# PHARMACY BOARD OF SIERRALEONE
# APPLICATION FORM FOR THE REGISTRATION OF A COSMETIC
**(FORM N )**

CHECKLIST

| Applicant's check list | | PBSL double check |
|---|---|---|
| ☐ | **Signed Declaration** | ☐ |
| ☐ | **Covering Letter** | ☐ |
| ☐ | **Certificate of Analysis of Finished Product** | ☐ |
| ☐ | **Real-time and Accelerated Stability Data** | ☐ |
| ☐ | **Manufacturing License** | ☐ |
| ☐ | **Free Sale Certificate** | ☐ |
| ☐ | **Certificate of Registration in Country of Origin** | ☐ |
| ☐ | **Completed Table A** | ☐ |
| ☐ | **Completed Table B** | ☐ |

**Applicant**

Name:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Signature:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Date:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

**PBSL Staff**

Name:_ _ _ _ _ _ _ _ _ _

Signature:_ _ _ _ _ _ _ _

Date:_ _ _ _ _ _ _ _ _ _

# APPLICATION FOR THE REGISTRATION OF A COSMETIC

*(To be submitted in duplicate)*

Cover letter addressed to:

**THE REGISTRAR**
**PHARMACY BOARD OF SIERRA LEONE**
**64 SIAKA STEVENS STREET**
**FREETOWN**
**SIERRA LEONE**
**P.M.B. 322**

**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.**

## A. PARTICULARS OF PRODUCT

Name of Cosmetic ……
Dosage Form…..…… Colour……
Commercial Presentation(s)…….…… Country of Origin: ……..

## B. PARTICULARS OF APPLICANT

Name of Applicant/Licence Holder: ……
Business Address:……..……
……
Phone: ……..…… Fax…..……e-mail……..……

## C. PARTICULARS OF MANUFACTURER

Name and Address of Manufacturer……..
……
Phone …… Fax …… e-mail ……

## D. PARTICULARS OF LOCAL AGENT

Name and Address of Local Agent……
……

Phone: …… Fax…… e. mail ……
Cosmetic Classification……..
Application Fee Paid…….……Date……

## E. CERTIFICATION BY A RESPONSIBLE PERSON IN THE APPLICANT COMPANY

**Certification**

I the undersigned certify that all the information in the accompanying documentation concerning this application for registration for:

Proprietary name:……

Approved generic name(s)[INN]:……

……

……

……..

Strength(s) per dosage unit:……..…….

……

Formulation:……

Applicant company:……...

……

is correct and true, and reflects the total information available.

Name:……

Position in company:……..

Signature:……

Date:…… Official Stamp:…….

## APPENDIX 1

***General Product Specifications***

Name of Cosmetic:……..

Name of Applicant: …….

Dosage Form …… Size……. Colour……

Please complete tables A or B attached as appendices V and VI detailing all active and non-active ingredients as indicated in the examples below:

(i) Example for completing Table A for active ingredients

| Approved chemical name | Quantity per dosage unit | Specification | Reason for inclusion of ingredient |
|---|---|---|---|
| Aloe vera | 2mg/150ml | U.S.P | |
| | | | |

(ii) Example for completing Table B for non-active ingredients

| Approved chemical name | Quantity per dosage unit | Specification | Reason for inclusion of non-active ingredient |
|---|---|---|---|
| Sodium laurylsulfate | 10%/g | B.P | Surfactant |

Specifications of packaging materials

……
……

……..……
……..

Any ingredient liable to cause dependence/and/or listed in the UN lists of psychotropic and narcotic drugs

……

If product contains any skin lightening ingredient(s) state the name(s) and strength

……

**NOTE:**

1. The chemical name must, where possible, be given in terms of the published list of an appropriate international body

2. Reference to the following publications will, where applicable, be accepted.

a. British Pharmacopoeia

b. European Pharmacopoeia

c. Pharmacopoeia of the United States of America

d. British Pharmaceutical Codex

e. Such other works of reference as may be approved by the Board

f. Where no reference is made to any of the specifications above, the inclusion specification used or any other such specification must be specified

APPENDIX II

***Manufacturing Procedures and Related Controls***

Name of

Cosmetic:……..

Name of Applicant:

……

Dosage Form: ……..……Size: ……Colour:

……

a. Give a brief summary of the manufacturing procedure

……
……
……

b. Name and address of the manufacturer and Certificate(s) of Analysis of the raw materials used

……
……
……

c. Attach the final analytical report and authorization for release and any other appropriate records

……
……
……

d. Proposed shelf-life of cosmetic

……
……

e. Stability data and justification on which shelf-life has been predicted

……
……

Attach names, address, and qualification of authorized persons in charge of product, quality control, packaging and release of product.

| SECTION | NAME OF AUTHORISED PERSON | ADDRESS | QUALIFICATION |
|---|---|---|---|
| **Quality Control** | | | |
| **Product Packaging** | | | |
| **Product Release** | | | |

APPENDIX III

***Administrative Status of the Product***

Name of Cosmetic: ……

Name of Applicant: …….

Dosage Form: …….. Strength: ……. Size: …… Colour: ……..

1.

a. Has the cosmetic been registered in the country of origin?

YES ☐ NO ☐

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

If NO, state the reason(s)

……

……

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

YES ☐ NO. ☐

If YES, list countries:

……

……

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

YES ☐ NO ☐

If YES, state detail

……
……

2. Is the cosmetic manufactured in other countries?

YES ☐ NO ☐

If YES, state details and list manufacturing plants from which imports can be made to PBSL

……
……

3. How do you envisage distributing the Cosmetic?

……
……
……

Attach four (4) copies of labels, package inserts and packaging materials proposed for marketing this product in PBSL.

## APPENDIX IV

## Toxicological Information

Name of Cosmetic:……

Name of Applicant: ……

Dosage Form: ……Strength: ……. Size:…… Colour: ……

Attach any relevant information on antidotes and management in case of accidental poisoning

……
……
……

## APPENDIX V

| Approved chemical name | Quantity per dosage unit | Specification | Reason for inclusion of ingredient |
|---|---|---|---|
| Aloe vera | 2mg/150ml | | U.S.P |
| | | | |

## APPENDIX VI

| Approved chemical name | Quantity per dosage unit | Specification | Reason for inclusion of non-active ingredient |
|---|---|---|---|
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