

**APPLICATION FORM FOR THE REGISTRATION OF**

**HOMEOPATHIC MEDICINE**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|   |  |  | **CHECKLIST**  |  |  |  |
| Applicant’s  |   |   |   |   |   |  FDA  |
| Check list    |   |   |   |   |   |  double check  |
|  Covering Letter  |   |   |   |   |   |    |
|  Signed Declaration  |   |   |   |   |    |

 Fully Completed Application (Appendix I-Iii)

  For Each Medicinal Ingredient, a Photocopy of the Monograph from the 

 Pharmacopoeia to Which the Applicant Attests

  For Homeopathic Medicines with A Specific use or Purpose, Photocopied from at Least one Homeopathic Reference to Support the Recommended use or Purpose of each Medicinal Ingredient

 Evidence to Support the Safety of Non-Active Ingredients 

 Quality Summary Report 

 Samples (As Per FDA Sample Schedule) 

 4 Copies Of Label & Packaging Material 

 4 Copies Of Package Insert 

**APPLICATION FORM FOR THE REGISTRATION OF**

**HOMEOPATHIC MEDICINE**

**(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 Homeopathic Medicine; ………………………………………………… 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 Homeopathic Medicine………………………………………………………………………….

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

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

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Ingredient No.  | Compendia Monograph  | Scientific or Botanical Name  | Common Name  | Quality per Dosage Unit  |   |
|  |  |  |  |  |  |
| 1  |   |  Arnica montana  |  Arnica Montana  |  D6  |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |
|   |   |   |   |   |   |

* + Attach separate sheet if necessary

1. List Non- active ingredients used as illustrated in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
| Ingredient No.  |  Scientific or Botanical Name  |  Common Name  |  Purpose  |
| 1.  | Eg: Ethyl Alcohol  |  Ethanol  |  Solvent  |
|   |   |  Distilled water  |  Solvent  |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
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|   |   |   |   |
|   |   |   |   |
|   |   |   |   |
|   |   |   |   |

* + Attached separate sheets if necessary

1. 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)

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

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

1. Give a brief summary of the manufacturing procedure.

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

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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