



**APPLICATION FORM FOR
THE REGISTRATION OF
NUTRITIONAL AGENTS**

PBSL-F-73/09



CHECKLIST

**Applicant's
check list**

**PBSL
double check**

- Covering Letter
- Signed Declaration
- Fully Completed Application
(Appendix I-IV)
- Certificate of Analysis
(Finished Product)
- Four (4) Copies of Label and
Packaging Material
- Four (4) Copies of Package Insert

Applicant

PBSL Staff

Name: _____

Name: _____

Signature: _____

Signature: _____

Date: _____

Date: _____

(To be submitted in duplicate)



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Cover letter addressed to:

**THE PHARMACY BOARD OF SIERRA LEONE
CENTRAL MEDICAL STORES COMPOUND
NEW ENGLAND VILLE
JOMO KENYATTA ROAD
FREETOWN
SIERRA LEONE
P. M. B. 322
E-mail: pharmbdsl@hotmail.com**

Samples and printed matter should 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
Name.....

Formulation:..... Strength:..... Colour:.....

Commercial Presentation(s):.....

Country of Origin/Processing/Manufacture.....

B. PARTICULARS OF APPLICANT

Name of Applicant:.....



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Business Address:.....
.....
.....

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

E-mail

C. PARTICULARS OF MANUFACTURER

Name of Manufacturer:.....

Premises Address:.....
.....

Postal Address:.....

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

E-mail

D. PARTICULARS OF LOCAL AGENT

Local Agent:.....



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Business Address:.....

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

E - mail

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

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.

| | | |
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Name:.....

Position in company:.....

Signature:.....

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

**APPENDIX I
GENERAL PRODUCT SPECIFICATIONS**

Name of Product.....

Formulation:..... Strength:..... Colour:.....

(a) List all active ingredients as illustrated in the table below:



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| Approved name | Quantity per dosage unit | Specification | Reason for inclusion of ingredient |
|---------------|--------------------------|---------------|------------------------------------|
| Garlic | 46 mg | BP | Improves circulation |

(b) List all non-active ingredients as illustrated in table below:

| Approved name of ingredient | Quantity per dosage unit | Specification | Reason for inclusion of ingredient |
|-----------------------------|--------------------------|---------------|------------------------------------|
| Starch | 112.6 mg | BP | Binder |
| Magnesium Stearate | 2.0 mg | BP | Lubricant |

(c) Give specifications of packaging materials (Where no specifications for packaging materials exist this must be mentioned)

.....

(d) Any claim of curative properties? If yes a valid evidence or documentation to support such a claim must accompany this application

.....

.....

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

- i. British Pharmacopoeia
- ii. European Pharmacopoeia
- iii. United States Pharmacopoeia
- iv. International Pharmacopoeia
- v. British Pharmaceutical Codex
- vi. Extra Pharmacopoeia
- vii. Such other works of reference as may be approved by the Board from time to time.



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APPENDIX II

MANUFACTURING PROCEDURE AND RELATED CONTROLS

Name of
Product.....
.....



Formulation.....Strength: Colour:

a) Give a brief summary of the manufacturing procedure
.....
.....
.....
.....

(b) Attach final analytical report and authorization for release.
.....

(c) State proposed shelf life of Product
.....

(d) Provide stability data and justification on which shelf-life has
been predicted.....

| | | |
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***Refer to PBSL Guidelines for Registration of Food / Dietary Supplement / Nutritional Agent or Sachet/Bottled Water**

APPENDIX III

ADMINISTRATIVE STATUS OF THE PRODUCT

Name of Product:

Formulation:.....Strength: Colour:.....

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

YES

NO



(i) If YES, list the countries

.....
.....

(b) Has the product been registered in any other country?

YES

NO

| | | |
|--|--|---|
|  | <p align="center">APPLICATION FORM FOR THE REGISTRATION OF NUTRITIONAL AGENTS</p> |  |
| <p align="center">PBSL-F-73/09</p> | | |

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

YES NO

(i) If YES, state details
.....

(d) Is the product manufactured in other countries?

YES NO

(i) If YES, state details and list manufacturing plants from which imports can be made to Sierra Leone.
.....



APPENDIX IV

LIST OF ATTACHED DOCUMENTS AND MATERIAL

Name of Product:.....

Formulation:.....StrengthColour

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

| | | |
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Note: The text of labels and written material should conform to labeling regulations in force in Sierra Leone (Please refer to The Pharmacy Board of Sierra Leone Guidelines on packaging and labeling).