



Document No.: VET/GUD/001

**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

Page 1 of 30



Zambia Medicines Regulatory Authority

**GUIDELINES ON THE APPLICATION FOR GRANT OF MARKETING AUTHORISATION
OF NUTRITIONAL SUPPLEMENTS AND FEED ADDITIVES FOR ANIMAL USE IN
ZAMBIA**

Contact details:
Head Office, Plot No 2350/M, Off Kenneth Kaunda International Airport Road
P.O. Box 31890, Lusaka, ZAMBIA
Tel: +260 211 220429,
E-mail: pharmacy@zamra.co.zm;
Website: www.zamra.co.zm

	Name	Designation	Date
Prepared by	Mr.Lyoko Nyambe	Director-Marketing Authorisation	25-05-2025
Reviewer	Mr. Makomani Siyanga	Director-General	25-05-2025
Approver	Mr Robert Simeza, SC	Board Chairperson	25-05-2025

Version No. 1



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

Contents

1. INTRODUCTION 4

2. OBJECTIVES 4

3. SCOPE 4

4. DEFINITION 4

 6.1 Applications 9

 6.2 Product application 9

 6.3 Requirements for an application 9

 6.4 Application fees 10

 6.5 Mode of Submission 11

 6.6 Screening..... 11

 6.7 Evaluation of applications for grant of Marketing Authorisation..... 12

 6.8 Quality analysis..... 12

 6.9 cGMP inspection of the manufacturing facility or Hazard Analysis Critical Control Point (HACCP) Certificate 12

 6.10 Grant of Marketing Authorisation..... 13

 6.11 Appeals..... 13

 6.12 Amendment to Marketing Authorisation for a Nutritional Supplement, Premix and Feed Additive..... 13

 6.13 Retention fees..... 13

 6.14 Vigilance 14

 6.15 Renewal of Marketing Authorisation..... 14

7. PRODUCT DOSSIER 14

 7.1 Dossier Format..... 14

 7.2 Part I: Administrative Documents and Product Summary 15

 7.3 Part II: Raw Materials Quality Data (Specification)..... 18

 7.4 Part III: Quality Data of Finished Product 20

 7.5 Part IV: Safety Data 24



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

7.6 Part V: Labelling Requirements for Nutritional Supplement, Feed Additives for animal use
24

8. ANNEXTURES..... 27

8.1 ANNEX 1: Dossier Submission Checklist..... 27

8.2 ANNEX 2 - Standards..... 30



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

1. INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) regulates medicines and allied substances in accordance with the provisions of the Medicines and Allied Substances Act No. 3 of 2013, (hereinafter referred to as “the Act”) and the relevant Regulations made thereunder.

These guidelines for Grant of Marketing Authorisation for nutritional supplements and feed additives for animal use are issued by the Authority pursuant to section 68 of the Act and prescribes the information to be incorporated in the applications for grant of Marketing Authorisation by an applicant who intends to place on the Zambian market nutritional supplements, and feed additives for animal use in accordance with Section 39 of the Act. The Authority may from time to time amend any part of these guidelines.

2. OBJECTIVES

These guidelines are intended to be the reference document for use by an applicant in the preparation of Product Dossiers by providing general guidance on the application requirements.

3. SCOPE

These guidelines apply to nutritional supplements, and feed additives for animal use.

4. DEFINITION

In these guidelines, unless the context otherwise requires -

“**Act**” Means the Medicines and Allied Substances Act (No. 3) of 2013;

“**Authority**” Means the Zambia Medicines Regulatory Authority;

“**Claim**” means any representation that states, suggests, or implies that a relationship exists between a nutritional supplement and health;
Version No. 1



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

“Composition” means the ingredients contained in a Nutritional Supplement and feed additive product and their proportions;

“Container closure system” means the sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the Nutritional Supplement product;

“Nutritional Supplement” means food supplement, dietary supplement, health supplement or nutraceutical product intended to supplement the diet, and shall include all of the following characteristics: -

- (a) contains one or more of the following: vitamins; minerals; amino acids; essential oils; natural substances of plant or animal origin; enzymes; substances with nutritional or physiological function.
- (b) is intended to be taken in the form of tablet, capsule, powder, softgel, gelcap, granules or liquid or any other conventionally approved dosage form.
- (c) is not represented for use as conventional feed
- (d) is labelled as such.

“Good Manufacturing Practices” Means a system for ensuring that products are consistently produced and controlled according to quality standards;

“Label” Means to affix to, or otherwise display on, a container or package, a notice describing the ingredient and contents thereof;



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

“Labelling” Means the label, instructions for use, and any other information that is related to identification, description, intended purpose and proper use of the Nutritional Supplement product, but excluding shipping documents;

“Laboratory” Means the National Drug Quality Control Laboratory; or an appropriate accredited laboratory recognised by the Authority;

“Local Responsible Person” Means a person, resident in Zambia, appointed by a foreign-based Marketing Authorisation Holder to be responsible for all regulatory matters in respect of products granted Marketing Authorisation with Power of Attorney;

“Manufacture” Means all operations involved in the production, preparation, processing compounding, formulating, filling, refining, transformation, packing, packaging, repackaging and labelling of Nutritional Supplement products;

“Manufacturer” Means any person or institution with the responsibility to develop and/or manufacture Nutritional Supplement products with the intention of making the Nutritional Supplement product available for use;

“Marketing Authorisation” Means the authorisation granted under section 39 of the Medicines and Allied Substances Act (No. 3) of 2013 for the placement of a medicine or allied substance on the Zambian Market;

“Product Dossier” Means the collection of the various documents and data (including Regulatory Data and Regulatory Documentation) concerning the research, development, manufacture, safety, quality and efficacy of a product submitted for marketing authorisation;

“Shelf Life” Means the period of time during which a Nutritional Supplement or feed additive product, if handled and stored correctly, is expected to stay within the set acceptance criteria as determined by Stability Studies;



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

“Efficacious” means, a product is capable of producing the intended results; suitably formulated using ingredients allowed in animal feed;

“Feed additives” means substances, micro-organisms or preparations, other than feed material, which are intentionally added to feed or water in order to; favorably affect the characteristics of feed, the characteristics of animal products, satisfy the nutritional needs of animals, the environmental consequences of animal production, animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feeding stuffs

“Technological additives” means any substance which favourably affects the characteristics of feed.

“Sensory additives” means any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals.

“Nutritional additives” means any substance added to feed to satisfy the nutritional needs of animals and includes, vitamins, pro-vitamins and chemically well-defined substances having similar effect, compounds of trace mineral elements, amino acids, their salts and analogues.

“Zootechnical additives” means any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment and includes the following functional groups, digestibility enhancers such as enzymes, micro-organisms and substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials, gut flora stabilizers such as micro-organisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora;

“Custom premix” means a mixture compiled on the written advice of a qualified person for a specific client or a mixture of registered ingredients mixed at the written request of an end user.

“Premix” means a product containing a mixture of two or more additives with substances used as carriers **intended for the manufacture of animal feeds** and contains nutrients and/or other ingredients in quantities and such ratios that it will supply the prescribed requirements for animals and may be organisms which protect feed against deterioration caused by micro-organisms or their metabolites..



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

“**Nutritional additives**”, includes the following functional groups are included: vitamins, pro-vitamins and chemically well-defined substances having similar effect; compounds of trace mineral elements; amino acids, their salts and analogues;

”**Medicated Premixes**” A medicated premix is a premix containing a medicine as defined by the Medicines and Allied Substances Act.

Note: All premixes containing coccidiostats are considered medicated and hence required to refer to Guidelines on Grant of Marketing Authorisation for Veterinary Medicines.

5. ABBREVIATIONS

ASEAN - Association of Southeast Asian Nations

BSE - Bovine Spongiform Encephalopathy

FAO – Food and Agricultural Organisation

GMP - Good Manufacturing Practice

MA - Marketing Authorisation

MAH - Marketing Authorisation Holder

TSE - Transmissible Spongiform Encephalopathies

INN - International Nonproprietary Names

INNМ - International Nonproprietary Names Modified

NDQCL - National Drug Quality Control Laboratory

WHO-World Health Organisation

ZAMRA - Zambia Medicines Regulatory Authority

Version No. 1



6. GENERAL REQUIREMENTS

6.1 Applications

An application for Marketing Authorisation of a nutritional supplement, or feed additive for Animal Use shall be made by:

- a) a manufacturer who intends to place a nutritional supplement, or feed additive for Animal Use for sale on the Zambian market;
- or
- b) the local responsible person with power of attorney from a foreign based manufacturer

6.2 Product application

An applicant shall submit an application in electronic text selectable/editable PDF format in a prescribed manner and form.

6.3 Requirements for an application

An application for grant of Marketing Authorisation for nutritional supplements, feed additives for animal use shall comprise the following:

- (a) Cover letter from the applicant;
- (b) A duly completed and signed application form;
- (c) Proof of payment of the prescribed application fee;
- (d) At least two (2) samples of the product packaged in the smallest commercial pack, where applicable, supplied with the intended consumer packaging labelled in English and shall be physically submitted to the Authority.
- (e) A duly completed checklist as set out in Annex 1 indicating the sections of the application that have been completed and the pages thereof; and



(f) Product dossier.

i. Documentation

An applicant shall submit a product dossier as an electronic, text selectable PDF format or in any other manner prescribed by the Authority.

ii. Language

An application and its supporting documents shall be in English. Other supporting documents (such as GMP certificates, Certificates of Analysis) submitted in a foreign language shall be accompanied with certified translated copies.

iii. Presentation of the application

Information shall be presented in legible manner with recommended font size of 12 in Times New Roman or Arial font type of 1.5 line spacing and standard margin.

Each page shall be numbered sequentially. Extension sheets, tables, diagrams and other supporting documents shall as far as possible be of the same size, well annotated, numbered and appropriately cross-referenced.

Where original certificates are in another language, copies shall be presented together with certified translations.

6.4 Application fees

An application for grant of Marketing Authorisation for a nutritional supplement, feed additives for animal use shall be accompanied by proof of payment of the prescribed fees as set out in the Medicines and Allied Substances (Fees) Regulations 2016.



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

An application for grant of Marketing Authorisation for a nutritional supplement, feed additives for animal use shall only be received where it is accompanied by the requirements for an application stated in clause 6.3 above.

Bank charges shall be borne by the applicant who shall ensure that proof of payment is submitted to the Authority.

Marketing Authorisation fees for a nutritional supplement, feed additives for animal use shall cover the costs of evaluating the initial submission only and exclude laboratory testing and GMP inspection fees which shall be charged separately.

If an applicant fails to provide all the requested information, or the submitted information is incomplete, deficient or irrelevant, the application shall not be accepted.

6.5 Mode of Submission

An applicant shall submit an application accompanied by a product dossier that is presented in an electronic text selectable or editable PDF format.

6.6 Screening

- a) An application shall be screened for completeness by the Authority before evaluation to ensure that there are no deficiencies that would hinder the evaluation process.
- b) Where deficiencies are identified during screening of an application, a request for additional information shall be made to the applicant.
- c) Subject to 6.6.1, an applicant shall be required to submit all the requested additional information within 60 days from the date of receipt of the request.
- d) Where an applicant does not respond to the request for additional information within 60 days, the application shall be rejected.

Version No. 1



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

- e) Where an applicant fails to provide all the requested information, or the submitted information is incomplete, deficient or irrelevant, the application shall be rejected.
- f) An application not submitted in the prescribed format shall be rejected.
- g) Where the application has been rejected, the applicant shall be informed in writing providing reasons for the rejection.

6.7 Evaluation of applications for grant of Marketing Authorisation

An application shall be evaluated on a first come first serve basis unless expedited evaluation has been authorised by the Authority.

Where the Authority processes an application for the Grant of Marketing Authorisation, the applicant shall be informed of the outcome of the evaluation process.

6.8 Quality analysis

A risk-based approach for quality analysis for veterinary nutritional supplement, premixes, feed additives for animal use and where necessary, samples shall be analyzed by the Authority or any other accredited laboratory against the claimed manufacturer's specifications in accordance with the latest available Zambian standards and International compendia such as British Pharmacopeia (BP), United States Pharmacopeia (USP), European Pharmacopeia (Ph. Eur) or International Organisation for Standardization (ISO) or any other relevant standards as prescribed by the Authority.

6.9 cGMP inspection of the manufacturing facility or Hazard Analysis Critical Control Point (HACCP) Certificate

The Authority may after review of an application carry out a Good Manufacturing Practice inspection of the manufacturing site.

An applicant shall be required to facilitate for GMP inspection of the manufacturing site in order to demonstrate compliance with current Good Manufacturing Practices (cGMP). A prescribed GMP inspection fee shall be payable.



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

6.10 Grant of Marketing Authorisation

The Authority shall grant Marketing Authorisation if the product meets the aspects of quality, safety and efficacy, and any other requirements as set out in these guidelines.

A Marketing Authorisation shall be valid for five (5) years subject to terms and conditions as may be specified by the Authority from time to time.

6.11 Appeals

An applicant who may be aggrieved by a decision made by the Authority for the grant of marketing authorisation may seek redress in accordance with the provisions of the Act

6.12 Amendment to Marketing Authorisation for a Nutritional Supplement, Premix and Feed Additive

A Marketing Authorisation Holder (MAH) who wishes to amend a Marketing Authorisation shall apply to the Authority. The application shall be accompanied by proof of payment of the prescribed amendment fee as set out in the Medicines and Allied Substances (Fees) Regulations 2016. Any such changes shall require approval by the Authority before the product is placed on the market.

6.13 Retention fees

A Marketing Authorisation Holder (MAH) shall pay the prescribed annual product retention fee for the following year by 31st December of each year. Where the MAH fails to pay the annual retention fee by 31st December:

- (a) The Authority shall not authorize the importation of the Nutritional Supplement, Premixes and Feed Additives;
- (b) In case of a locally manufactured Nutritional Supplements, Premixes and Feed Additives, the Authority shall not authorize the continued manufacture of the product;
- (c) The Marketing Authorisation issued shall be suspended; and



(d) The Marketing Authorisation may be revoked by the Authority.

6.14 Vigilance

A Marketing Authorisation Holder shall put in place a vigilance system to monitor the quality and safety of a Nutritional Supplement, Premixes and Feed Additives placed on the Zambian market. The MAH shall ensure that modalities to provide routine reports to the Authority on any findings regarding the product are in place. The MAH shall appoint a qualified person responsible for vigilance.

6.15 Renewal of Marketing Authorisation

A MAH who intends to renew a Marketing Authorisation shall apply to the Authority in the prescribed form.

The application shall be accompanied with proof of payment of the prescribed fee as set out in the Medicines and Allied Substances (Fees) Regulations 2016.

An application for renewal of MA shall be made at least one hundred and eighty (180) days before the expiry date of the Marketing Authorisation.

Applications for renewal shall be submitted in line with Guidelines for Renewal of Marketing Authorisation.

7. PRODUCT DOSSIER

7.1 Dossier Format

An applicant intending to place a Nutritional Supplement, Premixes, Feed Additives for animal use on the market shall be required to organize the product dossier in such a way that it meets these requirements. A product dossier shall be organised into five (5) parts as follows:

Part I: Administrative Documents and Product Summary



Part II: Raw Materials Quality Data (Specification)

Part III: Quality Data of Finished Product

Part IV: Safety Data

Part V: Labelling Requirements for Nutritional Supplement, Feed Additives for animal use

A Table of Contents shall be provided for each of the five (5) parts

7.2 Part I: Administrative Documents and Product Summary

This part shall contain the administrative documents and key summary information that are specific to a Nutritional Supplement, Feed Additives for animal use.

A. Administrative documentation:

1. A duly completed application form that shall include details of the applicant, proposed Marketing Authorisation Holder (MAH), the summary of product characteristics, details of the manufacturer and manufacturing site.
2. Details of the appointed local responsible person with power of Attorney (where applicable)
3. Any other relevant administrative documents (for example, Certificates of registration, free sale certificates, certificates of conformity (BSE/TSE), Manufacturing licenses, GMP certificates)
4. Where the product is not manufactured by the applicant, a contract between the applicant and the manufacturer of manufacture shall be submitted



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

B. An applicant shall provide technical information of product characteristics which will be known as summary of product characteristics (SMPC) and shall include the following:

- I. Name of product;
- II. Product Description;
- III. Qualitative composition and reference standards;
- IV. Quantitative composition and reference standards;
- V. Clinical particulars:
- VI. Indications
- VII. Dosage / inclusion rate and method of administration
- VIII. Contraindications
- IX. Special warnings and precautions for use
- X. Interaction with other medicinal products and other forms of interaction
- XI. Use in Pregnancy and lactation
- XII. Use in animal species or whose produce is meant for human consumption
- XIII. Undesirable effects

Version No. 1



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

- XIV. Overdose
- XV. Safety data
- XVI. List of active ingredients stating recommended daily allowance (where applicable)
- XVII. List of excipients
- XVIII. Incompatibilities
- XIX. Shelf life
- XX. Storage condition
- XXI. Nature and contents of container
- XXII. Special precautions for disposal and other handling
- XXIII. Details of Marketing Authorisation holder
- XXIV. Marketing authorisation number
- XXV. Date of grant of Marketing Authorisation
- XXVI. Details of the Manufacturer and Manufacturing site
- XXVII. Packaging
- XXVIII. Date of revision of the text of the SMPC (where applicable)



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

C. Maximum amounts of vitamins and minerals in Nutritional The Accepted pharmacopoeia references are the British Pharmacopoeia, European Pharmacopoeia, US Pharmacopoeia, the International Pharmacopoeia, the codex Alimentarius as well as recognized literature. In House methods shall be required to be validated

D.Safety Information:

Safety Information shall be provided that highlights the safety of all raw materials used in the formulation of the product for the target species including peer reviewed articles.

7.3 Part II: Raw Materials Quality Data (Specification)

This Module of the Application for the registration of a Nutritional Supplement / feed additive, concerns demonstration of the quality of the product, including the identity, impurities and stability of the ingredients. The data assessment also considers the manufacturing processes and standards of good manufacturing practice (GMP), as required.

This part shall include full technical information on the quality of the raw materials.

A. Specifications and analytical test methods of raw material:

1. Specifications for each raw material shall be provided; For raw materials of plant origin, parameters shall include amongst others:

a. Heavy Metals

b. Pesticide residues

c. Aflatoxins

2. Analytical test methods for each raw material;

Version No. 1



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

3. Analytical test results and copies of certificates of analyses for at least one batch of each raw material; and
4. Name and address of the manufacturer.

Where a raw material is of herbal nature, an applicant shall further provide information on the source of the ingredient, whether wild or cultivated.

B. An applicant shall provide data on the safety of the raw materials based on either of the following:

1. Data from the manufacturer or supplier; or
2. Reports and/or information from recognized international scientific organizations such as the CODEX Alimentarius commission, WHO or FAO.

C. Excipients used in the manufacture of Nutritional Supplement, Feed Additives for animal use shall comply to current national standards or other quality specifications such as those prescribed by ISO and any other internationally recognised standards.

An applicant shall be required to provide declarations on excipients of animal origin such as Transmissible Spongiform Encephalopathy (TSE)/ Bovine Spongiform Encephalopathy (BSE).

A declaration on Talc shall also be provided stating that the Talc used is free from Asbestos.

Additives/excipients such as fillers, artificial colours, sweeteners, flavours, or binders shall be listed by their specific names/E-numbers and qualified by words “natural” or “artificial” in descending order in weight or volume e.g. E110/Sunset yellow as artificial colourant.



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

7.4 Part III: Quality Data of Finished Product

This shall include detailed technical information on the quality of the finished product.

The following shall be provided:

i. Z Product Composition

A product should have both qualitative and quantitative composition (Unit and batch) and also information on International Nomenclature of Nutritional Supplement Ingredient (INCI) or other approved international reference names, corresponding concentrations of the raw material and the functions of each raw material.

The product composition shall be as presented in the table below:

S N	INN/Botanic al Name	Reference Standard/Mono graph	Quantity Per Unit (e.g. g/mg)	Quantit y Per Batch (e.g. g/kg)	Recommende d Daily Allowance	Reason for Inclusion
--------	------------------------	-------------------------------------	-------------------------------------	---	------------------------------------	----------------------------

a) Manufacturing

The following information/documents shall be provided in relation to manufacturing:

1. Manufacturer's contact details;

Version No. 1



2. Name and address of manufacturing site;
3. A copy of the manufacturing license and Good Manufacturing Practice (GMP) certificate or HACCP certificate;
4. Detailed manufacturing process including the process flow chart and narrative of the manufacturing process; and
5. In-process quality controls, equipment and their capacities, batch manufacturing and packing records.

b) Quality Specifications and Analytical Test Methods of The Finished Product

The following signed, dated and version-controlled documents shall be provided:

1. Quality specifications for the finished product;
2. Analytical test methods for the finished product;
3. Validation of the methods and
4. Three certificates of analysis for typical batches.

c) Quality specifications for the Packaging

The following information that shall include signed, dated and version-controlled documents/information shall be provided:

1. Quality specifications and analytical test methods for primary and secondary packaging materials;
2. At least one certificate of Analysis for primary and secondary packaging materials;



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

3. Container Closure System – Product Compatibility studies; and
4. Declaration that the materials used are feed grade.

d) Stability Data

I. Stability data for the finished product is essential for verification of the shelf life. To verify the shelf life, the applicant is required to submit the following information:

- a. Stability protocol
- b. Storage temperature and humidity for example long term studies at $30^{\circ}\text{C}\pm 2$ / 60 ± 5 Relative Humidity and accelerated studies at $40^{\circ}\text{C}\pm 2$ / $75 \pm 5\%$ Relative Humidity for at least 6 months;
- c. Stability indicating parameters monitored;
- d. Duration and frequency of study;
- e. Container closure system; and
- f. Discussion of the results.

II. Stability data shall be presented in a tabular form given below:

Long term stability studies

Version No. 1



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

30°C / 65/75 % Relative Humidity	Month 1	Month 2	Month 3...
Parameter 1			
Parameter 2			
Parameter 3			

Accelerated stability studies

40°C / 75 % Relative Humidity	Month 1	Month 2	Month 3...
Parameter 1			
Parameter 2			
Parameter 3			

Where available long-term stability data on primary batches does not cover the proposed shelf-life of the finished product that was granted at the time of approval, a commitment should be made by the applicant to continue the stability studies post approval in order to firmly establish the shelf life. Where the submission includes data from acceptable stability studies on at least three production batches a post approval commitment is considered unnecessary. Otherwise, one of the following commitments should be made:

Version No. 1



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

- (i) If the submission includes data from stability studies on at least three production batches, a commitment should be made to continue the long-term studies through the proposed shelf life and the accelerated studies for 6 months.
- (ii) Where the submission includes data from stability studies on fewer than three production batches, a commitment should be made to continue the long-term studies through the proposed shelf life and the accelerated studies for 6 months, and to place additional production batches, to a total of at least three, on long term stability studies through the proposed shelf life and on accelerated studies for 6 months.
- (iii) where the submission does not include stability data on production batches, a commitment should be made to place the first three production batches on long term stability studies through the proposed shelf life and on accelerated studies for 6 months. The stability protocol used for studies on commitment batches should be the same as that for the primary batches, unless otherwise scientifically justified.

Note: For further guidance, refer to the stability guidelines available on the Authority website.

7.5 Part IV: Safety Data

This part shall include detailed information on the safety assessment and data of the finished product and relevant efficacy data were applicable to support any claims made on a product.

For Nutritional Supplements containing herbal ingredient(s) an applicant shall submit additional information to demonstrate the safety of each herbal ingredient in human beings e.g. through bibliographic or scientific studies.

7.6 Part V: Labelling Requirements for Nutritional Supplement, Feed Additives for animal use

For the purposes of these guidelines the following are the general labelling requirements:



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

1. Nutritional Supplement / Feed Additives for animal use shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.
2. Nutritional Supplement, Feed Additives for animal use shall be labelled in such a way that:
 - a. It does not in any way either directly or indirectly purport to prevent, diagnose, treat, cure or mitigate any disease;
 - b. Imply that Nutritional Supplements can be used for the replacement of whole feed.
3. The label of the Nutritional Supplement / Feed Additive for animal use shall contain a cautionary statement where applicable e.g. adverse effects or risks of excessive intake, contraindications, any warning and precautions associated with the use of the product..

a) Requirements for Ingredients

1. Except for single ingredient Nutritional Supplements, a list of ingredients shall be declared on the label with the corresponding quantities per specified unit of measure.
2. All ingredients shall be listed in descending order by weight or volume at time of manufacture of Nutritional Supplement.
3. If the ingredient is from animal or plant, scientific name of the plant and part of animal or plant used shall be declared.
4. Label must declare in numerical form the amount of nutrients presents in the product per portion of the product as recommended for daily consumption or amount per unit for single use. The information should be provided in tabular format.
5. Labelling must include the quantity per intake for each ingredient, the form and source e.g. "calcium in form of calcium carbonate from oyster shell.



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

6. Additives/excipients such as fillers, artificial colours, sweeteners, flavours, or binders shall be listed by their specific names/E-numbers and qualified by words “natural” or “artificial” in descending order in weight or volume e.g. E110/Sunset yellow as artificial colourant.

b) Net content and weight

The net contents shall be declared in the metric system (SI units) by weight for solid or powdered products, volume for liquid or number for tablets and capsules.



Guidelines on the Application for Grant of Marketing Authorisation of Nutritional Supplements and Feed Additives for Animal Use in Zambia

8. ANNEXTURES

8.1 ANNEX 1: Dossier Submission Checklist

ZAMBIA MEDICINES REGULATORY AUTHORITY

MARKETING AUTHORISATION SECTION

Dossier Submission Checklist – Feed Additives and Nutritional Supplements

A completed copy of the checklist should be included in the dossier.

a) Supporting documents

Supporting documents	Yes (Y)/ No (N)/ Not aplicable (N/A)	Comment (Section and page number)	<i>For ZAMRA Use Only</i>
cover letter for application form			
Application form			
Proof of payment			



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

Samples (2)			
Samples CoA			
Free Sale Certificate			
GMP/HACCP Certificate and Manufacturing License			
Package insert			
Product Label (Mock up cartons)			

b) Product Dossier



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

SECTIONS	Description	Yes (Y) No (N)	Comment (Section and page number)	<i>For ZAMRA Use Only</i>
Part I	Administrative Documents and Product Summary			
Part II	Raw Materials Quality Data (Specification)			
Part III	Quality Data of Finished Product			
Part IV	Safety Data			
Part V	Labelling Requirements for Nutritional Supplements			



**Guidelines on the Application for Grant of Marketing
Authorisation of Nutritional Supplements and Feed Additives for
Animal Use in Zambia**

8.2 ANNEX 2 - Standards

The following pharmacopoeia and international standards are currently considered acceptable in their entirety:

- a) United States Pharmacopoeia (USP) including Dietary Supplements Compendium
- b) British Pharmacopoeia (BP)
- c) European Pharmacopoeia (Ph. Eur.)
- d) Pharmacopoeia Internationalis (Ph.I.)
- e) Japanese Pharmacopoeia (JP)
- f) Codex Alimentarius
- g) Ayurveda Pharmacopoeia of India (API)