APPLICATION FORM FOR THE REGISTRATION OF A FOOD/DIETARY/NUTRITIONAL SUPPLEMENT

CHECKLIST

Applicant's check list		FDB double check
☐	Covering Letter	☐
☐	Signed Declaration	☐
☐	Fully Completed Application (Appendix I-Iv)	☐
☐	Certifcate Of Analysis (Finished Product)	☐
☐	Four (4) Copies of Label and Packaging Material	☐
☐	Four (4) Copies of Package Insert	☐

APPLICATION FORM FOR THE REGISTRATION OF A FOOD/ DIETARY/NUTRITIONAL SUPPLEMENT

(To be submitted in duplicate)

Cover letter addressed to:

THE CHIEF EXECUTIVE
FOOD AND DRUGS BOARD
P.O.BOX CT 2783
CANTONMENTS,ACCRA
GHANA.

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.

Proprietary Name……. ……

Approved Name……

Dosage Form:……Strength:…… Colour:…….

Commercial Presentation(s):……

Country of Origin…….

Name of Applicant:……

Business Address:……

……

Phone:…… Fax:…….

e-mail ……..

Manufacturer:……

Premises Address:……

…….

Postal Address:……

Phone:……Fax:……..

e-mail …….

Local Agent:……

Business Address:……

Phone:…….. Fax:……

e-mail ……..

Declaration

I/We, the undersigned, hereby declare that all information contained herein and in the appendices is correct and true.

Name: ……..

Position:…….

Signature:……

Date: ……

Official stamp

APPENDIX I

GENERAL PRODUCT SPECIFICATIONS

Name of supplement……

Dosage form:…….Strength:……Colour:……

(a) List <u>all</u> 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 <u>all</u> 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) 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

MANUFACTURING PROCEDURE AND RELATED CONTROLS

Name of Supplement……

Dosage Form……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 supplement

……

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

……

***Refer to FDB Guidelines for Registration of Food Supplements**

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 imports can be made to Ghana.

……

APPENDIX IV

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 labelling regulations in force in Ghana (Please refer to Food & Drugs Board Guidelines on Labelling)