FDA/MCH/CHC/AP-RCO/2016/02



**FOOD AND DRUGS AUTHORITY**

**APPLICATION FORM FOR THE REGISTRATION OF**

**COSMETICS**

**Document No:** FDA/MCH/CHC/AP-RCO/2016/02

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**Version No.:** CO.02

 **APPLICATION FORM FOR THE REGISTRATION OF**

 **COSMETICS**

**APPLICANTS**  **FDA DOUBLE**

**CHECKLIST CHECKLIST**

Signed Declaration

 Covering Letter

 Certificate of Analysis of Finished Product

 Manufacturing License

h

* **Any relevant documentation or reference material which will aid in the registration process should be attached**

 **APPLICATION FORM FOR THE REGISTRATION OF**

 **COSMETIC PRODUCT**

(*TO BE SUBMITTED IN ONE HARD COPY, ONE SOFT COPY*)

**A. COVER LETTER**

ADDRESSED TO: **THE CHIEF EXECUTIVE OFFICER**

 **FOOD AND DRUGS AUTHORITY**

 **P.O.BOX CT 2783**

 **CANTONMENTS-ACCRA**

 **GHANA**

**Samples and printed matter to be forwarded by post or by other means and carriages; customs duty and clearance to be effected by the applicant in all instances.**

**B. PRODUCT INFORMATION**

Name of Cosmetic Product: ……………………………………………………………………………………………

………………………………………………………………………………………………………………………………………..

Formulation Type: ……………………………………………………………………………………………………………

Physical Description of Cosmetic Product: …………………………………………………………………………

Intended Use: …………………………………………………………………………………………………………………

Size s): …………………….…………………………………………………………………………………………………….

Variant(s) of the Cosmetic Product: …………………………………………………………………………………….

**C. DETAILS OF APPLICANT**

Name of Applying Company/ License Holder: ……………………………………………………………………….

………………………………………………………………………………………………………………………………………

Postal/Business Address: ……………………………………………………………………………………………………

…………………………………………………………………………………………………………………………………….

Tel No: …………………………………………………………………………………………………………………………

Fax: ………………………………………………………………………………………………………………………………

Email: …………………………………………………………………………………………………………………………….

Website…………………………………………………………………………………………………………………….

**D. DETAILS OF MANUFACTURER**

Name of Manufacturing Company: …………………………………………………………………………………

Postal/Business Address: …………………………………………………………………………………………....

……………………………………………………………………………………………………………………………………

Manufacturing Site/Location Address: …………………………………………………………………………………

……………………………………………………………………………………………………………………………………….

Tel No: …………………………………………………………………………………………………………………………

Fax: ………………………………………………………………………………………………………………………………

Email: ………………………………………………………………………………………………………………………………

Website: ……………………………………………………………………………………………………………………….

**E. DETAILS OF LOCAL AGENT**

Name of Company: ……………………………………………………………………………………………………….

……………………………………………………………………………………………………………………………………

Postal/Business Address:………………………………………………………………………………………………

………………………………………………………………………………………………………………………………….

Tel No: ……………………………………………………………………………………………………………………….

Email: …………………………………………………………………………………………………………………………

Website: …………………………………………………………………………………………………………….

Contact Person: .............................................................................................................

Tel. No: ........................................................................................................................

**F. DECLARATION**

I/We the undersigned, hereby declare that all the information contained herein and in the appendices is correct and true:

Name:……………………………………………………………………………………………………………………………

Position in Company:……………………………………………………………………………………………………….

Signature:………………………………………………………………………………………………………………………

Date:……………………………………………………………………………………………………………………………….

Official Stamp of Company:

…………………………………………………………………………………………………………………………………………

***(Declaration should be signed, stamped & dated by the Applicant)***

**G. GENERAL PRODUCT SPECIFICATIONS**

The following is a table of the ingredient list:

1. Active ingredients, giving their approved names, chemical names, quantity of active ingredient in the formulation and specification of the cosmetic product.
2. Other ingredients giving specifications, quantity and reasons for inclusion

e.g preservative, fragrance, antioxidant etc:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **APPROVED NAME OF INGREDIENT** | **CHEMICAL NAME** | **QUANTITY****IN THE FORMULATION** | **ACTIVE OR INACTIVE** | **SPECIFICATION** | **REASON FOR INCLUSION OF INGREDIENT** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. Does the product contain skin lightening agents

 YES ( ) NO ( )

 If Yes, (Provide details)

…………………………………………………………………………………………………………………………………

…………………………………………………………………………………………………………………………………

1. Proposed Shelf-Life of Cosmetic product:

………………………………………………………………………………………………………………………………

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**H. NOTE:**

1. The Chemical name must, where possible, be given in terms of the published list of an appropriate international body (e.g. INCI Name).
2. REFERENCE to the following publications will, where applicable, be accepted.
3. British Pharmacopoeia
4. European Pharmacopoeia
5. Pharmacopoeia Of The United States Of America
6. British Pharmaceutical Codex
7. International Pharmacopoeia
8. Extra Pharmacopoeia
9. Such other works of reference as may be approved by the Authority.

**I. ADMINISTRATIVE STATUS OF THE COSMETIC PRODUCT**

1. Has the cosmetic product been registered in the country of origin

 Yes ( ) No ( )

IF YES a valid certificate of registration in respect of such a cosmetic issued by the appropriate authority established for the registration of cosmetic products in the country must accompany this application.

1. Has an application for the registration of the cosmetic product been made in any other country?

Yes ( ) No ( )

If YES, list countries and attach copies of certificates:

…………………………………………………………………………………………………………………………………………

1. Has the registration of the cosmetic product been rejected, refused, deferred or cancelled in any country?

Yes ( ) No ( )

If Yes, state details

…………………………………………………………………………………………………………………………………………

1. Has an application for the registration of the cosmetic been made in any other country?

Yes ( ) No ( )

If Yes, list countries and attach copies of certificates:

…………………………………………………………………………………………………………………………………………

1. Is the cosmetic product manufactured in other countries?

Yes ( ) No ( )

If Yes, state details and list manufacturing plants from which imports can be made to Ghana.

…………………………………………………………………………………………………………………………………………

1. Attach four (4) copies of labels, package inserts and packaging materials proposed for marketing in Ghana