(February 2009)

A Guideline on

Notification of Cosmetic Product

Application

THE UNION OF MYANMAR

Ministry of Health

Departing Drug Administration

35, Min Kyaung Street, Dagon Township, Yangon, Myanmar,

(Phone. 95-1-245330, 245332)

Initiation application for Notification of Cosmetic Products

1. The company or person responsible for placing the cosmetic product in the market shall notify the Department of Health Food and Drug Administration in the original prescribed Notification form.

2. A single notification can be made for a range of cosmetic products or a palette of colours. However, the percentage of restricted substance will have to be declared for each colour in the range or palette. The application will have to file a new notification for colours added to an existing range or palette that are not included in the initial notification.

3. Form must be filled out in type print.

4. Enclosures submitted together with application form shall be marked with proper reference. A form which is filled incompletely or improperly will not be accepted.

5. Documents have to be submitted in file in an order as listed in "Documents Required for Notification of Cosmetic Product".

6. An application with incomplete documentation will not be accepted.

7. An application must be submitted in person by an authorized representative of owner of cosmetic products.

8. The submitted dossiers are not reclaimable in case of rejection of application for notification.

9. The validity of the cosmetic notification shall be (2) years commencing from the date of issuance of acknowledgement.

Updating Changes to Notified Cosmetic Products

1. Updating changes to notified cosmetic products shall be made only with the approval of Food and Drug Administration.

2. For this purpose, the holder of acknowledgement of receipt of cosmetic notification shall apply for Variation of Notification; to FDA, stating reason for change.

3. A photo copy of the acknowledgement of receipt of cosmetic notification shall be submitted together with the application.

Renewal of Cosmetic Notification

1. Application for renewal of notification shall be submitted 1 month before the validity of the notification terminates.

2. Application shall be submitted in the same manner as prescribed for application for notification of cosmetic products.

3. The documentary requirements are the same as that of an initial application. Information provided, however, has to be updated.

4. Failure to apply for renewal of notification shall result in invalidation of notification with effect from the date of expiry of the certificate.

Type of documents required for notification of cosmetic

Products

1. For importers/distributors

a). A copy of authorization letter from the product owner or manufacturer.

b) A copy of business license of the local company or certificate of incorporation.

c). Acknowledgement of cosmetic notification from the country of origin.

d). Full ingredient listing and the percentage of restricted ingredients.

e). Complete original label one set (outer and immediate packaging).

2. For manufacturers

a). A copy of business license of the manufacturer.

b). A copy of private industrial registration certificate.

c). A photo copy of cosmetic manufacturing license.

d). Full ingredient listing and the percentage of restricted ingredients.

e). Complete original label one set (outer and immediate packaging).

Labeling requirements of cosmetic products

1. The following particulars shall appear on the outer packing of cosmetic products or, where is no outer packaging, on the immediate packaging of cosmetic products.

a) The name of the cosmetic products and its function, unless it is clear from the presentation of the product.

b) Instructions on the use of the cosmetic products, unless it is clear from the product name or presentation.

c) Full ingredient listing with percentages of restricted ingredients.

d) Country of manufacture.

e) The name and address of the company or person responsible for placing the product on the local market.

f) The contents given by weight or volume, in either metric or both in matric and imperial system.

g) The manufacturer's batch number.

h) The manufacturing date or expiry date of the product.

i) Special precautions to be observed in use.

2. The particulars listed above shall appear in English and/ or National Language understood by the consumer where the product is marketed.

Product information files (PIF)

1. The company or person responsible for placing the cosmetic product in the market shall keep the following information readily accessible to the FDA.

a) Copy of the Notification form & the original acknowledgement receipt from FDA.

b) Authorization letter by product owner or agreement letter related to the product.

c) License to operate & certificate of incorporation of the local company.

d) The quantitative composition of the product; in case of perfume compositions, the name and code of the indentify of the supplier.

e) A statement of quality and functions of each raw material/ ingredient.

f) Specifications of the raw materials including water and finished product.

g) The available methods used by the manufacture to check the ingredients of cosmetic products corresponding with the Certificate of Analysis.

h) The criteria used for microbiological control of cosmetic products and chemical purity of ingredients of cosmetic products and/ or methods for checking compliance with those criteria.

i) Quality control procedure on product, label and packaging.

j) The stability testing data and report or stability assessment to support the expiry date.

k) The method of manufacture complying with the ASEAN Guidelines For Cosmetic Good Manu fracturing Practice of GMP Certificate from the country of origin.

l) Assessment of the safety for human health of the finished product, its ingredients, its chemical structure and its level of exposure. (Signed statement of opinion, including the name and qualifications of the safety assessor)

m) Existing data on undesirable effects on human health resulting from use of the cosmetic product.

n) Supporting data for claimed benefits of cosmetic products, based on its composition or on testes performed.

o) Records of the distribution of the cosmetic products for product recall purposes in case.

2. The above product information file must be available in English and/ or national language.