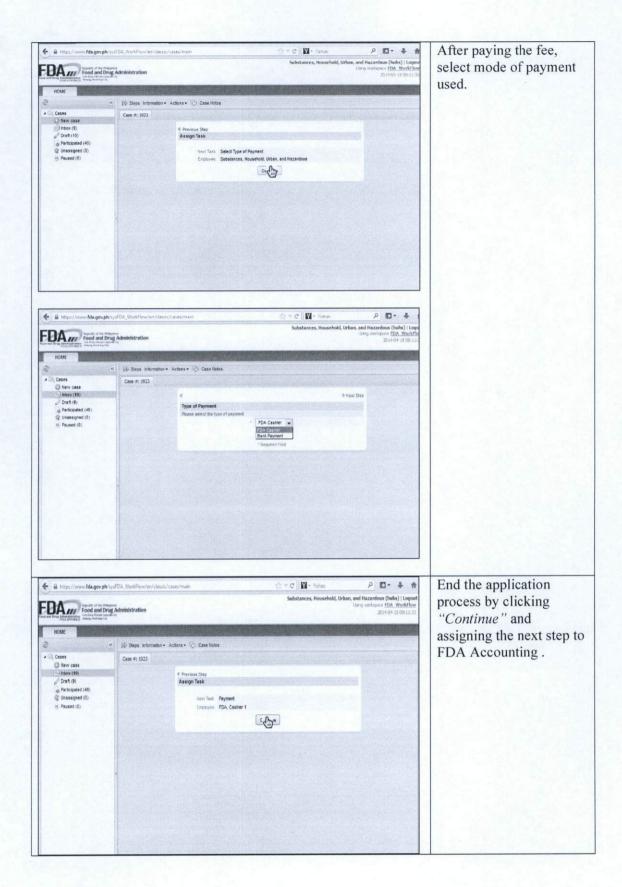


Print two (2) copies of the assessment slip then pay the required fee.

Options for payment are:

- 1. FDA Cashier
- 2. Any Landbank branch nearest you.





Annex B List of Regulated Chemicals

Chemical Name	Agency		Agency
1,1,1-Trichloroethane	Banned	Hydrochloric acid	PDEA
1,2-Diphenylhydrazine	EMB	Isosafrole	PDEA
1-phenyl-2-propanone	PDEA	Lead (II) nitrate	FED
3,4-methylenedioxyphenyl-	PDEA	Lead Compounds	EMB
2-propanone			
Acetic anhydride	PDEA	Lysergic acid	PDEA
Acetone	PDEA	Mercury Compounds	EMB
Ammonium nitrate	FED	Methyl Ethyl Ketone	PDEA
Ammonium perchlorate	FED	Mirex	EMB
Anthranilic acid	PDEA	N-acetyl-anthranilic acid	PDEA
Arsenic Compounds	EMB	Nitric acid	FED
Asbestos	EMB	Nitrocellulose	FED
Barium Nitrate	FED	Norephedrine	PDEA
Benzene	EMB	Pentachlorophenol	EMB
Beryllium Compounds	EMB	Phenylacetic acid	PDEA
Cadmium Compounds	EMB	Phosgene	EMB
Calcium Nitrate	FED	Piperidine	PDEA
Carbon Tetrachloride	Banned	Piperonal	PDEA
Chlorinated Ethers	EMB	Polybrominated	EMB
		Biphenyls (PBBs)	
Chlorofluoro Carbons	Banned except CFC 11,	Polychlorinated	EMB
(CFCs)	CFC 12	Biphenyls (PCBs)	
Chloroform	EMB	Potassium chlorate	FED
Chromium Compounds	EMB	Potassium nitrate	FED
Copper (II) nitrate	FED	Potassium perchlorate	FED
Cyanide Compounds	EMB	Potassium permanganate	PDEA
Dinitrocellulose	FED	Pseudoephedrine	PDEA
Ephedrine	PDEA	Safrole	PDEA
Ergometrine	PDEA	Selenium	EMB
Ergotamine	PDEA	Sodium chlorate	FED
Ethyl ether	PDEA	Sodium nitrate	FED
Ethylene Dibromide	EMB	Sodium perchlorate	FED
Ethylene Oxide	EMB	Sulfuric acid	PDEA
Halons	Banned	Toluene	PDEA
Hexachlorobenzene	EMB	Tributyltin	EMB
Hexachloroethane	EMB	Vinyl chloride	EMB