



Republic of the Philippines
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS

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03 January 2006

BUREAU CIRCULAR

No. 2006 - 001

TO: ALL COSMETICS ESTABLISHMENTS

SUBJECT: Updated Guidelines for the Submission of Application for Notification, Registration and Export of Cosmetic Products

To effectively and efficiently execute Administrative Order 2005-0025, subject of which is the Implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme and ASEAN Technical Documents, all applicants are directed to comply with the new requirements and procedures related to the receiving and processing of application for notification and registration as follows:

I. REQUIREMENTS

(Ref.: AO 2005-0025 Subject: Implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme and ASEAN Technical Documents)

A. Products for Notification

1. Documentary Requirements

- a. Forms to be accomplished correctly and completely
 - Revised Assessment Slip (Ref.: BC 20 s. 2005 Subject: Revised Assessment Slips)
 - Notarized Cosmetic Product Notification Form and Declaration (Annex A)
 - PART I ONLY of the BFAD Worksheet
- b. Attachments
 - Copy of Valid License to Operate

2. Technical Requirements

- Test for Heavy Metals done on the finished product (Ref.: BC 17 s. 2005 Subject: Update of Accepted Whitening Agents for Cosmetics)

- Unattached and readable specimen of all labeling materials per pack size [e.g. outer, immediate, package insert (if applicable)]
- Specimen of the finished commercial product (One specimen to represent the pack sizes) or digital picture/s (at least 5 x 5½ in size) of these samples showing the container and actual content of the product/s.

B. Products for Notification under the ASEAN Mutual Recognition Agreement (for products registered in ASEAN Countries with existing MRA with the Philippines)

1. Documentary Requirements

- a. Forms to be accomplished correctly and completely
 - Revised Assessment Slip (Ref.: BC 20 s. 2005 Subject: Revised Assessment Slips)
 - Notarized Mutual Recognition Agreement (MRA)
 - PART I ONLY of the BFAD Worksheet
- b. Attachments
 - Copy of Valid License to Operate
 - Certified True Copy or Original Certificate of Product Registration (for MRA)

2. Technical Requirements

- Test for Heavy Metals done on the finished product (Ref.: BC 17 s. 2005 Subject: Update of Accepted Whitening Agents for Cosmetics)
- Unattached and readable specimen of all labeling materials per pack size [e.g. outer, immediate, package insert (if applicable)]
- Specimen of the finished commercial product (One specimen to represent the pack sizes) or digital picture/s (at least 5 x 5½ in size) of these samples showing the container and actual content of the product/s.

C. Products for Cosmetic Regular Registration
(For products which do not fall under A or B)

1. Documentary Requirements

- a. Forms to be accomplished correctly and completely
 - Revised Assessment Slip (Ref.: BC 20 s. 2005 Subject: Revised Assessment Slips)
 - Notarized Information Sheet and Declaration
 - PART I ONLY of BFAD Worksheet
- b. Attachments
 - Copy of Valid License to Operate
 - Any of the following legalized documents shall be submitted for Imported Cosmetic Products:

- ii. Certificate of Free Sale and License to Operate / Manufacture
- iii. Certificate of Free Sale and Certificate of Good Manufacturing Practice
- iv. Certificate of Origin
- v. Certificate issued by the Board of Health or competent authority (For details refer to AO 2005-0025 Subject: Implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents)

2. Technical Requirements

a. Composition

- Qualitative composition of the product with INCI nomenclature of ingredients or any approved nomenclature as given in any standard reference that may be approved from time to time
- Quantitative composition is required for substances with restrictions for use
- The master formula of the product shall be made available to the cosmetic regulatory agency when requested or required.

b. Finished Product Description:

- Finished Product Specifications
- Test for Heavy Metals done on the finished product (Ref.: BC 17 s. 2005 Subject : Update of Accepted Whitening Agents for Cosmetics)
- Test Methods (when requested or necessary)

c. Unattached and readable specimen of all labeling materials per pack size [e.g. outer, immediate, package insert (if applicable)]

d. Specimen of the finished commercial product (One specimen to represent the pack sizes) or digital picture/s (at least 5 x 5½ in size) of these samples showing the container and actual content of the product/s.

e. Attestation to support special product claims (Ref.: BC No. 5 s. 2005 Subject: Consolidation and Update of Permissible Cosmetic Claims)

D. Products for Export only shall be subject to the same regulations as locally marketed cosmetics as stipulated in AO 2005-0025.

II. PROCEDURE

1. Secure the proper forms either by downloading from the BFAD website (http://www.bfad.gov.ph/Asean_Cosmetics_Harmonization.htm) or by photocopying the existing prototypes.
2. Completely fill up the necessary forms.

3. To facilitate the processing of the Certificates of Notification, make sure to download and fill up an electronic copy of the cosmetic product notification template in MS Excel format, also accessible through the BFAD website
(http://www.bfad.gov.ph/Asean_Cosmetics_Harmonization.htm)
4. Arrange the documents according to the checklist of requirements in an expandable color-guided long folder, using the following legend:

Green	:	Notification
Orange	:	MRA
Yellow	:	Regular Registration
Blue	:	Export

In arranging the documents, put identifying markers/separators in between sections, indicating the type of document/s as per registration requirements.
5. Together with the documentary and technical requirements, submit either: a) a set of representative sample/s in commercial presentation that shall be placed in a resealable plastic container/s, or b) digital picture/s (at least 5 x 5½ in size) of these samples showing the container and actual content of the product/s.
6. Application for notification and registration shall only be received every Thursday of the week. (Ref.: BC 21 s. 2005 Subject: Cut-Off Time for the Receiving of Payments of Fees in BFAD)

This Bureau Circular shall take effect immediately.


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