



APPLICATION FORM FOR THE REGISTRATION OF HOMEOPATHIC MEDICINE

CHECKLIST

Applicant's Check list	FDA 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-Iii)	
<input type="checkbox"/> For Each Medicinal Ingredient, a Photocopy of the Monograph from the Pharmacopoeia to Which the Applicant Attests	<input type="checkbox"/>
<input type="checkbox"/> 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	
<input type="checkbox"/> Evidence to Support the Safety of Non-Active Ingredients	<input type="checkbox"/>
<input type="checkbox"/> Quality Summary Report	<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
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

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)

.....
.....

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

.....
.....

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

.....

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

.....

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

.....

(6) 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

(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