# APPLICATION FORM FOR THE REGISTRATION OF HERBAL MEDICINAL PRODUCT

## CHECKLIST

| Applicant's Check list | | FDA double check |
|---|---|---|
| ☐ | COVERING LETTER | ☐ |
| ☐ | SIGNED DECLARATION | ☐ |
| ☐ | FULLY COMPLETED APPLICATION (APPENDIX I-II) | ☐ |
| ☐ | SAFETY REPORTS (ACUTE AND CHRONIC TOXICITY) | ☐ |
| ☐ | CERTIFICATE OF ANALYSIS (FINISHED PRODUCTS) | ☐ |
| ☐ | FREE SALE CERTIFICATE (FOREIGN PRODUCT) | ☐ |
| ☐ | STABILITY STUDY REPORT (FOREIGN PRODUCTS | ☐ |
| ☐ | SAMPLES (AS PER FDA SAMPLE SCHEDULE) | ☐ |
| ☐ | 4 COPIES OF LABEL & PACKAGING MATERIAL | ☐ |
| ☐ | 4 COPIES OF PACKAGE INSERT | ☐ |

# APPLICATION FORM FOR THE REGISTRATION OF HERBAL MEDICINAL PRODUCTS

**(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** |
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(1) List <u>all</u> 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** |
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(3) List any ingredient(s) liable to cause dependence and/or listed in the UN lists of psychotropic and narcotic drugs.

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## 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)

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(2) Give a brief summary of the manufacturing procedure.

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(3) State estimated shelf-life of the medicine.

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(4) Provide stability data and justification on which shelf-life has been predicted.

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

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(6) Attach toxicological, pharmacological and clinical information, as well as therapeutic effects of the herbal preparation.*

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*Refer to FDA Guidelines for Registration of Herbal Medicinal Products

(7) 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