|  |  |  |
| --- | --- | --- |
|  |  **FOOD AND DRUGS AUTHORITY**   | **DOC. TYPE: FORM** |
| **DOC NO.: FDA/DRI/HEB/AP-01** |
| **PAGE 1 OF 7** | **REV NO.: 01** |
| **EFFECTIVE DATE-07/2020** |
| **TITLE: APPLICATION FORM FOR THE REGISTRATION OF HERBAL****MEDICINAL PRODUCT** |

**CHECKLIST**

APPLICANT’S FDA

CHECK LIST CHECK LIST

|  |  |
| --- | --- |
|   |  COVERING LETTER |
|  |  |  |
|    |  SIGNED DECLARATION  |   |
|    |  FULLY COMPLETED APPLICATION (APPENDIX I-IV)  |   |
|    |  CERTIFCATE OF ANALYSIS (FINISHED PRODUCT)  |  |
|   |  SAFETY REPORT (ACUTE AND CHRONIC TOXICITY  |  |
|    |  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)**

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.**

Name of Herbal Medicinal Product; ………………………………………………………

Dosage Form: ………………………Strength: ……………………Colour:..……………… Commercial Presentation (s): ………………………………………………………………... Country of Origin: …………………………………………………………………………... Name of Applicant: ………………………………………………………………………….

Business Address: …………………………………………………………………………….

…………………………………………………………………………………………………..

Phone:……………………. .…….. Fax:………………………………….

e-mail:………………………………………………………………………

Name of Manufacturer:…………………………………………………………………………

Premises Address ……………………………………………………………………………… ………………………………………………………………………………………………….

Postal Address:………………………………………………………………………………… Phone:………………………………………… Fax:….…………………………………..

e-mail………………………………………………………………………………………….

Name of Local Agent: …………………………………………………………...................

Business Address: ………………………………………………………………………….

Phone: ……………………………………… Fax: …………………………………………

e-mail: ………….…………………………………………………………………………….

Application fee paid………………………………………………………………………….

**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 1**

**PRODUCT DETAILS**

Name of Medicine…………………………………………………………………………….

Name of Applicant……………………………………………………………………………

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

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Scientific or Botanical Name  | Common Name or Synonym  | Part of plant used  | Quantity Per dosage unit  | Chemical Constituent  | Reason for inclusion of ingredient  |
| **Eg: Citrus aurantifolia**  | **Ankaa (Akan name)**  |  **Fruit,** **leaves**  | **200 mg**  | **Reducing sugars, polyuronides, etc**  | **Treatment of urinary retention and yaws**  |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |

(1) List all non-active ingredients as illustrated in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
| Approved Name of Ingredient  | Common Name or Synonym  | Quantity per dosage unit  | Reason for inclusion of ingredient  |
| **Eg: Xylopia aethiopica**  | **Hwentia (Akan name)**  | **10 mg**  | **Preservative**  |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |

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

…………………………………………………………………………………………………

…………………………………………………………………………………………………

**APPENDIX II**

PARTICULARS OF MANUFACTURING PROCEDURE AND RELATED CONTROLS

1. Origin or source of the raw materials, steps taken to prevent presence of foreign matter (sand, stones, insects, etc.)

………………………………………………………………………………………………………………………

…………………………………………………………………………………………………………………………

………………………………………………………………………………………………………………………

…………………………………………………………………………………………………………………………

……………………………………………………………………………………………………………………..

1. Give a brief summary of the manufacturing procedure.

…………………………………………………………………………………………………………………………

…………………………………….………………………………………………………...........................

………………………………………………………………………………………………………………………..

…………………………………………………………………………………………………………………………

…………………………………………………………………………………………………………………………

…………………………………………………………………………………………………………………………

…………………………………………………………………………………………………………………………

1. State estimated shelf-life of the medicine.

…………………………………………………………………………………………………

1. Provide stability data and justification on which shelf-life has been predicted.

…………………………………………………………………………………………………

1. An acceptable certificate of analysis testifying that the medicine is of proven quality and issued by a recognised public analyst.

………………………………………………………………………………………………

1. Attach toxicological, pharmacological and clinical information, as well as therapeutic effects of the herbal preparation.\*

……………………………………………………………………………………………..

\*Refer to FDA Guidelines for Registration of Herbal Medicinal Products

1. Attach text of labels and other written materials available with the herbal/homeopathic medicine, including the underlisted information.

i. Indication ii. Dosage and administration iii. Contraindications iv. Adverse reactions v. Precautions

vi. Use in pregnancy and lactation vii. Treatment of over dosage viii. Interactions with other drugs or food ix. Storage conditions