FOOD AND DRUGS AUTHORITY

GUIDELINE FOR REGISTRATION OF FOOD/NUTRITIONAL/DIETARY SUPPLEMENTS

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TABLE OF CONTENT

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1. SCOPES

In pursuance of Section 118 of the Public Health Act 2012, Act 851, this guideline is made to provide guidance to applicants on the procedure for registering food/nutritional/dietary supplements in Ghana. Applicants are encouraged to familiarize themselves with this document and the above law before completing the registration form.

2. INTERPRETATION

In this guideline, unless the context otherwise states: -

"**Authority**" means Food and Drugs Authority

"Product" means – a food, dietary or nutritional supplement

"**Applicant**" means the product owner or licence holder. Representatives of licence holders may not hold themselves as applicants unless they own the product.

"**Food/Dietary or Nutritional Supplement**" means - concentrated sources of nutrients or other substances produced in a pharmaceutical dosage form such as tablets, gelatine capsules (soft or hard), sachets, syrups and powders. Dietary components include herbs, vitamins and minerals (with concentration less than the recommended daily allowance), natural oils, royal jelly, pollen and bee propolis. All these ingredients can be included in dietary supplements on the condition that their sole function is supplementation and improvement of body function.

"**Medicinal Purpose**" means - use for treating or preventing a disease, diagnosing or ascertaining the presence and extent of a physiological function, contraception, inducing anaesthesia, altering normal physiologic function permanently or temporarily in any way in humans.

"**Variation**" means - a change in the indication(s), dosage recommendation(s), drug classification and/or patient group(s) for a previously registered drug being marketed under the same name in Ghana. A variation also includes, but is not limited to, a change in the product name, site of manufacture and/or source of ingredients.

3. REQUIREMENT

3.1. GENERAL REQUIREMENTS

Registration

a. An application for the registration of food/nutritional/dietary supplements shall be made in writing.
b. An application form shall be completed in accordance with the sequence of appendices dated, signed and stamped by the applicant/license holder.

All certificates accompanying registration documents shall be submitted in English.

c. This shall be submitted in duplicate(hard and (or) soft copy) and accompanied by:

I. A covering letter addressed to the CEO of the Authority,
II. Samples of the product as specified in the Authority's samples Schedule, packed in the final package ready for sale.
III. A non-refundable fee prescribed in the Authority's approved fees Schedule.

Variation

a) An application for the variation of registration of a product prior to re-registration shall be made to the Authority. This variation shall be approved by the Authority before any importation of the product shall be made into the country.

b) The application shall be accompanied by:

I. Supporting documentation for the variation.
II. Samples reflecting the variation as specified in the Authority's samples Schedule.
III. Non-refundable variation fee as specified in Authority's approved fees Schedule.

Re-Registration

a. An application for the re-registration of a Herbal medicinal product should be made 3 (three) months before the expiration of the registration.

b. The application shall be accompanied by:

I. Supporting documentation for any changes since the product was last registered
II. Samples as specified in the Authority's Sample Schedule.
III. A non-refundable application fee as specified in the Authority's Fee Schedule.

The re-registration shall be approved by the Authority before any importation of the product, other than those used as samples for the purpose of this application, shall be made into the country.

3.2. SPECIFIC REQUIREMENTS

The presentation of the product shall not have any resemblance in spelling and pronunciation of name or packaging to another product that has been previously registered by the Authority.

All samples of oral liquid preparations (solutions, syrups) shall have an appropriate graduated plastic measure included in the final package.

All samples submitted shall conform to labelling regulations in force in Ghana (*Refer to Food and Drugs Authority Guidelines for Labelling of Products*).

If the product is manufactured on contract basis, evidence of the contract shall be submitted. This information shall be clearly stated on the product label and package insert.

Stability study reports, performed under the conditions specified below shall be submitted:-

a) WHO Zone IV B climatic conditions

Condition	**Accelerated**	**Real Time**
Storage Temperature	40 $\pm$ 2 ^{o}C	30 ^{o}C
Relative Humidity	75 $\pm$ 5 %	70 %
Duration	6 months	Until end of shelf life

b) The stability study shall be conducted in the container closure system in which it will be marketed in Ghana.

4. **The Authority** in considering an application:

   a) shall satisfy itself that the there is need to have the product registered in Ghana.

   b) reserves the right to conduct a Good Manufacturing Practice (GMP) audit inspection on the manufacturing facility for the product at a fee prescribed by the Authority.

   c) may ask the applicant to supply such other information as may be required to enable it reach a decision on the application.

I. An appeal for the review of an application may be made in writing to the Ministry of Health within thirty (30) days of receipt of the rejection notice.

II. Where the Authority is satisfied that there is the need to register a product and all requirements for its registration have been satisfied, it shall do so and issue to the applicant a certificate of registration, subject to such conditions as may be prescribed by the Authority from time to time.

III. The registration of a product under these regulations, unless otherwise revoked, shall be valid for a period of three (3) years and may be renewed.

IV. No information given in this application shall be disclosed by the Food and Drugs Authority to a third party except:-

   a) with the written consent of the licence holder; or

   b) in accordance with the directive of the Directors of FDA; or

   c) for the purpose of a legal process under the Public Health Act 2012, Act 851

5. **The Authority** shall cancel, suspend, or withdraw the registration of a product if:-

   a) the grounds on which it was registered is later found to be false; or

   b) the circumstances under which it was registered no longer exist; or

   c) any of the provisions under which it was registered has been contravened; or

   d) the standard of quality, safety and efficacy, as prescribed in the documentation for registration is not being complied with; or

e) the premises, in which the product or part thereof is manufactured, packaged or stored by or on behalf of the holder of the certificate of registration is unsuitable for the manufacture, packaging or storage of the food/nutritional supplement.

f) Where the registration of a food/nutritional supplement is suspended, withdrawn or cancelled, the Authority shall cause the withdrawal from circulation of that product and shall accordingly cause the suspension, cancellation or withdrawal to be published in the Gazzette.