



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2017-083

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TO : ALL COSMETIC MANUFACTURERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES

SUBJECT : Guide on the Proper Accomplishment of the Product Ingredient List Section of the Cosmetic Electronic Notification (e-Notification) Version 2.0

Pursuant to the issuance of Administrative Order (A.O.) No. 2005-0015 "Adoption of the Association of Southeast Asian Nation (ASEAN) Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents" and A.O. No. 2005-0025 "Implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents," the Food and Drug Administration (FDA), then called the Bureau of Food and Drugs (BFAD), has adopted and implemented the ASEAN Cosmetic Directive (ACD) in 2005 to eliminate technical barriers to trade of cosmetic products without compromising public health and safety. This has shifted the regulatory process from a pre-market approval to a post-marketing surveillance (PMS) system and has made way for the implementation of the cosmetic notification scheme.

In September 2015, FDA has implemented the cosmetic electronic notification (e-notification) version 2.0 through the issuance of FDA Memorandum Circular (FMC) No. 2015-011 "Guidelines for Electronic Notification of Cosmetic Products (Cosmetic E-Notification Version 2.0) using the FDA E-Portal" which aimed to further enhance the efficiency of the cosmetic notification application process and promote transparency of information.

Though the use of FDA e-Portal for cosmetic notification is new to the agency's stakeholders, the information required to be submitted are the ones that are found in the ASEAN cosmetic notification template previously used in the manual and first version of the cosmetic e-notification system. FMC No. 2015-011 provided for a number of reminders that must be followed to ensure that cosmetic notification applications lodged with FDA will not be disapproved. One of these reminders is that *"all ingredients must be specified 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."*

However, after assessing the efficiency of the cosmetic e-notification version 2.0 as well as the proficiency of stakeholders in using the new system, statistics show that 56.11% of the disapproved applications or 5.02% of the total applications received are disapproved due to errors/incompleteness of the full ingredient list required in the application of cosmetic notification.



In order to aid compliance of cosmetic stakeholders, FDA has developed an illustrative guide reiterating how to properly fill out and accomplish the product ingredient list section of the cosmetic notification template. The guide, as annexed, is made available in both English and Filipino versions and may be downloaded via the FDA website (www.fda.gov.ph).

For more information or inquiries on cosmetic e-notification, you may visit the FDA website, email us at aseannotation@fda.gov.ph or call us at (02)857-1984.

Dissemination of the information to all concerned is requested.


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REMINDERS

GUIDELINES ON FILLING UP THE INGREDIENT LIST

Cosmetic e-Notification System Version 2.0 thru FDA e-Portal



Variant 

 Leave blank if not applicable


* Full Ingredient Name 

Use INCI or approved nomenclature in standard references;
* Required field

Function 

Required for ingredients with restrictions and/or limitations as per the

Percentage (%) of Ingredient 

 ASEAN Cosmetic Ingredient Annexes III, VI & VII)

INDICATE THE FULL INGREDIENT LIST OF THE COSMETIC PRODUCT

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.

FUNCTIONS AND PERCENTAGES SHALL BE DECLARED FOR SUBSTANCES WITH RESTRICTIONS

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

ONE INGREDIENT PER ROW

To add new row, click **NEW**

To delete row, click **DELETE**

AFTER FILLING UP, CLICK NEXT TO GENERATE ORDER OF PAYMENT

MGA PAALALA

PARAAN NG PAGSAGOT NG "INGREDIENT LIST"

Cosmetic e-Notification System Version 2.0 gamit ang FDA e-Portal



Variant 

* Full Ingredient Name 

Function 

Percentage (%) of Ingredient 

Iwanang blangko kapag ang produkto ay walang "variant"

Gamitin ang pangalan ng kimika mula sa *INCI* o ibang *standard references*

Ang pulang simbolo na *asterisk (*)* ay nangangahulugang ang parteng ito ay dapat lagyan ng impormasyon.

Ang mga ito ay kailangang ibigay kung ang kimikang ginamit ay naturingang "restricted ingredient" at makikita sa *ASEAN Cosmetic Ingredient Annexes (ANNEXES III, VI at VII)*

ILAGAY ANG LAHAT NG MGA INGREDIENT NA GINAMIT SA PAGGAWA NG KOSMETIKO

Ang lahat ng *ingredient* o kimika ay dapat isulat/ibigay gamit ang mga pangalan nito na naaayon sa mga *standard reference* tulad ng *International Cosmetic Ingredient Dictionary*, *British Pharmacopoeia*, *United States Pharmacopoeia*, *Chemical Abstract Services*. Para sa mga *ingredient* na nagmula sa halaman, ilagay naman ang kanilang *scientific name* na binubuo ng *genus* at *species*. Halimbawa, para sa *papaya extract*, ang pangalang ilalagay ay *Carica papaya*.

ANG FUNCTION O GAMIT AT PERCENTAGES O DAMI NG "RESTRICTED INGREDIENTS" AY DAPAT IBIGAY

Ang *function* o gamit at *percentages* o dami ng kimika sa kabuuang produkto ay dapat ibigay kung ang mga ito ay *restricted ingredients* na matatagpuan sa *annexes* ng *ASEAN Cosmetic Directive*.

MAAARING MAGLAGAY LAMANG NG ISANG INGREDIENT KADA HANAY

PARA MAGDAGDAG NG PANIBAGONG HANAY, I-CLICK LAMANG ANG **NEW** ICON NA MATATAGPUAN SA BANDANG ITAAS NG **VARIANT**.

PARA NAMAN TANGGALIN ANG HANAY, I-CLICK LAMANG ANG **DELETE** ICON NA MATATAGPUAN SA DULO NG HANAY.

PAGKATAPOS ILAGAY ANG LAHAT NG MGA IMPORMASYONG HINIHINGI, I-CLICK ANG **NEXT** UPANG MAKAKUHA NG **ORDER OF PAYMENT**