PHARMACY BOARD OF SIERRALEONE

APPLICATION FORM FOR THE REGISTRATION OF A FOOD/DIETARY SUPPLEMENT/NUTRITIONAL AGENT OR SACHET/BOTTLED WATER

(FORM P)

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

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

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

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

PBSL Staff

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

Signature:_ _ _ _ _ _ _ _

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

APPLICATION FORM FOR THE REGISTRATION OF A FOOD/ DIETARY PRODUCT / NUTRITIONAL AGENT OR SACHET/BOTTLED WATER

(To be submitted in duplicate)

Cover letter addressed to:

THE REGISTRAR
PHARMACY BOARD OF SIERRA LEONE
NEW ENGLAND VILLE
FREETOWN
SIERRA LEONE
P.M.B. 322

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……

B. PARTICULARS OF APPLICANT

Name of Applicant:……

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:……

Business Address:……

Phone:……Fax:……

E - mail ……

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 I

GENERAL PRODUCT SPECIFICATIONS

Name of Product……

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

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

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.

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*……

***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

(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:……..Strength ……..Colour ……

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

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).