|  |  |  |
| --- | --- | --- |
|  |  **FOOD AND DRUGS AUTHORITY**   | **DOC. TYPE: FORM** |
| **DOC NO.: FDA/DRI/HEB/SP-01** |
| **PAGE 1 OF 7** | **REV NO.: 01** |
| **EFFECTIVE DATE-07/2020** |
| **TITLE: APPLICATION FORM FOR THE REGISTRATION OF A** **FOOD/DIETARY/NUTRITIONAL SUPPLEMENT**  |

**CHECKLIST**

APPLICANT’S FDA

CHECK LIST CHECK LIST

|  |  |
| --- | --- |
|   |  COVERING LETTER |
|  |  |  |
|    |  SIGNED DECLARATION  |   |
|    |  FULLY COMPLETED APPLICATION (APPENDIX I-IV)  |   |
|    |  CERTIFCATE OF ANALYSIS (FINISHED PRODUCT)  |  |
|    |  FREE SALE CERTIFICATE (FOREIGN PRODUCT)  |   |
|   |  STABILITY STUDY REPORTS  |

 SAMPLES (AS PER FDA’S SAMPLE SCHEDULE

 4 COPIES OF LABEL & PACKAGING MATERIAL

 4 COPIES OF PACKAGE INSERT

(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

**APPENDIX I**

**GENERAL PRODUCT SPECIFICATIONS**

Name of supplement………………………………………………………………………

Dosage form:………………………… Strength:………………… Colour:…………………

1. List all active ingredients as illustrated in the table below:

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

1. List all non-active ingredients as illustrated in table below:

|  |  |  |  |
| --- | --- | --- | --- |
| Approved name of Ingredient  | Quantity per dosage unit  | Specification  | Reason for inclusion of ingredient   |
| **Eg. Starch**  | **112.6mg**  | **BP**  | **Binder**  |
| **Eg. Magnesium** **Stearate**  | **02.00mg**  | **BP**  | **Lubricant**  |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |

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

…………………………………………………………………………………………………

1. 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: …………………………

1. Give a brief summary of the manufacturing procedure

…………………………………………………………………………………………………

…………………………………………………………………………………………………

…………………………………………………………………………………………………

…………………………………………………………………………………………………

………………………………………………….

1. Attach final analytical report and authorization for release.

 ………………………………………………………………………………………………

1. State proposed shelf life of supplement

…………………………………………………………

1. 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:………………………

1. Has an application for the registration of the supplement been made in any other country?

YES/NO\*

* 1. If YES, list countries

…………………………………………………………………………………………………

…………………………………………………………………………………………………

1. Has the supplement been registered in any other country? YES/NO\*

1. Has the registration of the supplement been rejected, refused, deferred or cancelled in any country? YES/NO\*
	1. If YES, state details

…………………………………………………………………………………………………

1. Is the supplement manufactured in other countries? YES/NO\*

* 1. 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)