APPLICATION FORM FOR THE REGISTRATION OF A DRUG
[HUMAN AND VETERINARY]

CHECKLIST

Applicant's check list		FDB double check
☐	Covering Letter	☐
☐	Signed Declaration	☐
☐	Fully Completed Application (Appendix I-IV)	☐
☐	Drug Master File/Process Validation Protocol	☐
☐	Complete Batch Records	☐
☐	Certificate(s) of Analysis (Raw Materials)	☐
☐	Certifcate of Analysis (Finished Product)	☐
☐	Certificate of Pharmaceutical Product	☐
☐	Clinical Trial/Bioequivalence Certificate	☐
☐	Stability Study Reports for Three (3 Batches	☐
☐	Name and Address of Qualified Persons	☐
☐	Samples of the Product	☐
☐	Reference Standards	☐
☐	Four (4) Copies of Label and Packaging Material	☐
☐	Four (4) Copies of Package Insert	☐

APPLICATION FORM FOR THE REGISTRATION OF A DRUG [ALLOPATHIC HUMAN AND VETERINARY]

(To be submitted in duplicate)

Cover letter 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.

Proprietary name…….

Approved name (INN)…….

Dosage form:……Strength:…… Colour:……

Commercial presentation(s):……..

Country of Origin……

Category of distribution:

POM (Prescription only medicines) ☐

P (Pharmacy medicine) ☐

OTC (Over-the-counter medicine) ☐

Pharmacological classification:……

Name of Applicant:……

Business Address:……

……

……

……..

Phone:…… Fax:……

e-mail ……

Name of 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 is correct and true.

Name:…… .....

Position:……

Signature:……

Date:……

Official Stamp:

APPENDIX I

GENERAL PRODUCT SPECIFICATIONS

Name of drug……

Name of applicant……

Dosage form…….Strength……Colour……

(a) Attach list of all active ingredients in the format illustrated in the example below:

Approved chemical name	Quantity per dosage unit	Reason for inclusion of ingredient	Specification
Paracetamol	325 mg	Analgesic	BP
Diclofenac sodium	50 mg	Analgesic/anti-inflammatory	BP

(b) Attach list of <u>all</u> non active ingredients in the format illustrated in example below:

Approved name of Ingredient	Quantity per dosage unit	Specification	Reason for inclusion of ingredient
Starch	112.6 mg	BP	Binder
Magnesium stearate	2.0 mg	BP	Lubricant

(c) Additional raw materials (if any) used in the manufacturing process but not present in the final product.

(d) Give specifications of packaging materials (where no specifications for packaging materials exist, this must be mentioned)

……
……

(e) List any ingredient liable to cause dependence and /or listed in the United Nations lists of psychotropic and narcotic drugs?

……

Reference to the following publications will, where applicable be accepted:

i. British Pharmacopoeia
ii. European Pharmacopoeia
iii. United States Pharmacopoeia-
iv. International Pharmacopoeia
v. British Pharmaceutical Codex
vi. Extra Pharmacopoeia
vii. Such other works of reference as may be approved by the Board from time to time.

APPENDIX II

PARTICULARS OF MANUFACTURING PROCEDURE, RELATED CONTROLS AND DOCUMENTATION

Name of Drug……

Name of Applicant ……

Dosage Form……Strength …… Colour ……

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

(b) Indicate the particulars of manufacturer(s) of each raw material used in the table below

Name of raw material	Name of manufacturer	Address

Attach the following:
(i) Original copies of certificate(s) of analysis of raw materials
(ii)Certificate(s) of in-house quality control tests performed on raw materials

(c) Attach a copy of a complete Drug Master File and process validation protocols for the manufacture of this product.

(d) Attach the complete batch records including the final analytical report and authorization for release.

(e) Attach names, addresses and qualifications of Authorized Person(s) in charge of production, quality control, packaging and release of product

(f) State estimated shelf-life of drug ……

(g) Provide stability data and justification on which shelf life has been predicted*

……

***Refer to FDB Guidelines for Registration of Allopathic Drugs**

APPENDIX III

ADMINISTRATIVE STATUS OF THE PRODUCT

Name of Drug …….

Name of Applicant……

Dosage Form……Strength ……. Colour……

(a) Attach a copy of Certificate of Pharmaceutical Product issued by the competent authority in accordance with the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

(b) Has an application for the registration of the drug been made in any other country?
YES NO

(i) If YES, list countries

……

……

(c) Has the drug been registered in any other country?
YES NO

(i) If YES attach copies of certificates of registration in respect of such drug issued by the appropriate authority established for the registration of drugs in the country.

……..

(d) Has the registration of the drug been rejected, refused, deferred or cancelled in any country?
YES NO

(i) If YES, state details

……

(e) Is the drug manufactured in other countries?
YES NO

(i) If YES, state details and list manufacturing plants from which imports can be made to Ghana.

……

APPENDIX IV

TOXICOLOGICAL, PHARMACOLOGICAL AND CLINICAL INFORMATION

Name of Drug……

Name of Applicant……

Dosage Form……Strength ……Colour ……

GENERICS

(a) Bioequivalence data shall be required for **all** oral solid dosage forms.This shall be a comparative study with the innovator product or a verifiable Lead Market Brand acceptable to the Board.

NEW CHEMICAL ENTITIES AND INNOVATOR PRODUCTS

(b) Particulars referring to the pharmacological**,** toxicological and efficacy data obtained from preclinical studies undertaken on the drug

(c) All documentation referring to the tests which have been performed on **humans** regarding the efficacy of the drug (Phases I, II and III)

(d) Reference standards for the active ingredient, related substances, and identifiable impurities should be submitted.

SOLID ORAL OSAGE FORMS

(e) Dissolution test reports shall be submitted

APPENDIX V

LIST OF ATTACHED DOCUMENTS AND MATERIAL

Name of Drug…….

Name of Applicant…….

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

Attach 4 (four) copies of labels, package inserts and packaging materials proposed for marketing in this country

The text of labels and written material should conform to labelling regulations in force in Ghana (Refer to *Food & Drugs Board Guidelines on Labelling*)