PHARMACY BOARD OF SIERRALEONE

APPLICATION FORM FOR THE REGISTRATION OF A CHEMICAL SUBSTANCE

(FORM I)

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 **PBSL Staff**

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

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

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

APPLICATION FOR THE REGISTRATION OF A HOUSEHOLD CHEMICAL SUBSTANCE

(To be submitted in duplicate)

Cover letter addressed to:

THE REGISTRAR #
PHARMACY BOARD OF SIERRA LEONE
CENTRAL MEDICAL STORES
NEW ENGLAND VILLE
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 Chemical Substance……
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 ……..
Chemical Substance 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 Chemical

substance:…….

Name of

Applicant:……

……..

Application

Number:…….....

Dosage Form:…… Strength:…… Size:…….

Colour:……

The following is a table of the: adopt formula for cosmetics application form

a. Active ingredients, giving their approved names, chemical names, specification and quantity in a dosage unit of the household chemical:

b. Other ingredients giving specifications and quantity and reasons for inclusion e.g. preservative, fragrance, antioxidant, etc.

Approved Name	Chemical substance Name	Quantity Per Dosage Unit	Active or Non-Active	Specification	Reason for Inclusion of Ingredient

Specifications of additional raw materials (if any) used in the manufacturing process and not in the final product

…….
……
……
……
…….. ……

Specifications of packaging materials

……

Where no specifications for raw materials and packaging materials exist, this must be mentioned

……

……

……

Does product contain a skin lightening cream.

Yes ☐ No ☐

If Yes, provide details

……

NOTE

1. The Chemical substance 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. International Pharmacopoeia

    f. Extra Pharmacopoeia

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

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APPENDIX II

Manufacturing Procedures and Related Controls

Name of Chemical substance:……..

Name of Applicant:……..

Dosage Form:…….Strength:……..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. Certificates of Quality Control Tests performed on the raw materials

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……
……
……

d. Attach a final analytical report and authorization for release and any other appropriate records

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……

e. Proposed shelf-life of chemical substance

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……
……

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

……
……
……

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

……
……
……
……
……

APPENDIX III

Administrative Status of the Product

Name of Chemical substance:……

Name of Applicant:……..……..

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

1.

a. Has the household chemical substance 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 chemical substances in the country must accompany this application.

If NO, state the reason(s)

……..……..……
……
……
……

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

YES ☐ NO. ☐

If YES, list countries and attach copies of certificates:

……..……
……..……
……..……
……..……

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

☐ ☐

YES NO

YES, state details

……
……
……
……..

1. Is the chemical substance manufactured in other countries?

YES ☐ NO ☐

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

……
……..……..……
……..…….....
.....
.....

2. Attach text of labels and other written material which would be made available with the products in accordance with Appendices IV and V

3. How do you envisage distributing the household chemical substance?

……

……..……

……

APPENDIX IV
Toxicological Information

Name of Chemical Substance:……..

Name of Applicant:……..

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

1. List documents attached on any toxicological trials undertaken

……..……
……..……
……..……
……

2. List documents attached on any adverse effects of the substance on humans or animals

……
……..……
……
……..……..……
……..……
……

3. State details of residue of the substance in plant and animal species intended for human consumption (if applicable)

……
……
……
……
……
……

4. Provide information on antidotes and management in cases of accidental poisoning

APPENDIX V

List of Attached Documents and Materials

Name of Chemical Substance:……..……

Name of Applicant:……

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

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

……..……
……
……..……..……
……..……
……..……
……

The text of labels and written material shall conform to labelling regulations in force in Sierra Leone (Pharmacy Board of Sierra Leone Guidelines on Labelling of Products).