



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



FDA MEMORANDUM CIRCULAR  
No. **2015-011**

31 JUL 2015

**SUBJECT: Guidelines for Electronic Notification of Cosmetic Products  
(Cosmetic E-Notification Version 2.0) Using the FDA E-Portal**

## **I. BACKGROUND**

The ASEAN Cosmetic Directive aims to eliminate technical barriers to trade of cosmetic products without compromising public health and safety to the ASEAN population including the Filipino consumers through harmonization of technical requirements among ASEAN member states.

In March 2013, through FDA Memorandum Circular (FMC) No. 2013-011, the FDA implemented the electronic notification of cosmetic products (Cosmetic e-Notification). This aided in streamlining the previous manual means of application to an electronic form, lessening the transfer of paper documents and physical submission of applications.

In the second quarter of 2014, the development of the FDA E-Portal aided in the notification of other health products also under the jurisdiction of the Center for Cosmetics Regulation and Research (CCRR).

## **II. OBJECTIVES**

To further enhance the efficiency of the application process and promote transparency of information, the Cosmetic E-Notification process will now be undertaken using the FDA E-Portal. This Memorandum Circular hereby provides the application procedure of Cosmetic E-Notification using the FDA E-Portal and hereby updates Bureau Circular No. 2007-013-A and FMC No. 2013-011.

## **III. SCOPE AND COVERAGE**

This Memorandum Circular shall cover establishments and representatives of establishments that shall place cosmetic products in the market.

## **IV. GENERAL APPLICATION PROCEDURE**

### **1. Submission of Application**

Submission of the application shall be done using the FDA E-Portal, accessible through <https://www.fda.gov.ph>. An applicant must acquire a CCRR User account from CCRR to access the E-Portal (FDA Memorandum Circular No. 2015- 010). To file an application, follow the procedure outlined below.



- 1.1 Login by entering the username and password of the provided CCRR User Account.
- 1.2 In the HOME tab, select New case in the navigation pane to proceed to the notification form.
- 1.3 The cosmetic product notification form is divided into several parts as provided by the application wizard. These include:
  - 1.3.1 Declaration;
  - 1.3.2 Particulars of the Product;
  - 1.3.3 Local Company Responsible for Placing the Product in the Market and Establishment Information;
  - 1.3.4 Details of the Person Representing the Company; and,
  - 1.3.5 Product Ingredient List.
- 1.4 Accomplish the notification form, as provided in parts, by following the application wizard.
- 1.5 An assessment slip will be generated at the end of the step.
  - 1.5.1 Download the generated assessment slip by clicking Open.
  - 1.5.2 To continue with your application, click Next. The application will then be placed in the Participated folder in the navigation pane.
  - 1.5.3 The status of the application may be checked in the Participated folder as indicated by the Task column.
- 1.6 To complete the application submission, the applicant must assign the next step to FDA Accounting/Cashier.

## 2. Payment of Application

Cosmetic e-Notification applications may be paid through the payment options made available by FDA.

## 3. Result of Application

A cosmetic e-notification application may either be acknowledged or disapproved. This may be correspondingly issued with an acknowledged notification or letter of disapproval. The result of application may be downloaded by following the procedure outlined below:

- 3.1 Download the result of application by clicking Open.
- 3.2 Click Next Step to proceed with the next task.

Any change in the declared information in the acknowledged product notification will constitute a new notification application.

## 4. Revalidation of Application

Acknowledged cosmetic notifications may be revalidated for a new validity date, where, the new validity date will be based on the date of acknowledgement of the revalidation application. The same process of application for cosmetic e-notification applies for revalidation. There must be no modifications from the information provided in the previously acknowledged notification to avail of revalidation. Hence, any changes to the information will constitute a new notification application. To apply for the revalidation of the notification, follow the procedure outlined below:



- 4.1 Select the application as found in the inbox.
- 4.2 Select the option Revalidation Application in the dropdown list found in the displayed form.
- 4.3 Choose the desired validity from the dropdown list.
- 4.4 Click Continue to proceed with your application.

5. Cancellation of Notification

Acknowledged cosmetic product notifications may be cancelled at the option of the applicant. To cancel an acknowledged notification, follow the procedure outlined below:

- 5.1 Select the application as found in the inbox.
- 5.2 Select the option Cancellation of Notification in the dropdown list found in the displayed form.
- 5.3 Click Continue to end the process.

**V. IMPORTANT REMINDERS**

1. Prior application, ensure that the local company responsible for placing the cosmetic product in the market has a valid License-to-Operate (LTO).
2. Fill-in the fields as completely as possible. Fields marked with a red asterisk (\*) are required to be filled-in. Mark fields with Not Applicable, if the field is not applicable.
3. In the product ingredient list, all ingredients must be specified by using the nomenclature accepted in the standard references listed in the ASEAN Cosmetic Labeling Requirements. Botanicals and extracts of botanicals should be identified by its genus and species. The genus may be abbreviated. The functions and percentages of ingredients must be declared if they are substances with restrictions for use as specified in the annexes of the ASEAN Cosmetic Directive.
4. One (1) notification application shall be submitted for each product per manufacturer.
5. Components of kits/sets shall be notified individually, where the specific component is to be declared in the space provided under the field, Product Presentation/s.
6. Any change in the declared information in the acknowledged product notification will constitute a new notification application.

**VI. PROCESSING TIME**

Applications will be processed preferably within fourteen (14) calendar days. This timeline begins at the time the payment transaction reference number has been verified by FDA Accounting/Cashier, and ends at the time the result of the application has been sent to the applicant's account.

**VII. FEES**

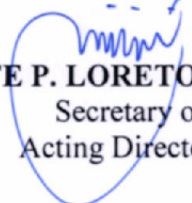
Applications shall be charged with fees pursuant to the existing rules on fees and charges.

**VIII. TRANSITION PERIOD**

FDA-CCRR will no longer receive applications filed through the previous Cosmetic e-Notification procedure outlined by FMC 2013-011 starting 15 August 2015 but will still process those applications submitted before said date.

**IX. EFFECTIVITY DATE**

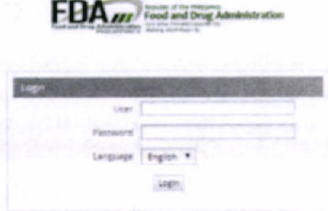
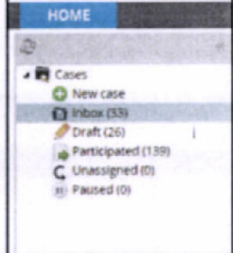


Full implementation of Cosmetic e-Notification using the FDA E-Portal will be on 15 August 2015.

  
**JANETTE P. LORETO-GARIN, MD, MBA-H**  
Secretary of Health  
Acting Director General<sup>1</sup>



## ANNEX A

### Submission of the Cosmetic e-Notification Application using FDA E-Portal

<p>1. Access the FDA e-Portal at <a href="https://www.fda.gov.ph">https://www.fda.gov.ph</a></p> <p>2. Login by entering the <u>username</u> and <u>password</u> of the provided CCRR User account.</p>			
<p>3. In the <u>HOME</u> tab, select <u>New case</u> in the navigation pane to proceed to the notification form.</p>			
<p>4. Accomplish the notification form as provided in parts by the Application Wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable.</p>			
<p><b>Notification Form</b></p>			
<p><b>Declaration</b></p> <ul style="list-style-type: none"> <li>Proceed with the application by selecting your response using the drop-down list and clicking 'Continue'.</li> </ul>			



- Validity of the notification may either be 1, 2, or 3 years at the option of the applicant.

- Product Information**

**Product Name**

\* Brand Name:

\* Brand Name:

\* Number of Years Applied for:

**Product Variants or Trade Names**

**Item**

\* Variant/Trade Name

1.

2.

\* Product Type:

\* Intended Use:

\* Product Presentation:

**Additional Product Information**

Product information, including existing packaging sizes and their corresponding label trade identification number (LTIN) may be updated here. Please note that once information has been submitted, it will no longer be modifiable. Hence, any change to the provided information would merit a new notification application.

**Item**

Packaging Size:

Packaging Type:

LTIN:

**Item**

- Place the appropriate and valid LTO number of the company responsible for placing the cosmetic product in the market.

- [◀ Previous Step](#) [▶ Next Step](#)

### Local Company Responsible for Placing the Product in the Market

\* Company Name (As listed in LTO)

\* Address (As listed in LTO)

\* Region

\* LTO No.

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### Contact Information

[▶ New](#)

Type	Detail	Action
1 Telephone ▼	(02) 123-4567	Delete

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### Establishment Information

\* Please select the activity of the local company responsible for placing the product in the market  
 ▼

\* Is the product directly sourced? ☒ Yes ▼

\* Country of Manufacture  ▼

\* Complete Name of Manufacturer

\* Complete Address of Manufacturer

\* Required Field

- The name and designation of the person representing the company will automatically reflect the current user.

- 
- Previous Step
- Next Step
- ### Details of the Person Representing the Company
- Name: Household, Urban, and Hazardous Substances
- Designation:
- Contact Details:
- New
- | Type      | Detail       |
|-----------|--------------|
| Telephone | (02)123-4567 |
- Delete
- Next



### Product Ingredient List

- Indicate the full ingredient list of the cosmetic product indicated in the application. The function and percentage of restricted ingredients in the formulation are required to be provided. Non-declaration of such information may result in the disapproval of the application.
- To continue to the next step, click 'Next'.

10000 Information Actions Case History

Case # 17735

Previous Step Next Step

Product Ingredient List

New

Variant	Full Ingredient Name	Function	Percentage (%) of Ingredient	Action
	RICINUS COMMUNIS SEED OIL			Delete
	OLEIC/UNSATURATED POLYESTER			Delete
	CARBOCUTANIC TRIGLYCERIDE			Delete
	HYDROGENATED POLYCYCLOPENT			Delete
	EUPHORBIA CERIFERA WAX			Delete
	METHYLA PIPERITA OIL			Delete
	HYDROGENATED PALM GLYCERIDE			Delete
	ETHYLHEXANOL	PRESERVATIVE	0.2	Delete
	METHOXYPROPANEDIOL			Delete
	UNELLIN			Delete
	CI 77361 / CHROMIUM OXIDE GREEN			Delete
	CI 77361			Delete
	CI 77361			Delete
	CI 77361			Delete

Next

5. An assessment slip will be generated at the end of the step.
- Download the generated assessment slip by clicking 'Open'.
  - To continue with your application, click 'Next'. The application will then be placed in the 'Participated' folder in the navigation pane.
  - The status of the application may be checked in the 'Participated' folder as indicated by the 'Task' column.

Previous Step Next Step

Output document: Order of Payment


Description: An Assessment Slip for Payment. Please DOWNLOAD via clicking OPEN and PRINT TWO (2) Copies to be presented to the Cashier.

Create Date: 2015-05-21 16:15:55


File (.pdf) [Open](#)

Next Step

### Assessment Slip



Republic of the Philippines  
Department of Health  
**Food and Drug Administration**  
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City



**Cosmetic Notification  
Assessment Form**

**Date:** 2015-05-21

**Case No:** 17735

**Reference No:** 100000017-20

**Company Name:** COMPANY ABC COMMERCIAL CORPORATION

**Brand Name:** BRAND ABC

**Product Name:** BRAND ABC COLOR BALM LIPSTICK

**Variants:** PINK, RED

**No of Variants:** 2

**Years Applied:** 1

**Application Fee:** 600

**LRF:** 10

**Amount:** Php610

6. A cosmetic e-notification application may either be acknowledged or disapproved and correspondingly issued with an acknowledged notification form or letter of disapproval, respectively.

[Previous Step](#)
[Next Step](#)

Output document: Notification of Cosmetic Product

Description: Notification of Cosmetic Product. Please DOWNLOAD via clicking OPEN.

Create Date: 2015-05-22 16:06:21

File (.pdf) [Open](#)

[Next Step](#)


### Acknowledged Product Notification

32 Notification of Cosmetic Product.pdf - Adobe Reader


File Edit View Window Help

My Files

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Republic of the Philippines  
 Department of Health  
**Food And Drug Administration**  
Chino Davao, Pilanes Corporation City, Alibang, Marikina City



**Notification of Cosmetic Product**

Pursuant to the existing rules and regulations of the Food and Drug Administration (FDA) for the notification of cosmetics, the product notification is hereby acknowledged.

Cosmetic Notification Number: NN-1009000177358  
 Validity: 22 May 2016

**Particulars of the Product**  
 Brand Name: BRAND ABC  
 Product Name: BRAND ABC COLOR BALM LIPSTICK  
 Variant/s: PINK, RED

**Particulars of the Manufacturer**  
 Name of the Manufacturer: COSMETIC LABORATORIES, INC.  
 Address of the Manufacturer: 123 ABC AVENUE, ONTARIO  
 Country of Manufacturer: Canada

**Particulars of the Local Company Responsible for Placing the Product in the Market**  
 Name of the Company: COMPANY ABC COMMERCIAL CORPORATION  
 Address of the Company: 1F CLOSED BUILDING, 123 ABC AVENUE, MAKATI CITY  
 LTO Number: CCR-NCB-CD-000

The product is allowed to be sold in the local market subject to compliance with the requirements of the ASEAN Cosmetic Directive and the FDA laws, and its implementing rules and regulations. This notification should not be taken as a guarantee and/or endorsement of the safety, quality, and claimed benefit of the product. Any subsequent changes to the information submitted in this notification will render this notification invalid and a new notification will have to be submitted.

The company hereby ensures that they shall respond and cooperate fully with the FDA with regard