



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

CHECKLIST

Applicant's
Check list

FDB
double check

- | | | |
|--------------------------|---|--------------------------|
| <input type="checkbox"/> | COVERING LETTER | <input type="checkbox"/> |
| <input type="checkbox"/> | SIGNED DECLARATION | <input type="checkbox"/> |
| <input type="checkbox"/> | FULLY COMPLETED APPLICATION (APPENDIX I-IV) | <input type="checkbox"/> |
| <input type="checkbox"/> | CERTIFICATE OF ANALYSIS (FINISHED PRODUCT) | <input type="checkbox"/> |
| <input type="checkbox"/> | FREE SALE CERTIFICATE (FOREIGN PRODUCT) | <input type="checkbox"/> |
| <input type="checkbox"/> | STABILITY STUDY REPORTS | <input type="checkbox"/> |
| <input type="checkbox"/> | SAMPLES (AS PER FDA SAMPLE SCHEDULE) | <input type="checkbox"/> |
| <input type="checkbox"/> | 4 COPIES OF LABEL & PACKAGING MATERIAL | <input type="checkbox"/> |
| <input type="checkbox"/> | 4 COPIES OF PACKAGE INSERT | <input type="checkbox"/> |

**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 AUTHORITY
P.O.BOX CT 2783
CANTONMENTS-ACCRA
GHANA.**

Samples and printed matter should be forwarded to the Authority 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.....

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

(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

- British Pharmacopoeia
- European Pharmacopoeia
- United States Pharmacopoeia
- International Pharmacopoeia
- British Pharmaceutical Codex
- Extra Pharmacopoeia
- 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

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

(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 FDA 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 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 four (4) 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 Ghana (Refer to Food & Drugs Authority Guidelines on Labeling)