
	APPLICATION FORM FOR THE REGISTRATION OF COMPLEMENTARY AND ALTERNATIVE MEDICINES	
	PBSL-F-73/07	

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"/> | Sterility Testing Certificate | <input type="checkbox"/> |

Applicant

PBSL Staff

Name: _____



Name: _____

Signature: _____

Signature: _____

Date: _____

Date: _____

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(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
E-mail: pharmbds1@hotmail.com**

Samples and printed matter to be forwarded to the Board through the local agent; customs duty and clearance to be effected by the applicant in all instances.

A. PARTICULARS OF PRODUCT

Proprietary Name.....

Approved/Generic Name(s).....

Colour.....Formulation.....

Commercial Presentation(s)/Page Size.....Strength(s) per dosage Unit.....

B. PARTICULARS OF APPLICANT

Name of Applicant/License Holder:.....

Business Address:.....



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Phone:..... Fax:.....

E-mail:.....

C. PARTICULARS OF MANUFACTURER

Name of Manufacturer:.....

Full Premises Address of Manufacturer:.....

Phone:..... Fax.....

E-mail:..... Website.....

D. PARTICULARS OF LOCAL AGENT



Name of Local Agent:.....

Business Address:

Phone:..... Fax.....

E-mail:..... Website.....

Classification/Type of Herbal/Medicine

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Intended Use:

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

Name:.....

Position in company:.....

Signature:.....

Date:..... Official Stamp:.....

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APPENDIX I

Manufacturing Procedures and Related Controls

Name of Herbal Medicine

Name of Applicant

Classification/Type of Herbal Medicine

Size Colour

1. Details of manufacturing procedure and documentation.

a. Give a brief summary of the manufacturing procedure.

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b. Attach documents showing analytical control procedures performed during the manufacturing process.



c. Attach relevant Certificates for the Quality of the finished products (sensitivity, specificity, sterility, pyrogen test, etc)

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d. Attach the final analytical report and authorization for release of the finished product:

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e. Indicate name(s), address(es), and qualification(s) of authorized person(s) in charge of product quality control, packaging and release of product.

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SECTION	PERSON NAME OF AUTHORIZED	ADDRESS	QUALIFICATION
Quality Control			
Product Packaging			
Product Release			

f. Estimated shelf-life of the Herbal Medicine

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

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APPENDIX II
Administrative Status of the Product

Name of Herbal Medicine:.....

Name of Applicant:.....

Classification/Type of Herbal Medicine.....

.....

Pack Size:..... Colour:.....

1.



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

YES

NO

If **YES**, list the countries

.....
.....
.....

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b. Has the product been registered in the country of origin?

YES

NO

IF **YES**, attach a copy of certificates of registration in respect of such a device issued by the appropriate authority established for the registration of Medical Device in the country.

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

YES

NO

If **YES**, state details

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2. Is the product manufactured in other countries?

YES

NO



If **YES**, state details and list manufacturing plants from which import can be made to the PBSL.

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APPENDIX III

List of Attached Documents and Materials

Name of Herbal Medicine.....

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Name of Applicant.....

Classification/ Type of Herbal Medicine

Size.....Colour.....

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

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*** The text of labels and written material should conform to existing labeling regulations of the Pharmacy Board of Sierra Leone.**