



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City



21 January 2008

BUREAU CIRCULAR
No. 2007-013-A

SUBJECT: Amendment to Bureau Circular No. 2007-013 "Updated Guidelines for the Implementation of the Association of South East Asian Nation (ASEAN) Cosmetic Directive and the Association of South East Asian Nation (ASEAN) Common Technical Documents"

Bureau Circular No. 2007-013 dated 21 December 2007 was issued providing the "Updated Guidelines for the Implementation of the Association of South East Asian Nation (ASEAN) Cosmetic Directive and the Association of South East Asian Nation Common Technical Documents".

However, a review of the said Circular reveals potential issues that may be raised which can lead to confusion and thereby derail the effective implementation of Administrative Order No. 2005-0015, hence, this amendment. In so doing and for purposes of convenience, the full text of Bureau Circular No. 2007-013 is reproduced hereunder, the amendments or modifications are highlighted accordingly.

"In order to align national standards with the ASEAN Cosmetic Directive (ACD) as declared in Administrative Order No. 2005-0015 the following guidelines *and all its amendments* are hereby adopted.

I. **COSMETIC PRODUCT NOTIFICATION REQUIREMENTS**

The company or person responsible for placing the cosmetic products in the market shall notify BFAD of the place of the manufacture or of initial importation before the product is placed in the market.

MANDATORY REQUIREMENTS

1. The Documentary and Technical Requirements for Products for Notification

- a. Completed Revised Assessment Slip (Ref. BC 20 s. 2005: Subject Revised Assessment Slips).
- b. Completed ASEAN Notification Template.

An ASEAN Notification Template was developed to be used in all applications for cosmetic notification ***which shall be submitted / filed only once*** to facilitate compliance with the Guidelines. ***While the above template may be reproduced by applicant companies, the content thereof shall not be modified, otherwise, the notification shall be invalidated.***

- c. ***Official Receipt (OR) evidencing payment of the required fees pursuant to existing rules on fees.***
- d. Valid License to Operate of the applicant
 - i. For Manufacturers – List of Product Lines must be reflected
 - ii. For Traders – List of Toll Manufacturer/s and List of Product Lines must be reflected
 - iii. For Importer/Distributor – List of Product Source/s for imported cosmetic products, as well as, the Actual Manufacturer/s of the Product/s must be reflected
 - iv. For Wholesaler/Distributor – List of Product Source/s must be reflected

II. PROCEDURE

A. For New Products

1. Secure the proper forms either by downloading from the BFAD Website (<http://www.bfad.gov.ph>) or by photocopying the existing prototypes.
2. Completely fill up the necessary forms. Forms should be printed in an A4 size of paper.

3. Arrange the documents accordingly in a Clear Book Filler (size A4).
4. Application for notification shall be received, **as well as, follow-ups or inquiries entertained** from Tuesday to Friday of the week until March 2008 and every Thursday and Friday of the week thereafter.
5. Two (2) copies of Notification template in original form shall be submitted. One copy to be retained by BFAD should be placed in a clear sheet and the other copy will be returned to the applicant company after appropriate acknowledgment by BFAD. Applications shall be stamped as received upon submission by the applicant of the required documents, to acknowledge receipt thereof.

Notwithstanding the acknowledgement of receipt of the required documents, the BFAD reserves the right to further issue a letter/notice to the company in case of clarification or is **not precluded in determining and imposing remedial actions and legal penalties under the situation** when the cosmetic product subject of the application failed to conform to any of the existing standards or specifications set by the Bureau.

B. For Existing Products

1. Submit the original acknowledged Notification Template and a photocopy of the front page where the acknowledgement of receipt was stamped.
For issued Certificate of Product Registration (CPR) or Certificate of Product Listing (CPL), the original copy shall be submitted. The applicant shall submit a completed ASEAN Notification Template in two original copies.
All notified or approved cosmetic products which expired on 31 December 2007 shall be submitted on or before 31 March 2008, otherwise, the existing products shall be automatically classified as new, hence, the procedure in Part II-A shall be followed.
2. A letter informing BFAD on the specific criteria on the ASEAN Cosmetic Directive (ACD) in which the cosmetic product does not comply, if any.
3. Fill up the assessment slip identified above.
4. Application for notification of existing product shall be received **as well as, follow-ups or inquiries entertained** from Tuesday to Friday of the week until March 2008 and every Thursday and Friday of the week thereafter.

5. ***Upon submission of the official receipt evidencing payment of the required fees, the original copy of acknowledged Notification Template shall be stamped for additional validity in accordance with Part V below.***

For CPR/CPL, the Notification Template shall be acknowledged as evidence of receipt, the validity thereof shall also be in accordance with Part V below.

Notwithstanding the granting of additional validity of the Notification, the BFAD reserves the right to further issue a letter/notice to the company in case of clarification or is not precluded in determining and imposing remedial actions and legal penalties under the situation when the cosmetic product subject of the application failed to conform to any of the existing standards or specifications set by the Bureau.

III. NOTIFICATION LEADTIME

The notification shall be processed and completed preferably within a maximum of three (3) working days provided that the notification application complies with the requirements of this Bureau.

IV. ***GUIDELINES FOR THE CHANGES OF INFORMATION (s) IN THE PRODUCT NOTIFICATION OR CPR/CPL***

1. ***Change(s) in the Product Notification that require(s) mere letter-request and the necessary documents that affect the change(s)***

- a. Product Presentation (single product, palettes in a range, etc.)
- b. Name and/or address of company without change of distribution rights
- c. Authorize person representing the company
- d. Pack sizes, packaging materials and labels

The above change(s) shall require appropriate fees in accordance with existing rules on fees.

2. Change(s) that require(s) the submission of a new Product Notification and mandatory requirements specified in Part I above.

- a. Product name, brand name or variant name
- b. Company change due to change of distribution rights
- c. Product types
- d. Intended use
- e. Formulation
- f. Change or addition of claims
Manufacturer/s and assembler/s (name and address)

3. Existing valid CPR's/CPL's with change(s) in information mentioned in the two (2) preceding paragraphs (1 and 2) except, letter c of paragraph 1, shall require the submission of a new product notification and mandatory requirements.

V. NOTIFICATION VALIDITY

For initial submissions, covering new products, the notification shall be valid for a period of one (1) to three (3) years maximum at the option of the applicant.

Those products with CPR/CPL or products with issued notification for the year 2007 shall be granted an additional validity based on the date of application for the year 2007.

Those applications or notifications submitted prior to the year 2007 shall have one year validity.

VI. Updates on the ASEAN Cosmetic Directive (ACD)

Appendix I ASEAN Illustrative List	September 2007
Appendix II ASEAN Labeling Requirement	December 2006
Appendix III ASEAN Claim Guideline	June 2007
ASEAN Cosmetic Directive Guidelines for Product Information File (PIF)	June 2007
ASEAN Guidelines for the Safety Assessment of a Cosmetic Product	December 2006
ASEAN Microbial Limit	June 2007
Updated Annexes of Ingredients	June to September 2007

Company/s or person/s responsible for placing the cosmetic product/s in the market are responsible for continually checking any updates and amendments to the ACD for proper guidance and compliance through the following websites:

www.bfad.gov.ph (under ASEAN Cosmetic Harmonization)

www.aseancosmetic.org

www.asean.org

VII. EFFECTIVITY

This order issued shall take effect immediately.


Prof. LETICIA BARBARA B. GUTIERREZ, M.S.
Director