CENTER FOR COSMETICS
REGULATION AND RESEARCH

ELECTRONIC COSMETIC PRODUCT NOTIFICATION

COSMETIC E-NOTIFICATION USING THE FDA E-PORTAL

USER MANUAL

FDA E-PORTAL
COSMETIC E-NOTIFICATION

OUTLINE

I. BACKGROUND

COSMETIC PRODUCT NOTIFICATION

With the adoption and implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme in 2005 by virtue of DOH Administrative Order No. 2005-0015 and 2005-0025, the notification scheme for cosmetic products was implemented. This was first fully implemented as a manual application process through FDA Bureau Circular No. 2007-013-A.

The application process went electronic in March 2013 through FDA Memorandum Circular No. 2013-011. This shift aimed to streamline the process by updating the submission of application requirements from the previously manual form to online submissions.

In August 2015, to further enhance the efficiency of the application process and transparency of information, the cosmetic product notification scheme was updated and incorporated in the FDA E-Portal.

II. FDA E-PORTAL

A. WHAT IS THE FDA E-PORTAL?

This is accessible via https://www.fda.gov.ph, and is the portal for several types of applications filed electronically with the FDA. Users of the E-Portal are provided with accounts to access the processes. Using this portal, tasks (i.e. steps in the procedure) are accomplished in a simple workflow, and cases (i.e. applications) are filed using specialized forms.

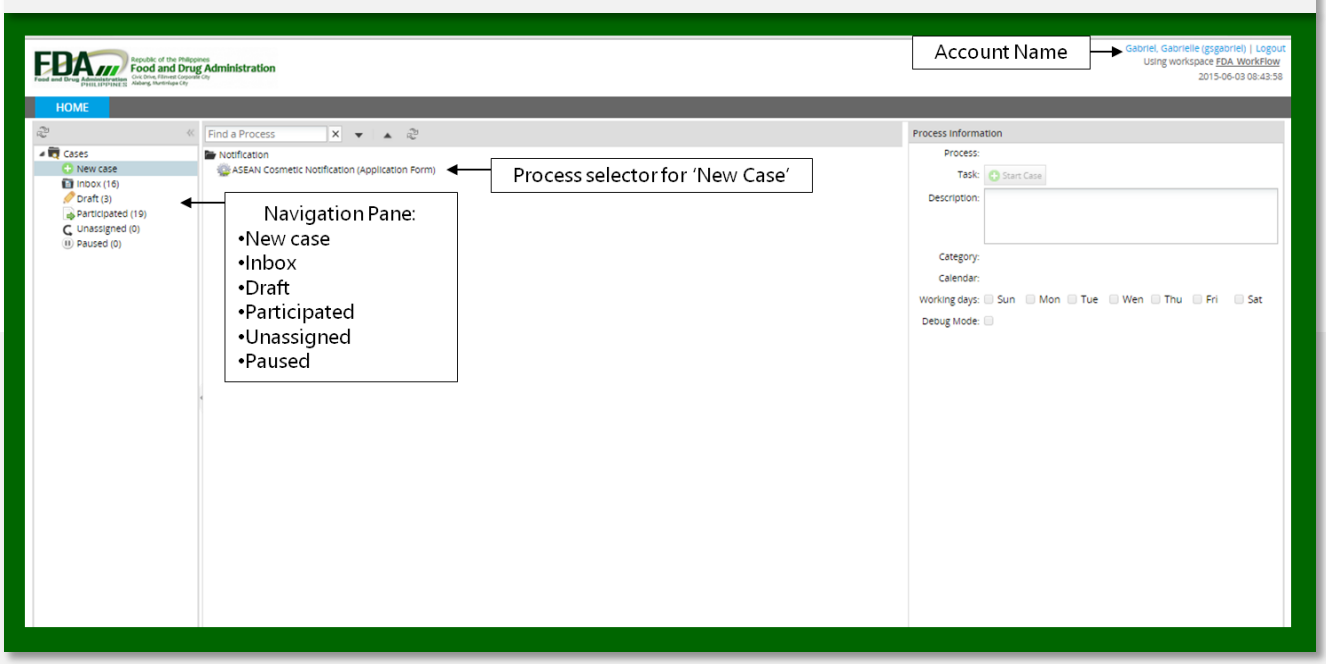
NAVIGATING THE E-PORTAL

The interface may be likened to common e-mail programs. It has two key parts:

1. Navigation pane
   - Found at the left side of the interface
   - It contains the following folders:
     a. New Case – selected when an applicant wishes to apply for a new application;

        When 'New Case' is selected in the navigation pane, the window displays the list of processes which may be availed by the applicant. To proceed with submitting an application, the user may select from the list their preferred process to be undertaken.

New Case View

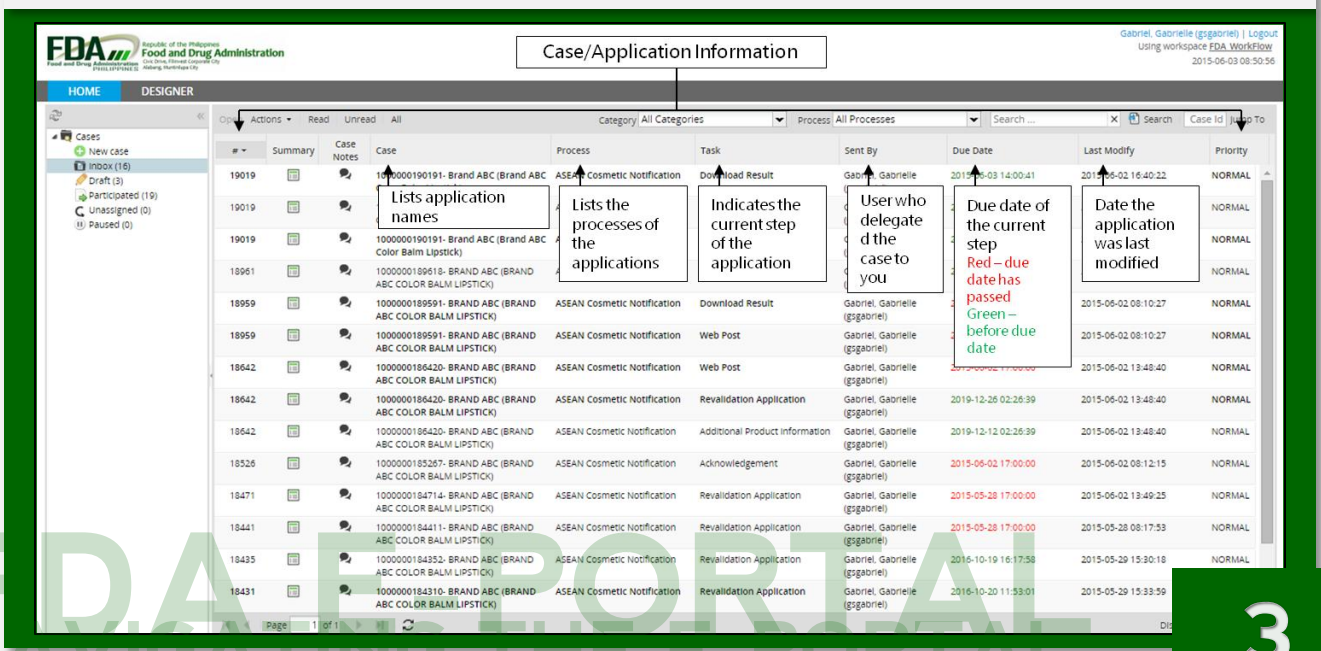


b. Inbox – displays all current tasks delegated to the user;

When 'Inbox' is selected in the navigation pane, the window displays the list of applications that are currently for further action (i.e. pending tasks) by the user. It is a tabular representation with columns provided for:

1) # - case number
2) Summary – summary of application
3) Case Notes – notes on the application by authorized users
4) Case – name of the application
5) Process – process where the application is lodged
6) Tasks – current task to be undertaken for the application
7) Sent By – User name of the last user who delegated the case
8) Due Date – due date by which the task ends,
9) Last Modify – date by which the application was last modified
10) Priority – level of priority of a case (all applications are, by default, of Normal priority). Other folders in the navigation pane will display a similar tabular presentation of information as shown in the figure below.

Inbox View



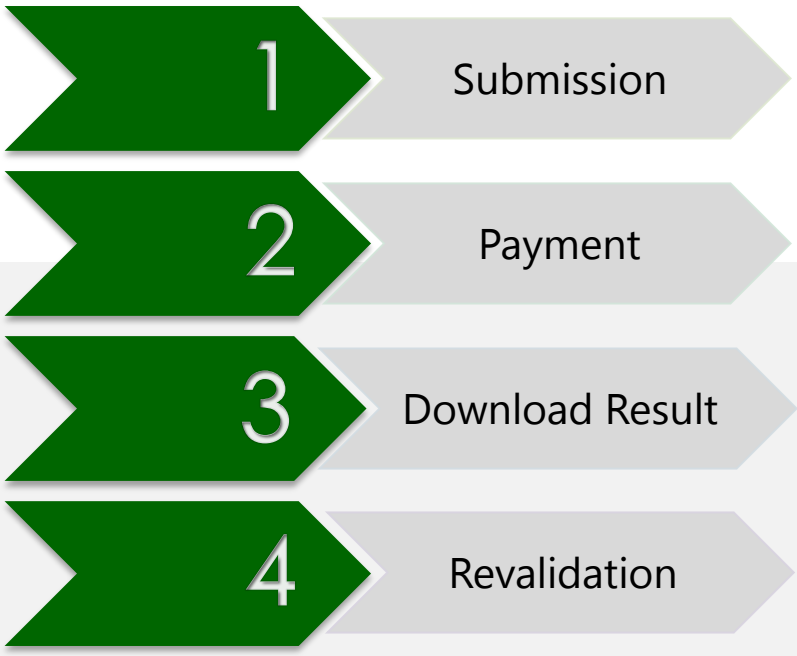
c. Draft – displays all cases started but not fully accomplished
d. Participated – displays all applications with completed tasks
e. Unassigned – displays all applications with no current user delegated
f. Paused – displays all paused applications

2. Window

This displays dynamic content, depending on the selected folder in the navigation pane

III. APPLICATION PROCEDURE

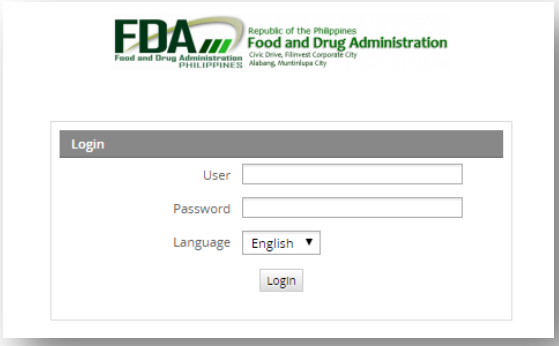
The process consists of 4 (four) main parts: Submission, Payment, Download Result, and Revalidation.



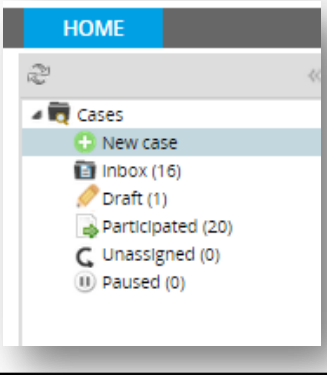
1 SUBMISSION

OVERVIEW OF SUBMISSION

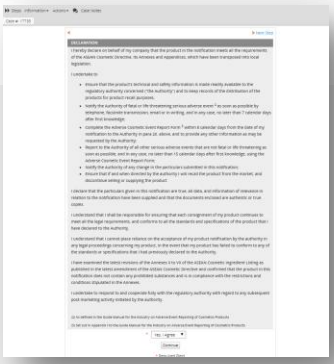
1. Access the FDA e-Portal at https://www.fda.gov.ph
2. Login by entering the username and password of the provided CCRR User account.



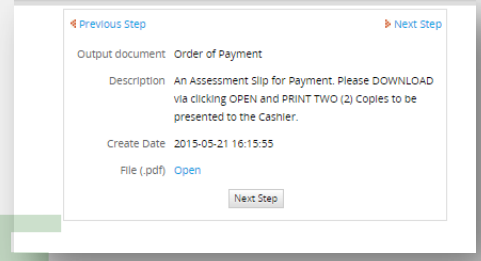
3. In the HOME tab, select New case in the navigation pane to proceed to the notification form.



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 fields with Not applicable, if not applicable.



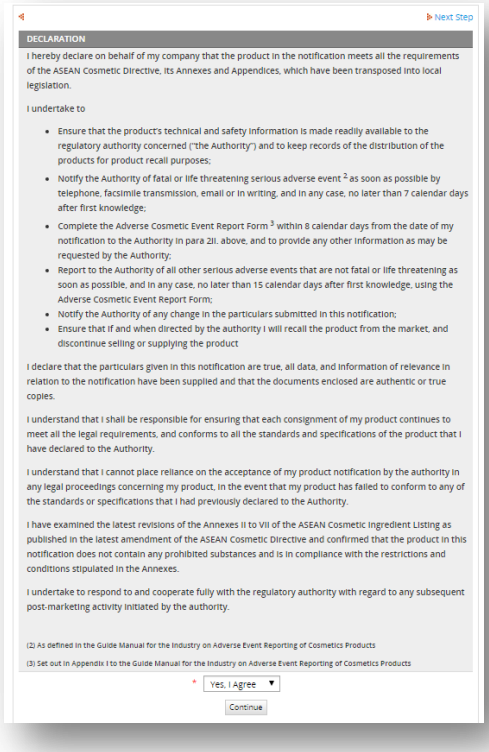
5. An assessment slip will be generated at the end of the step.
   - Download the generated assessment slip by clicking Open.
   - To continue with your application, click Next. The application will then be placed in the Participated folder in the navigation pane.
   - The status of the application may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



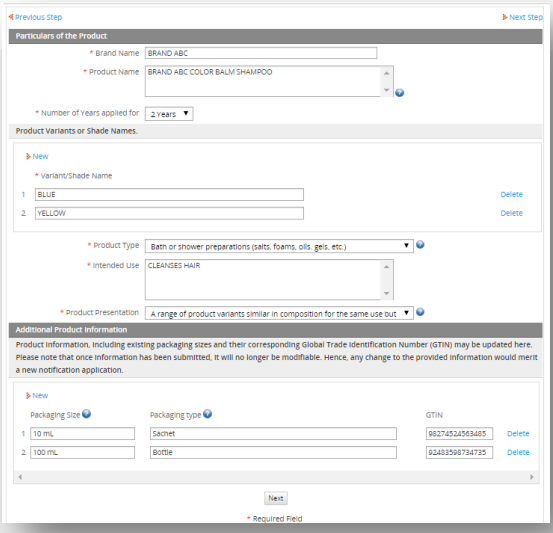
GUIDELINES IN FILLING THE NOTIFICATION FORM

1. DECLARATION

   Proceed with the application by selecting your response using the drop-down list and clicking Continue.

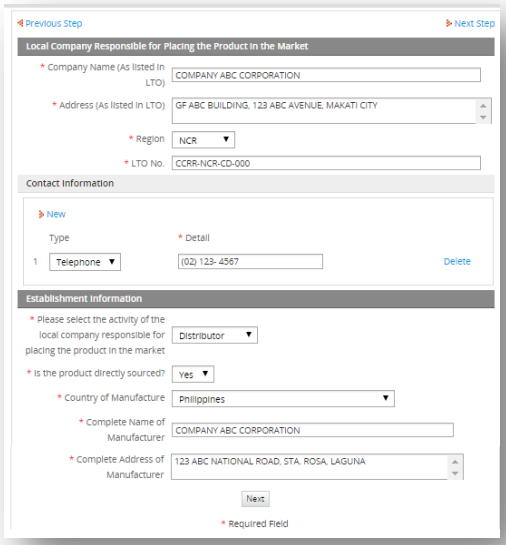


2. PARTICULARS OF THE PRODUCT
   - Validity of the notification may either be 1, 2, or 3 years at the option of the applicant.
   - To add variants/packaging sizes/ packaging types, GTIN into the list, click New to add another line. Click Delete if you wish to delete the entry.
   - Utilize the drop-down lists when selecting the Product Type and Presentation. When Others is selected, please specify using the provided space.
   - To continue to the next step, click Next.



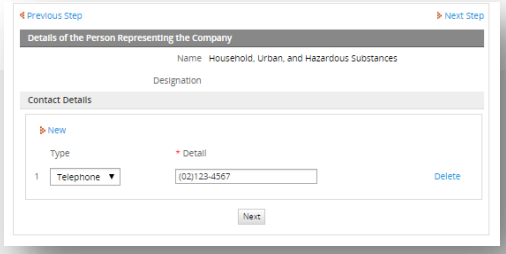
3. LOCAL COMPANY RESPONSIBLE FOR PLACING THE PRODUCT IN THE MARKET

- Place the appropriate and valid LTO number of the company responsible for placing the cosmetic product in the market.
- Select the activity of the company as per the provided LTO and fill-in the additional fields provided:
  - Distributor – Country of Manufacture, Supplier Details (if applicable), Manufacturer details
  - Trader – Manufacturer details
- Ensure that the provided information is consistent with the current valid LTO of the company.
- To continue to the next step, click Next.



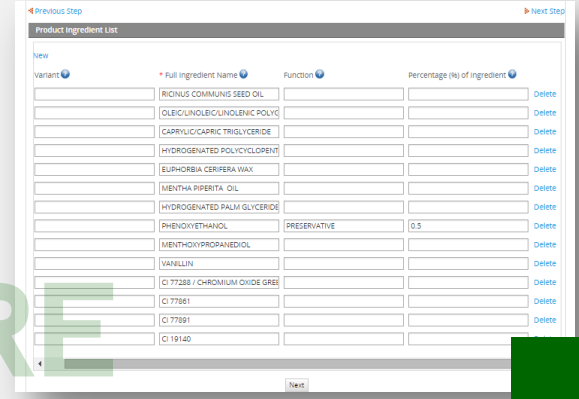
4. DETAILS OF THE PERSON REPRESENTING THE COMPANY

- The name and designation of the person representing the company will automatically reflect the current user.
- To continue to the next step, click Next.



5. 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.
- To continue to the next step, click Next.

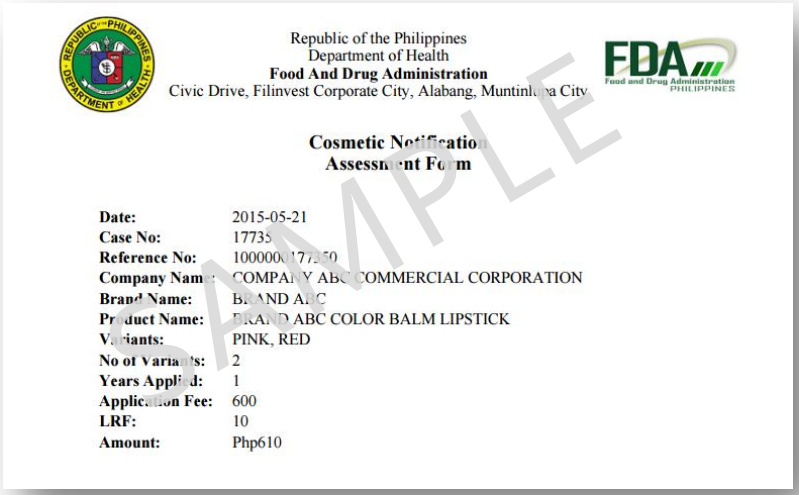


INFORMATION TO BE DECLARED IN THE PRODUCT NOTIFICATION

BRAND NAME	The complete name of the product should be given, in the following sequence: brand name, line name (if applicable), product name, if a single shade is notified, the shade name/number (e.g. BRAND ABC PRODUCT XYZ EYSHADOW SHADE 1).If there are different shades, the shade name/number for each shade shall be declared.
PRODUCT NAME	
PRODUCT VARIANTS	
PRODUCT TYPES	The illustrative list (ACD Annex I) is not exhaustive and you can include other types of cosmetic products not in the list by selecting others and specifying what it is.
INTENDED USE	This refers to the function or use of the product and not the directions for use e.g. to moisturize the face, hand, etc.
PRODUCT PRESENTATIONS	A SINGLE PRODUCT exists in a single presentation form. A RANGE OF VARIANTS SIMILAR IN COMPOSITION FOR THE SAME USE BUT DIFFERS IN COLOURS, FLAVOURS ETC is a range of cosmetic products, which are similar in composition and produced by the same manufacturer, and are intended for the same use but are available in different shades of colour (e.g. lipsticks, eye shadows or nail polish but not composite packs of different types). PALETTE(S) IN A RANGE OF ONE PRODUCT TYPE refers to a range of colours as defined above, which may be presented in a series of palettes. COMBINATION PRODUCTS IN A SINGLE KIT refer to similar and/ or different product types packed and sold in a single kit. They cannot be sold separately (e.g. a make-up kit of eye and lip colours; a set of skin-care products sold in a single kit). Please note that components of such kits must be notified separately.
LOCAL COMPANY RESPONSIBLE FOR PLACING THE COSMETIC PRODUCT IN THE MARKET	It refers to the local company responsible for placing the cosmetic products in the market, which may be a local manufacturer or an agent appointed by a manufacturer to market the product or the company that is responsible for bringing in the product for sale in the country, etc.
ESTABLISHMENT INFORMATION	It refers to the particulars of the manufacturer and/or supplier of the notified cosmetic product.
PERSON REPRESENTING THE LOCAL COMPANY	It refers to the person representing the local company responsible. The e-notification program automatically reflects the account details of the applicant in this portion.
PRODUCT INGREDIENT LIST	All the ingredients in the product must be specified by using the nomenclature from the latest edition of standard references (International Cosmetic Ingredient Dictionary, British Pharmacopoeia, United States Pharmacopoeia, Chemical Abstract Services). Botanicals and extract 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.

2 PAYMENT

1. Download the generated assessment form and print copies as needed. Note the Reference Number for the payment option/s to be availed.

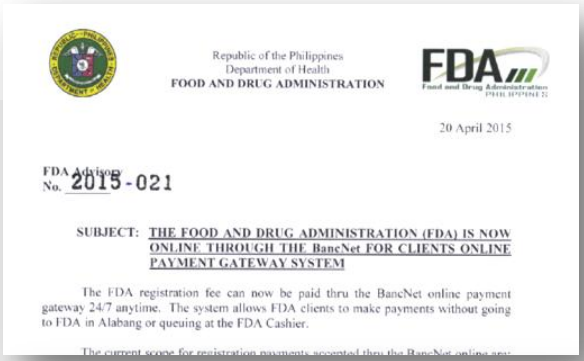


Republic of the Philippines
Department of Health
Food And Drug Administration
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

Cosmetic Notification Assessment Form

Date:	2015-05-21
Case No:	17735
Reference No:	100000017[illegible]50
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

2. Clients may pay for their applications through the bank facilities made available by FDA.
The current payment options available are through BancNet online payment (FDA Advisory No. 2015-021) and the LandBank OnColl Payment Facility (FDA Memorandum Circular No. 2013-015).



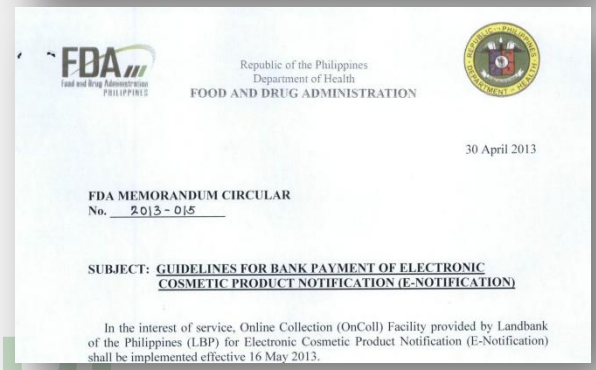
Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

20 April 2015

FDA Advisory No. 2015-021

SUBJECT: THE FOOD AND DRUG ADMINISTRATION (FDA) IS NOW ONLINE THROUGH THE BancNet FOR CLIENTS ONLINE PAYMENT GATEWAY SYSTEM

The FDA registration fee can now be paid thru the BancNet online payment gateway 24/7 anytime. The system allows FDA clients to make payments without going to FDA in Alabang or queuing at the FDA Cashier.



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

30 April 2013

FDA MEMORANDUM CIRCULAR
No. 2013-015

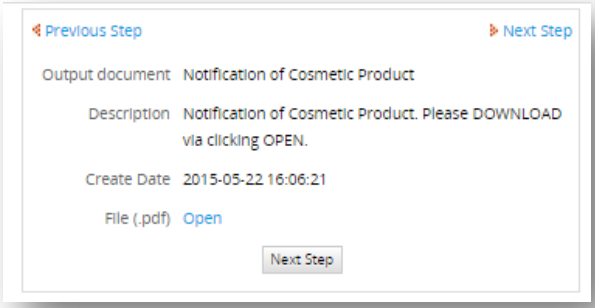
SUBJECT: GUIDELINES FOR BANK PAYMENT OF ELECTRONIC COSMETIC PRODUCT NOTIFICATION (E-NOTIFICATION)

In the interest of service, Online Collection (OnColl) Facility provided by Landbank of the Philippines (LBP) for Electronic Cosmetic Product Notification (E-Notification) shall be implemented effective 16 May 2013.

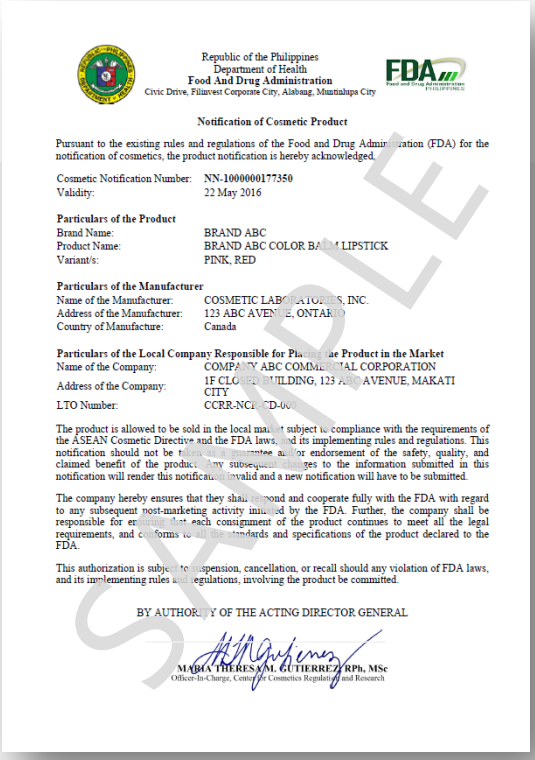
RESULT OF APPLICATION

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

1. Download the result of application by clicking Open.
2. Click Next Step to proceed with the next task.



ACKNOWLEDGED COSMETIC PRODUCT NOTIFICATION



Republic of the Philippines
Department of Health
Food And Drug Administration
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa 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-1000000177350
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 Manufacture: 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 CLC BUILDING, 123 ABC AVENUE, MAKATI CITY
LTO Number: CCRR-NCR-CD-00

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.

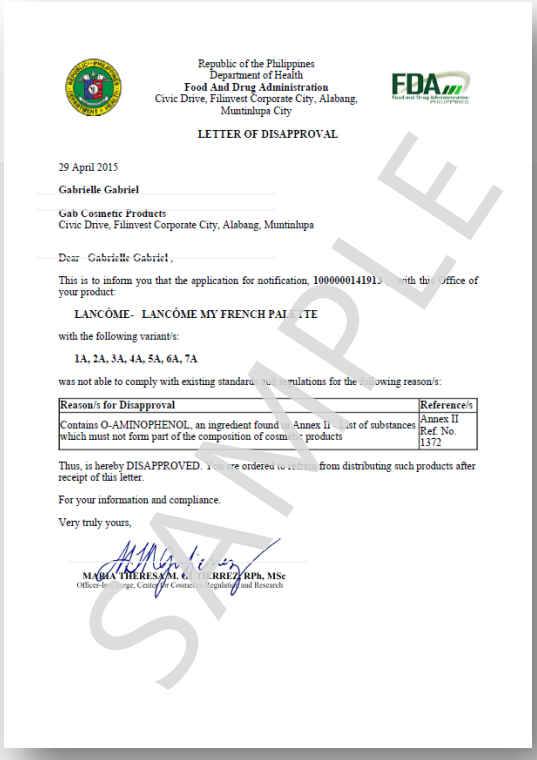
The company hereby ensures that they shall respond and cooperate fully with the FDA with regard to any subsequent post-marketing activity initiated by the FDA. Further, the company shall be responsible for ensuring that each consignment of the product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product declared to the FDA.

This authorization is subject to suspension, cancellation, or recall should any violation of FDA laws, and its implementing rules and regulations, involving the product be committed.

BY AUTHORITY OF THE ACTING DIRECTOR GENERAL

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

LETTER OF DISAPPROVAL



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

LETTER OF DISAPPROVAL

29 April 2015

Gabrielle Gabriel

Gab Cosmetic Products
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa

Dear Gabrielle Gabriel,

This is to inform you that the application for notification, 1000000141913 with the Office of your product:

LANCÔME- LANCÔME MY FRENCH PALETTE

with the following variant/s:

1A, 2A, 3A, 4A, 5A, 6A, 7A

was not able to comply with existing standards and regulations for the following reason/s:

Reason/s for Disapproval	Reference/s
Contains O-AMINOPHENOL, an ingredient found in Annex II - List of substances which must not form part of the composition of cosmetic products	Annex II Ref. No. 1372

Thus, is hereby DISAPPROVED. You are ordered to refrain from distributing such products after receipt of this letter.

For your information and compliance.

Very truly yours,

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

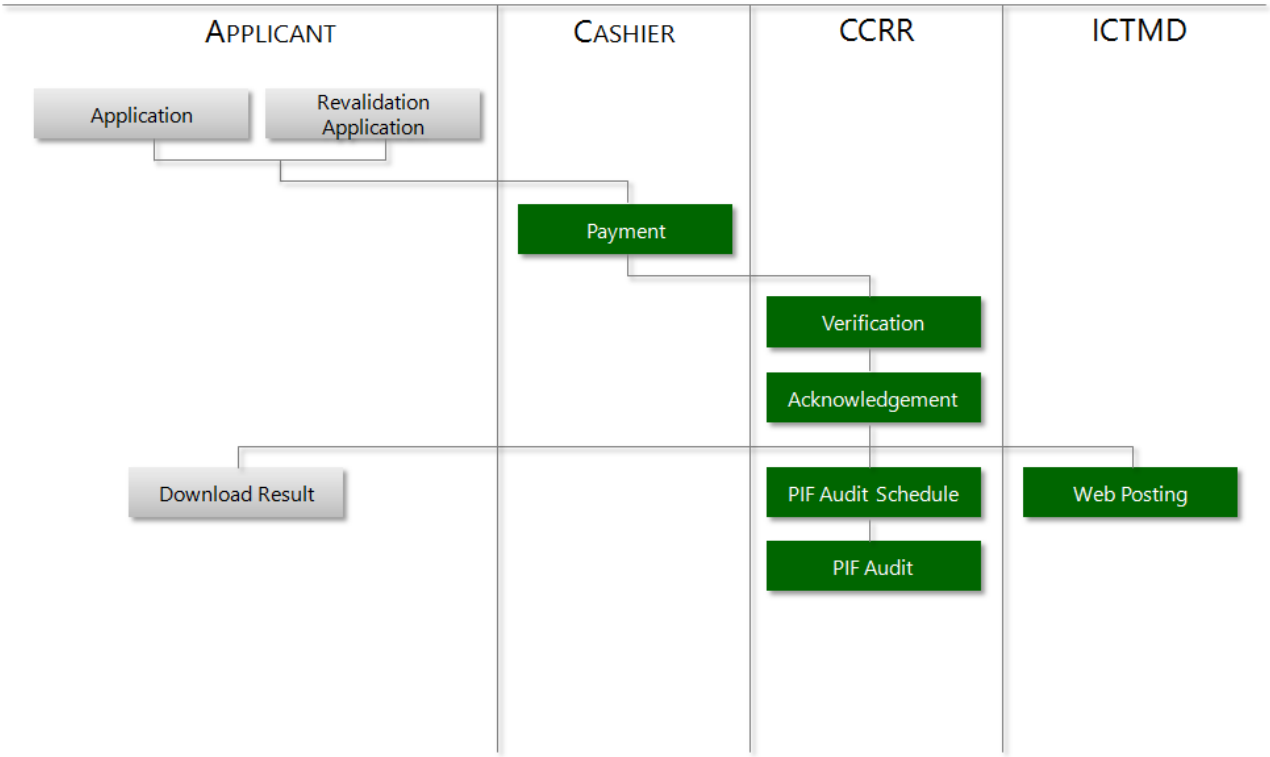
4 REVALIDATION

- Acknowledged cosmetic notifications may be revalidated for a new validity date, where the new validity date will be based on the date of submission of the revalidation application.
- The same process of application for cosmetic e-notification applies for revalidation. In the e-portal, the previously acknowledged case must be selected to continue with the task for Revalidation Application.
- There must be no modifications from the information provided during the previous application to avail of revalidation. Hence, any changes to the information will constitute a new notification application.
- In the event that the notification is desired to be cancelled, the applicant may choose to cancel the application. This option is available in the Revalidation Application Task.

IV. BUSINESS PROCESS FLOW

COSMETIC PRODUCT NOTIFICATION

A cosmetic notification application undergoes the following business process flow:



1. PAYMENT
   Applications, after being routed by the applicant to the Cashier for payment, shall undergo payment validation.
2. VERIFICATION
   Once the payment has been appropriately validated, CCRR will start processing the application through verification of the information declared in the application. A recommendation for either acknowledgement or disapproval will then be provided.
3. ACKNOWLEDGEMENT
   Applications appropriately verified and possessing adequate recommendations will then be routed to the CCRR-Director for acknowledgement or disapproval. An acknowledged product notification or letter of disapproval will be made available in the Download Result task of the applicant.
4. PIF AUDIT SCHEDULE AND PIF AUDIT
   When a notification has been recommended for audit, it will be routed within CCRR for appropriate action.
5. WEB POSTING
   When an application has been acknowledged, it will also be routed to the Information Communication Technology Management Division (ICTMD) for posting on the FDA website (http://www.fda.gov.ph).

Disclaimer

This booklet is available for download at http://www.fda.gov.ph, free-of-charge. Produced for the purposes of information, this should not be taken as an exhaustive guide on Cosmetic Product Notification. It is highly recommended for the reader to refer to the FDA Issuances, and the ASEAN Cosmetic Directive, its Annexes, and its Appendices for further information. For updates on the implementation of the Cosmetic e-Notification, visit the FDA Philippines website.

References

Administrative Order No. 2005-0015
Administrative Order No. 2005-0025
Bureau Circular No. 2007-013-A
FDA Memorandum Circular No. 2013-011
FDA Memorandum Circular no. 2013-015
FDA Advisory No. 2015-021
FDA Memorandum Circular No. ____
FDA Memorandum Circular No. ____

Food and Drug Administration
Center for Cosmetics Regulation and Research
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa
http://www.fda.gov.ph

For inquiries/suggestions/comments,
contact the FDA-CCRR e-Notification Team at:
(02) 857 1984
info@fda.gov.ph

FDA E-PORTAL
COSMETIC E-NOTIFICATION

/gsg2Jul2015