



**APPLICATION FORM
FOR THE
REGISTRATION OF A
COSMETIC PRODUCT**

PBSL-F-73/08



CHECKLIST

**Applicant's
check list**

**PBSL
double check**

- | | | |
|--------------------------|---|--------------------------|
| <input type="checkbox"/> | Signed Declaration | <input type="checkbox"/> |
| <input type="checkbox"/> | Covering Letter | <input type="checkbox"/> |
| <input type="checkbox"/> | Certificate of Analysis of Finished Product | <input type="checkbox"/> |
| <input type="checkbox"/> | Real-time and Accelerated Stability Data | <input type="checkbox"/> |
| <input type="checkbox"/> | Manufacturing License | <input type="checkbox"/> |
| <input type="checkbox"/> | Free Sale Certificate | <input type="checkbox"/> |
| <input type="checkbox"/> | Certificate of Registration in Country of Origin | <input type="checkbox"/> |
| <input type="checkbox"/> | Completed Table A | <input type="checkbox"/> |
| <input type="checkbox"/> | Completed Table B | <input type="checkbox"/> |

Applicant

PBSL Staff

Name: _____

Name: _____

Signature: _____

Signature: _____

Date: _____

Date: _____

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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



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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]:.....

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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

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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

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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

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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

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.....
.....

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

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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



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.....
.....

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.

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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

.....

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APPENDIX V

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



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