GUIDELINES FOR THE EVALUATION OF APPLICATION FOR REGISTRATION OF A NEW DRUG (ND)

1. SCOPE
In pursuance of Section 18 of the Food and Drugs Law 1992, P.N.D.C.L 305B, as amended by Act 523, 1996, these guidelines are hereby made to provide guidance to applicants on the procedure for registering a new drug in Ghana. Applicants are encouraged to familiarize themselves with this document and the above law before completing the registration form.

2. DEFINITION OF TERMS

a) “New chemical entity” means a chemically or biologically Active Pharmaceutical Ingredient (API) that has not been used as an ingredient of any pharmaceutical or biological product.

b) “Innovator Product” means a means a new chemical entity which has received a patent on its chemical formulation or manufacturing process, obtains approval from a regulatory authority after extensive testing and is sold under a brand name.

c) “New drug” means a generic copy of an innovator product:
   i) That has not previously been issued with a market authorization as a pharmaceutical or biological product in Ghana, or
   ii) Which has been marketed in Ghana for a period of less than ten (10) years or any another period to be determined by the Board from time to time, for public health reasons.

3. REQUIREMENTS

3.1 General Requirements

- An application for the registration of a new drug shall be made in writing to the Board as may be prescribed from time to time.

The application should be accompanied by:

- Submission of all documentation as per Board’s guidelines for registration of allopathic drugs (Refer to Guidelines for Registration of Allopathic Drugs)
- Samples of the product in the final package as per Food and Drugs Board sample schedule
- A non-refundable application fee of $2000
3.2 SPECIFIC REQUIREMENTS

3.2.1 Name and Labelling

3.2.1 The product name, package or label shall not bear resemblance to that of the innovator product or a previously registered product.

3.2.3 The labelling of the product should be in accordance with the Board’s requirements for labelling of products (Refer to Guidelines for Labelling)

3.2.2 Additional documentation

a) Drug master file for the active pharmaceutical ingredient (API) including details of route of synthesis

b) Forced degradation (Stress testing) report including chromatographs for the API and finished product (as per ICH guidelines)

c) Complete analytical method validation protocol and report for API and finished product (as per ICH guidelines Q2A and 2B)

d) Complete analytical method validation protocol and report for related substances and impurities (as per ICH guidelines Q3A and 3B)

3.2.3 Bioequivalence Study

a) A comprehensive bioequivalence study report conducted in accordance with the Board’s guidelines for conducting bioequivalence studies shall be submitted. (Refer to guidelines for conducting bioequivalence studies).

3.2.4 Clinical Trial

a) A protocol for the conduct of a local Phase III clinical trial in Ghana shall be submitted.

b) The report of the clinical trial shall be submitted to the Board upon completion of the study.