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

18 December 2006

BUREAU CIRCULAR
No. 2006 - 017

SUBJECT: Amendment to Bureau Circular 2006-001 "Updated Guidelines for the Submission of Application for Notification, Registration and Export of Cosmetic Products"

For the effective implementation of A.O. No. 2005-0025 (Subject: Implementation of the ASEAN Harmonized Cosmetic Regulatory Scheme and ASEAN Common Technical Documents), BC No. 2006-001 is hereby amended as follows:

I. REQUIREMENTS

A. The Documentary and Technical Requirements for Products for Notification are hereby amended as follows:

1. Documentary Requirements

a. Forms to be accomplished correctly and completely

- Revised Assessment Slip (Ref. BC 20 s. 2005: Subject Revised Assessment Slips).
- **Two (2) copies of the Notarized Cosmetic Product Notification Form and Declaration using the revised form (Annex A hereof).**
- PART I ONLY of the BFAD Worksheet.

b. Attachments

- Copy of Valid License to Operate

► **For Manufacturers – With reflected or attached List of Cosmetic Trader/s and List of Product Lines.**

► **For Traders – With reflected or attached List of Toll Manufacturer and List of Product Lines.**
► **For Importer/Distributor – With reflected or attached List of Product Source of imported cosmetic products as well as actual manufacturer of the product.**
► **For Wholesaler/Distributor – With reflected or attached List of Product Source.**

2. Technical Requirements

- Test for Heavy Metals done on the finished products **(Ref: BC No. 13 s. 2006, Subject: Amendment to Bureau Circular No. 17 s. 2005)**
- **Two (2) copies of unattached specimen of all labeling materials [outer, immediate, package insert (if applicable)] in commercial presentation which shall be legible, comprehensible and indelible.**
- **Two (2) copies of unattached Facsimile of the labeling materials complying with the ASEAN Labeling Requirements contained in the ASEAN Harmonized Regulatory Scheme (For products with non-complying labels with ASEAN), which shall be legible, comprehensible and indelible.**
- Specimen of the finished commercial product (One specimen to represent the pack size) or digital picture/s (at least 5 x 51/4 in size) of these samples showing the container and actual content of the product/s.

B. **Paragraph B of BC No. 2006-001 (Products for Notification under the ASEAN MRA) is hereby deleted.**

C. The Documentary and Technical Requirements for Cosmetic Products for Regular Registration is hereby amended as follows:

1. Documentary Requirements

a. The forms required in BC No. 2006-001 **remain effective**.

b. Attachments

- Copy of Valid License to Operate

► **For Manufacturers – With reflected or attached List (as approved by BFAD) of Cosmetic Trader/s and List of Product Lines.**

► **For Traders – With reflected or attached List (as approved by BFAD) of Toll Manufacturer and List of Product Lines.**

► **For Importer/Distributor – With reflected or attached List (as approved by BFAD) of Product Source of imported cosmetic products as well as actual manufacturer of the product.**

► **For Wholesaler/Distributor – With reflected or attached List (as approved by BFAD) of Product Source.**

- The legalized documents required to be submitted for imported cosmetic products in BC No. 2006-001 **remain effective**.

2. Technical Requirements

a. The requirements as to Composition in BC No. 2006-001 **remain effective**.

b. Finished Product Description
► Finished Product Specification
► Test for Heavy Metals done on the finished products **(Ref: BC No. 13 s. 2006, Subject: Amendment to Bureau Circular No. 17 s. 2005)**
► Test Methods (when requested or necessary)

c. ● **Unattached specimen of all labeling materials [outer, immediate, package insert (if applicable)] in commercial presentation which shall be legible, comprehensible and indelible.**

● **Unattached Facsimile of the labeling materials complying with the ASEAN Labeling Requirements contained in the ASEAN Harmonized Regulatory Scheme (For products with non-complying labels with ASEAN), which shall be legible, comprehensible and indelible.**

d. Specimen of the finished commercial product (One specimen to represent the pack size) or digital picture/s (at least 5 x 51/4 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 applicable to locally marketed cosmetics as stipulated in A.O. 2005-0025.

II. PROCEDURE

The Procedure laid down in BC No. 2006-001 is hereby amended as follows:

1. Paragraphs 1 and 2 of BC No. 2006-001 **remain effective**.

2. Paragraph 3 of BC No. 2006-001 is **deleted**.

3. Arrange the documents according to the checklist of requirements in an expandable color-guided long folder using the following legend:

   Green : Notification
   Yellow : Regular Registration
   Blue : Export

   In arranging the documents, put identifying markers/separators in between sections, indicating the type of documents as per application requirements.

4. Paragraphs 4 and 5 of BC No. 2006-001 **remain effective**.

5. **For Product Notification Applications, the BFAD shall stamp as received the Revised Cosmetic Product Notification Form (Annex A), upon submission by the applicant of the required documents, to acknowledge receipt thereof instead of issuing a Certification. 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 when the cosmetic product subject of the application failed to conform to any of the existing standards or specifications set by the Bureau.**

Items III and IV are hereby added to BC NO. 2006-001, to read as follows:

III. CHANGES IN THE PRODUCT NOTIFICATION FORM

To align with the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS) the following rules shall apply to any changes on the particulars as reflected in the initial product notification form.

a. Types of changes for Product Notification that require letter of request and the necessary documents that affect the change(s)

1. **Product Presentation (single product, palettes in a range, etc.)**
2. **Name and/or address of company without change of distribution rights**
3. **Person representing the company**
4. **Pack sizes, packaging materials and labels**

b. Types of changes that require new product notification in accordance with A.O. 2005-0025

1. **Product name, brand name or variant name**
2. **Company change due to change of distribution rights**
3. **Product types**
4. **Intended use**
5. **Change or addition of claims**
6. **Formulation**
7. **Manufacturer and/or assembler (name and/or address)**

IV. CHANGES IN THE CERTIFICATE OF PRODUCT REGISTRATION

The following changes shall require an amendment of Certificate of Product Registration (CPR) following the list of requirements listed in PSD-CSA-03 (Worksheet for Amendment).

1. **Change in Manufacturing site**
2. **Change of Manufacturer**
3. **Change of Packer/Repacker**

The following changes shall require re-issuance of new CPR

1. **Change in product name, brand name or variant name**
2. **Change in Business name and/or address of company**
3. **Change in ownership**

Requests for Amendments and re-issuance of new CPR will be submitted and received at the Public Assistance, Information and Compliance Section (PAICS) during Thursdays only.

This Circular shall take effect on 01 January 2007.

PROF. LETICIA BARBARA B. GUTIERREZ, MS
Director

- o Hair care products
  - products for waving, straightening and fixing
  - setting products,
  - cleansing products (lotions, powders, shampoos),
  - conditioning products (lotions, creams, oils),
  - hairdressing products (lotions, lacquers, brilliantine's)
  - Antidandruff products with active(s) already known in the market (e.g. ZPT, Climbazole, Piroctone Olamine, etc.)
- o Shaving product (creams, foams, lotions, etc.)
- o Products for making-up and removing make-up from the face and the eyes
- o Products intended for application to the lips
- o Products for care of the teeth and the mouth ***without fluoride***
- o Products for nail care and make-up
- o Products containing SPF $\leq$ 15
- o Products for tanning without sun
- o Skin whitening products listed within **B.C. 13 s. 2006**
- o Anti-wrinkle/Anti-ageing products (with reference to visible skin appearance)
- o Baby Wipes
- o Contouring/Firming (without reference to weight loss)
- o Cellulite product (without reference to weight loss)
- o Product that helps prevent stretchmark
- o Hand Sanitizing product and product with 40%-69% content of alcohol
- o Product for the management of acne-prone skin (containing salicylic acid)
- o Others (please specify)

_____

3. Intended use

_____

_____

4. Pack size(s)

_____

_____

_____

5. Product presentation(s)

- o Single product
- o A range of product variants similar in composition for the same use but differs in colours, flavours etc.
- o Palette(s) in a range of one product type
- o Combination products in a single kit
- o Others (please specify) _____

PARTICULARS OF MANUFACTURER/ASSEMBLER

[Please attach in a separate sheet if there are more than one manufacturer/assembler]

6. Name of manufacturer:

Address of manufacturer (state country):

Country

Tel**:** Fax**:**

7. Name of assembler (Please tick accordingly. May tick more than one box):

□ Primary assembler □ secondary assembler

A manufacturer is a company which is engaged in any process carried out in the course of making the cosmetic product. The manufacturing process includes all operations of purchase of starting materials, bulk intermediates and products, formulation and production (such as grinding, mixing, encapsulation and/or packaging), quality control, release, storage and distribution of cosmetic products and the related controls.

A primary assembler is a company which is engaged in a process of enclosing the product in a primary/immediate container which is labeled or to be labeled before the product is sold or supplied in it.

A secondary assembler is a company which is engaged only in a process of labeling the product container where the product is already enclosed in its primary container and/or packing the product which is already enclosed in its labeled primary container into a carton which is labeled or to be labeled, before the product is sold or supplied.

Address of assembler (state country):

Country

Tel**:** Fax**:**

PARTICULARS OF COMPANY (importer, distributor, local manufacturer, etc) responsible for placing the cosmetic product in the market

8. Name of company:

Address of company:

Tel**:** Fax**:**

Business Registration Number/License to Operate Number (submit a copy of the License to Operate Certificate):

PARTICULARS OF PERSON REPRESENTING THE LOCAL COMPANY

9. Name of person:

Residential address:

Tel**:** Email:

Designation in the company:

PRODUCT INGREDIENT LIST

10. Please check the following boxes

- o **I have examined the latest revisions of the Annexes II to VII of the ASEAN Cosmetic Ingredient Listing as published in the latest amendment of the ASEANs Cosmetic Directive and confirmed that the product in this notification does not contain any prohibited substances and is in compliance with the restrictions and conditions stipulated in the Annexes.**

- o **I undertake to respond to and cooperate fully with the regulatory authority with regard to any subsequent post-marketing activity initiated by the authority.**

- o **I have examined and informed the Bureau on the non-conformance of my product on the restrictions and conditions stipulated in the Annexes IV – Colorant, VI- Preservatives and VII – UV Filters of the ASEAN Cosmetic Directive be allowed to use until such time that full implementation of the directive is adopted.**

(Please indicate the full ingredient listing, functions and percentage of restricted ingredients in the annexes of the ASEAN Cosmetic Directive, if present)

No	Full Ingredient name (use INCI or approved nomenclature in standard references)		
		Percentage (%) of Restricted Ingredients	**Functions**
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			

12			
13			
14			
15			
16			
17			
18			
19			
20			

11. Attach a copy of the product label

DECLARATION

1. I hereby declare on behalf of my company that the product in the notification meets all the requirements of the ASEAN Cosmetic Directive, its Annexes and Appendices which have been transposed into the local legislation, including the following:

   - absence of substances prohibited in cosmetic products
   - compliance with the warning labels and concentration limits of restricted substances
   - absence of non-permissible claims
   - compliance to claims under B.C. 5 s. 2004 and its amendment supported by a technical justification or clinical studies to substantiate label claims.
   - Product/s intended for Local and Export Use.

2. I undertake to abide by the following conditions:
   i. Ensure that the product's technical and safety information is made readily available to the regulatory authority concerned ("the Authority") and to keep records of the distribution of the products for product recall purposes;
   ii. Notify the Authority of fatal or life threatening serious adverse event[1] as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 7 calendar days after first knowledge;
   iii. Complete the Adverse Cosmetic Event Report Form[2] within 8 calendar days from the date of my notification to the Authority in para 2ii. above, and to provide any other information as may be requested by the Authority;
   iv. Report to the Authority of all other serious adverse events that are not fatal or life threatening as soon as possible, and in any case, no later than 15 calendar days after first knowledge, using the Adverse Cosmetic Event Report Form;
   v. Notify the Authority of any change in the particulars submitted in this notification;

[1] As defined in the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products
[2] Set out in Appendix I to the Guide Manual for the Industry on Adverse Event Reporting of Cosmetics Products

3. I declare that the particulars given in this notification are true, all data, and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies.

4. I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.

5. I understand that I cannot place reliance on the acceptance of my product notification by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

6. I acknowledge and agree to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from the notification of cosmetic products concerned

_____

[Printed Name and Signature of person responsible for placing the product in the market] [Date]

[Company stamp]

_____

[Printed Name and Signature of person responsible for submitting the application on behalf of the company] [Date]

PROF. LETICIA BARBARA B. GUTIERREZ, M.S.
Director
Bureau of Food and Drugs
Alabang, Muntinlupa City

Attention: PRODUCT SERVICES DIVISION
Cosmetic Section

Dear Prof. Gutierrez:

In accordance with R.A. 3720, A.O. 2005-0015 and other related issuances, we wish to apply for the **registration** of our product identified below:

Name of Product	
Brand name	
Variant/s	
Product description / use	
Methods of administration (Direction for use)	
Precautions to be observed during use of product	
Declaration of shelf life (for all products)	
Method of decoding batch reference	
Pack sizes available	
Name and address of the product owner, manufacturer, or assembler	

Along with this application are the documents listed in the Checklist of Requirements for Registration and representative samples of our product/s.

We categorically declare that:

1. The data and information submitted in connection with this application are complete, true and correct.
2. The products does not contain non-permissible ingredients or prohibited substances
3. Restricted substances, if any, are within the content limit.
4. We acknowledge and agree to indemnify and/or hold BFAD free and harmless against any and all third party claims arising from the registration of the cosmetic product concerned.

DATE OF SUBMISSION:

NAME AND ADDRESS OF APPLICANT:
COMPANY REPRESENTATIVE:
POSITION:
SIGNATURE:

This form covers only the requirements under paragraph, 1.2.4 and 1.2.5, Section IV of A.O. 2005-0025 and should be notarized
Pursuant to paragraph 1.1.1 of the same section.

BUREAU OF FOOD AND DRUGS
PRODUCT SERVICES DIVISION – COSMETIC SECTION
BFAD Worksheet

BFAD USE ONLY

RSN / CN: _____
CR / ECR: _____
OR Number: _____
Amount: _____
Date Received: _____

PART I (Client Use only)

☐ Registration ☐ Notification ☐ Export

Brand Name: _____

Product Name: _____

Variant/s: _____

Manufacturer/ Repacker: _____

Source: _____

Importer / Distributor/ Trader: _____

PART II (BFAD Use)

I. Pre-Assessment

A.

	Received	Remarks
Administrative Documents		
1. Revised Assessment slip		
2. Information Sheet and Notarized Company's Declaration		
3. Revised Notarized Cosmetic Product **Notification Form** and Declaration		
4. PSDCos Form (Part I only)		
5. Copy of Valid License to Operate		
6. For Imported Cosmetics Products Only		
a. CFS and License to Operate or Manufacture		
b. CFS and CGMP		
c. Certificate of Origin		
d. Certificate issued by the Board of Health or competent authority.		
Technical Information		
7. Formulation		
a. Qualitative composition		
b. Quantitative composition for substances with restrictions for use		
d. Master formula (as requested)		
8. Finished Product Description		
a. Finished Product Specifications		
b. Test results for Heavy Metals done on the finished product		
c. Test Methods (as requested)		
9. Labeling Materials		
10. Specimen of the finished commercial product (or Digital picture)		
11. Attestation to support special product claims…		

Assessed By/ date:

II. Referral to the Advisory Committee for BFAD Claims for your consideration:	Referred by/ date:
III. Recommendation of the Advisory Committee for BFAD	Recommended by/ date:
IV. Final Evaluation (RECOMMENDATION) □ Approval □ Denial	Evaluated by/ date:

APPLICATION REQUIREMENTS

Products for Cosmetic Notification

1. Documentary Requirements

   1.1 Forms to be accomplished correctly and completely

   - θ Revised Assessment Slip (Ref: BC 20 s. 2005 Subject: Revised Assessment Slips) (PAICS copy and Accounting's copy)
   - θ **2 Notarized copies of the Revised Cosmetic Product Notification Form and Declaration (Annex A)**
   - θ BFAD Worksheet: PART I ONLY

   1.2 Attachments

   - θ Copy of Valid License to Operate
     - For Manufacturers – List of Cosmetic trader/s and List of Product Lines must be reflected.
     - For Traders – List of Toll Manufacturer and List of Product Lines must be reflected.
     - For Importer/Distributor – List of Product Source for Imported Cosmetic products as well as the Actual Manufacturer must be reflected
     - For Wholesaler/Distributor – List of Product Source must be reflected

2. Technical Requirements

   - θ Test results for Heavy Metals (Pb,As,Hg,Cd) done on the finished product **(Ref.: B.C. 13 s. 2006 Subject: (Amendment to B.C. 17 s. 2005: Further Updating the Accepted Whitening Agents for Cosmetics)**
   - θ **2 copies of unattached specimen of all labeling materials in commercial presentation [e.g. outer, immediate, package insert (if applicable)] shall be legible, comprehensible and indelible.**
   - θ **Establishments whose products with commercial labels not complying with the ASEAN Labeling Requirements shall submit 2 copies of unattached and legible facsimile of proposed compliant labeling materials.**
   - θ 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 actual container and content of the product/s.

APPLICATION REQUIREMENTS

Products for Cosmetic Registration

1. Documentary Requirements

1.1 Forms to be accomplished correctly and completely

- θ Revised Assessment Slip (Ref: BC 20 s. 2005 Subject: Revised Assessment Slips) (PAICS copy and Accounting's copy)
- θ Notarized Declaration and Information Sheet containing the following:
  - Product description/ use
  - Methods of administration (Direction for use)
  - Precautions to be observed during use of product
  - Declaration of shelf-life (for all products)
  - Method of decoding batch reference
  - Pack sizes available
  - Name and address of the product owner, manufacturer, or assembler

- θ BFAD Worksheet: PART I ONLY

1.2 Attachments

- θ Copy of Valid License to Operate of the applicant

  - For Manufacturers – List of Cosmetic Trader/s and List of Product Lines must be reflected.
  - For Traders – List of Toll Manufacturer and List of Product Lines must be reflected.
  - For Importer/Distributor – List of Product Source for Imported Cosmetic products as well as the Actual Manufacturer must be reflected
  - For Wholesaler/Distributor – List of Product Source must be reflected

- θ Any of the following legalized/Authenticated documents shall be submitted for Imported Cosmetic Products:
  - Certificate of Free Sale and License to Operate / Manufacture
  - Certificate of Free Sale and Certificate of Good Manufacturing Practice
  - Certificate of Origin
  - 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)

- θ The License to Operate/Manufacture or Certificate of Origin shall indicate that the manufacturing plant meets the national requirements in terms of hygiene, safety and quality

- θ In the event that there is no issuing regulatory agency in all cases, the documents may be issued by recognized associations. Qualification of these associations rests with the industry or any country agency and a list shall be made available to all ASEAN Member Countries.

2. Technical Requirements

2.1 Composition

- θ 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
- θ Quantitative composition is required for substances with restrictions for use
- θ The master formula of the product shall be made available to the cosmetic regulatory agency when requested or required.

2.2 Finished Product Description:

- θ Finished Product Specifications
- θ Test results for Heavy Metals (Pb,As,Hg,Cd) done on the finished product **(Ref.: B.C. 13 s. 2006 Subject: (Amendment to B.C. 17 s. 2005: Further Updating the Accepted Whitening Agents for Cosmetics)**
- θ Test Methods (when requested or necessary)

2.3 Attestation to support special product claims. Attestation should contain the following information:

- θ Name, position and specialization of investigator/s performing the test/study
- θ Curriculum vitae and/or proof that the investigator/s is/are Board Certified Specialist shall be made available to the cosmetic regulatory agency
- θ Name and address of the establishment conducting the test/study
- θ Result/s and conclusion
- θ Summary of test report including protocol, as necessary

3. **Unattached specimen of all labeling materials [e.g. outer, immediate, package insert (if applicable)] shall be legible, comprehensible and indelible.**

4. **Establishments whose products with labels not complying with the ASEAN Labeling Requirements shall submit unattached and legible facsimile of proposed compliant labeling materials.**

5. Specimen of the finished commercial product (One specimen to represent that pack sizes) or digital picture/s (at least $5x5^{1/2}$ in size) of these samples showing the actual container and content of the product/s.