



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.

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System



www.tuv.com
ID: 9101073206

- 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: