



# FOOD AND DRUGS AUTHORITY

08<sup>th</sup> January 2024  
FDA/DNC/GDL - 07/02  
Technical Advisory Committee on Safety of Medicines

## Guideline on Registration of Veterinary Nutritional-Dietary Supplements

Draft written by Drug and Herbal Medicines Directorate	N/A
Draft reviewed by QMS	N/A
Start of public consultation	N/A
Adopted by TAC	1 <sup>st</sup> June 2017
Final Quality Assurance Review	11 <sup>th</sup> December 2023
Approved by CEO	14 <sup>th</sup> December 2023
Date of coming into effect	8 <sup>th</sup> January 2024

## Document Revision History

<b>Date of Revision</b>	<b>Version Number</b>	<b>Changes made and/or reasons for revision</b>
15 <sup>th</sup> June 2017	01	Initial issue
08 <sup>th</sup> January 2024	02	General review of the Guideline in line with the current structure.

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## Executive Summary

This guideline specifies the minimum requirements of procedure and documentation for registering veterinary nutritional/dietary supplements in Ghana.

### 1. Introduction

#### 1.1 Legal Basis

This Guideline is developed in pursuance of Section 118 of the Public Health Act, 2012, Act 851.

#### 1.2 Scope

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 veterinary nutritional/dietary supplements in Ghana. Applicants are encouraged to familiarize themselves with this document and the above law before completing the registration form.

### 2. Definitions

In this guideline, unless the context otherwise states:

- “**Authority**” means Food and Drugs Authority
- “**Product**” means – a dietary or nutritional supplement for veterinary use
- “**Applicant**” means the product owner or license holder. Representatives of license holders may not hold themselves as applicants unless they own the product
- “**Local agent**” means locally appointed representative
- “**Veterinary Nutritional/ Dietary 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, natural oils, or any component prescribed by the Authority for use as a nutritional/ dietary supplement. All these ingredients can be included in dietary supplements on the condition that their sole function is supplementation and improvement of body function.
- “**Variation**” means - a change in the indication(s), dosage recommendation(s), classification, target species for a previously registered veterinary nutritional/ dietary supplement 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**

##### **3.1.2 Registration**

1. An application for the registration of veterinary nutritional/dietary supplements shall be made and submitted through the local agent/ local representative.
2. An application form shall be completed, dated, signed and stamped by the applicant/license holder.
3. All required documentation and certificates shall be attached in the sequence specified in the veterinary nutritional/ dietary supplement application form.
4. Completed applications shall be submitted in duplicate as two soft copies.
5. The completed application shall be accompanied by:
  - i. A covering letter addressed to the CEO of the Authority (hard copy)
  - ii. Samples of the veterinary product as specified in the Authority's Samples Schedule and packed in the final package ready for sale.
  - iii. A non-refundable fee prescribed in the Authority's approved Fees Schedule.

##### **3.1.3 Variation**

In the event of post-approval changes, the Authority shall be notified of the changes and implemented upon approval from the Authority.

- a) An application for the variation of a registered veterinary nutritional/ dietary supplement shall be made to the Authority and shall be approved by the Authority before any importation/ sale in the country.
- b) The variation application shall be accompanied by:
  - i. Supporting documentation for variation.
  - ii. Samples reflecting the variation as specified in the Authority's samples Schedule.
  - iii. Nonrefundable variation fee as specified in Authority's approved fees Schedule.

### 3.1.4 Renewal of Registration

- a) An application shall be submitted for the renewal of registration after the validity of the registration of product has expired.
- b) An application for the renewal of a veterinary nutritional/ dietary supplement shall be made 3 (three) months before the expiration of the registration.
- c) The application shall be accompanied by:
  - i. Certificate of analysis of the finished product
  - ii. Long term stability report for three commercial batches of the finished product
  - iii. Free Sale Certificate issued by the competent regulatory authority in the country of origin of the finished product
  - iv. Samples as specified in the Authority's Sample Schedule.
  - v. A non-refundable application fee as specified in the Authority's Fee Schedule.

### 3.2 Specific Requirements

- The presentation of the veterinary nutritional supplement 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 multi-dose liquid and powder preparations shall have an appropriate graduated measure included in the final package.
- All samples submitted shall conform to the Product Literature Standard for Veterinary Medicines in force in Ghana (*Refer to Food and Drugs Authority Product Literature Standard for Veterinary Medicines*).
- For products manufactured on contract basis, evidence of the contract shall be submitted to the Authority. 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:

<b>Condition</b>	<b>Accelerated</b>	<b>Real Time</b>
Storage Temperature	40 + 2 °C	30 °C
Relative Humidity	75 + 5 %	75 %
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.

- The Authority in considering an application:
  - a. Shall satisfy itself that 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 to reach a decision on the application.
- 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.
- 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.

#### **4. Cancellation of an Application**

**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 veterinary nutritional/dietary supplement.
- f) Where the registration of a veterinary nutritional/dietary 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 Gazette.