FDA MEMORANDUM CIRCULAR
No. 2013-011

SUBJECT: ELECTRONIC COSMETIC PRODUCT NOTIFICATION (E-NOTIFICATION)

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. With this, the FDA Philippines will now implement electronic cosmetic product notification (e-notification) and hereby updates B.C. 2007-013A.

Procedure:

1) Send an e-mail containing the following to aseannotification@fda.gov.ph
   * Notifications shall be limited to ten (10) notifications per day per company.

   (Subject) Product name

   (Body of e-mail)
   Product Name:
   No. of Variants:
   Packaging Type/s (Primary Container) and Packaging Size/s:
   No. of Years Applied:
   Applicant Company:
   LTO:

   (Attachments) ACD_Form.pdf and Ingredient.csv

Guidelines in filling-up the ASEAN Notification Form (ACD_Form.pdf):

1. Fill in the necessary information in ALL CAPS, except for Trademark, Corporate De Facto (e.g. GmbH), and e-mail Address.
2. Tick the appropriate boxes under Sections 2. Product Type(s), 4. Product presentation(s), and 10. Product Ingredient List.
3. In filling-up the date under the Declaration, ensure to use the Calendar Button or follow the FDA Date Format, dd MMMM yyyy, (e.g. 03 March 2013).
4. DO NOT RENAME THE FORM, make sure that the form maintains its correct filename (ACD_Form.pdf)
5. DO NOT COMMIT ANY SPELLING MISTAKES. FDA will not be liable for this.
6. Make sure to input the appropriate e-mail address in the ASEAN Notification Form (ACD_Form.pdf). This e-mail address shall be the recipient of any replies sent during the e-notification process.
Guidelines in filling-up the Ingredient List Template (Ingredient.csv):

1. Fill in the necessary fields.
2. For multiple-variant products, make sure to indicate the variant in variant column in every row.
3. For the Restricted Ingredients, make sure to provide the function of that ingredient and its corresponding percentage.
4. For mixtures of ingredients, use the word “and” instead of a comma (,) and include its corresponding percentage enclosed with a parenthesis
   Example: METHYLCHLOROISOThIAZOLINONE (0.000575%) AND METHYLIISOThIAZOLINONE (0.000225%)
5. DO NOT RENAME THE TEMPLATE. Make sure that the template maintains its correct filename (Ingredient.csv), otherwise, your application will be rejected.
6. DO NOT COMMIT ANY SPELLING MISTAKES. FDA will not be liable for this.

* Forms can be downloaded from [http://www.fda.gov.ph/industry-corner/downloadables/197-asean-cosmetic-harmonization](http://www.fda.gov.ph/industry-corner/downloadables/197-asean-cosmetic-harmonization)

2) An automatically-generated e-mail shall be received by the applicant company (thru the authorized e-mail address) to indicate receipt of the application e-mail.

3) Wait for the reply containing the Assessment form. Replies containing the assessment form shall be sent electronically to the notification e-mails during working days, from Mondays to Fridays, 8:00AM to 3:00PM.

4) Pay the corresponding fee at any Landbank branch using the e-payment system (wait until further notice) or at the FDA Cashier. The assessment form shall be valid only for 5 working days after being sent.

5) After payment, send a scanned copy of the Official Receipt (OR) as a reply to the Assessment form e-mail. An automatically-generated e-mail shall be received by the applicant company to indicate receipt of the OR.

6) The reply containing either an acknowledged notification form or a letter of disapproval will be sent preferably after five (5) working days upon receipt of the scanned OR.

7) Upon receipt of the acknowledged notification, print and affix the company stamp and signature of the authorized person.

Reminders:
- Each applicant should strictly follow the instructions as stated above in the ASEAN Notification Template.
- One (1) notification application should be submitted for each product per manufacturer.
Components of kits/sets shall be notified individually. After the acknowledgement of the components, a letter informing the FDA shall be sent enumerating that the products are included in a kit/set.

During the transition period from 15 March until 15 April 2013, receiving of cosmetic notifications through e-notification shall be on Mondays to Thursdays only. CCRR shall continue to receive cosmetic notification applications filed manually every Friday only prior to full implementation.

Please be reminded that if there are changes in the product notification, the following will be handled as follows:

<table>
<thead>
<tr>
<th>Types of Change</th>
<th>Product Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand name</td>
<td>New</td>
</tr>
<tr>
<td>Company change due to change of distribution rights</td>
<td>New</td>
</tr>
<tr>
<td>Product types</td>
<td>New</td>
</tr>
<tr>
<td>Product presentation(single product, palettes in a range, etc)</td>
<td>Amendment</td>
</tr>
<tr>
<td>Intended use</td>
<td>New</td>
</tr>
<tr>
<td>Product name</td>
<td>New</td>
</tr>
<tr>
<td>Formulation</td>
<td>New</td>
</tr>
<tr>
<td>Manufacturer and or assembler (name and/or address)</td>
<td>New</td>
</tr>
<tr>
<td>Name and/or address of company without change of distribution rights</td>
<td>Amendment</td>
</tr>
<tr>
<td>Person representing company</td>
<td>Amendment</td>
</tr>
<tr>
<td>Pack sizes, packaging materials, labels.</td>
<td>Amendment, but not applicable if the information need not be submitted in Product Notification Form.</td>
</tr>
</tbody>
</table>

This Order shall take effect immediately.

KENNETH Y. HARTIGAN-GO, MD
Acting Director IV