PHARMACY BOARD OF SIERRA LEONE

APPLICATION FORM FOR THE REGISTRATION OF A FOOD SUPPLEMENT
(FORM O)

CHECK LIST

Applicant's check list	**PBSL double check**
☐ Covering Letter	☐
☐ Signed Declaration	☐
☐ Fully Completed Application (Appendix I-V)	☐
☐ Drug Master File/Process Validation Protocol	☐
☐ Complete Batch Manufacturing Record	☐
☐ Certificate(s) of Analysis (Raw Materials)	☐
☐ Certificate of Analysis (Finished Product)	☐
☐ Certificate of Pharmaceutical Product	☐
☐ Clinical Trial	☐
☐ Stability Study Reports for Three (3) Batches	☐
☐ Name and Address of Qualified Person	☐
☐ Samples of the Product	☐
☐ Primary Standard	☐
☐ Four (4) Copies of Label and Packaging Material	☐
☐ Four (4) Copies of Package Insert	☐

Applicant	**PBSL Staff**
Name:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Name:_ _ _ _ _ _ _ _ _ _ _ _
Signature:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Signature:_ _ _ _ _ _ _ _ _
Date:_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Date:_ _ _ _ _ _ _ _ _ _ _ _

APPLICATION FORM FOR THE REGISTRATION OF A FOOD SUPPLEMENT

(To be submitted in duplicate)

Cover letter addressed to:

THE REGISTRAR
PHARMACY BOARD OF SIERRA LEONE
CENTRAL MEDICAL STORE
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……

Dosage Form:……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

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:……

……

Dosage form……

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 supplement……

Dosage form:……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
Folic acid	4 mg	BP	Food supplement

(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
Purified Talc	3.00 mg	BP	Lubricant
Gelatin	2.00 mg	BP	Binder

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

……

(d) List any ingredient liable to cause dependence and /or listed in the UN lists of psychotropic and narcotic drugs

……

……

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

PARTICULARS OF MANUFACTURING PROCEDURE, RELATED CONTROLSAND DOCUMENTATION

Name of Supplement.....

Name of Applicant .....

Dosage Form.....Strength ..... Colour .....

(a) Give a brief summary of the manufacturing procedure

.....

.....

.....

(a) Indicate the particulars of manufacturer(s) of each raw material used in the table below:

Name of raw material	Name of manufacturer	Address

Attach the following:

(i) Original copies of certificate(s) of analysis of raw material

(ii) Certificate(s) of in-house quality control tests performed on raw materials

(b) Attach a copy of a complete Drug Master File and process validation protocols for the manufacture of this product.

(c) Attach the complete batch records including the final analytical report and authorization for release.

(d) Attach names, addresses and qualifications of Authorized Person(s) in charge of production, quality control, packaging and release of product

(e) State estimated shelf-life of drug.....

(f) Provide stability data and justification on which shelf life has been predicted*

.....

***Refer to PBSL Guidelines for Registration of Food / Dietary Supplement / Nutritional Agent**

APPENDIX III

ADMINISTRATIVE STATUS OF THE PRODUCT

Name of supplement: ……

Dosage Form:……Strength: ……. Colour:……

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

YES NO

(i) If YES, list the countries

……

……

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

YES NO

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

YES NO

(i) If YES, state details

……

(d) Is the supplement manufactured in other countries?

YES NO

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

……

APPENDIX IV

TOXICOLOGICAL, PHARMACOLOGICAL AND CLINICAL INFORMATION

Name of Supplement.....

Name of Applicant.....

Dosage Form.....Strength .....Colour .....

GENERICS

(a) Bioequivalence data shall be required for **all** oral solid dosage forms. This shall be a comparative study with the innovator product or a verifiable Lead Market Brand acceptable to the Board.

NEW CHEMICAL ENTITIES AND INNOVATOR PRODUCTS

(b) Particulars referring to the pharmacological, toxicological and efficacy data obtained from preclinical studies undertaken on the drug

(c) All documentation referring to the tests which have been performed on **humans** regarding the efficacy of the drug (Phases I, II and III)

(d) Primary standards for the active ingredient, related substances, and identifiable impurities should be submitted.

SOLID ORAL DOSAGE FORMS

(e) Dissolution test reports shall be submitted

Note: This section is applicable to New Chemical Entities

Dissolution test is not applicable for multivitamin.

APPENDIX V

LIST OF ATTACHED DOCUMENTS AND MATERIAL

Name of Supplement……

Dosage Form……..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 Pharmacy Board of Sierra Leone Guidelines on packaging and labeling)