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FOOD AND DRUGS AUTHORITY

GUIDELINES FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS

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INTRODUCTION

This guideline applies only to veterinary medicinal products. This guideline prescribes the minimum information required for submission of documentation as well as the appropriate format and organisation of the requisite data.

In this new format, each application is organised into parts. Applicants should not modify the overall organisation of the format. Applicants are requested to carefully read this guideline, fill in application form with requisite documentation and submit two electronic copies (in a Portable Document Format (PDF), on CD-Rom).

The guideline is divided into three parts as follows:

- I. Part One-: Administrative information**
- II. Part Two- A: Quality Documentation on Active Pharmaceutical Ingredient**
- III. Part Two- B: Quality Documentation on Finished Veterinary Product IV.
Part Three: Safety and Residue Information**

OBJECTIVE

This guideline presents a common format for the preparation of an application that will be submitted to the Food and Drugs Authority (FDA) for registration of veterinary medicinal products.

This revised guideline has been improved to assist in the following;

- Preparation of documentation for veterinary medicinal products by providing clear guidance on the format.
- Provide guidance on the technical and other general data requirements.
- Give more details on the requirements for active pharmaceutical ingredients (API) as well as finished veterinary medicinal products.

SCOPE

This guideline is issued in pursuance of Section 118 of the Public Health Act, 2012, Act 851, to provide guidance to applicants on the organization of information to be presented in registration applications for veterinary medicinal products.

LANGUAGE

All applications and supporting documents shall be in English and legible. Where material is not originally in English, a copy in the original language and a full translation should be submitted, the accuracy of the translation is the responsibility of the applicant. Authentication of the translation has to be done at the nearest Ghana Embassy or by the National Drug Regulatory Authority of the country from where the document originates. Reports submitted only in a language other than English will not be accepted.

DATA PRESENTATION

All information, data, tables, diagrams, attachments must be legible of font size 12 or more and shall be presented on in soft copy on CD-ROM. All pages shall be numbered sequentially with the format page numbered as **page x of y** and have a table of contents indicating the sections and page numbers in the relevant sections of the application form. Before submitting the completed form, check that you have provided all requested information. Acronyms and abbreviations should be defined the first time they are used in each part.

OFFICIAL REFERENCES AND TEXTS

When direct reference is made to specifications, quality control procedures and test methods in official compendia (FDA officially recognised list of publications), text books or standard publications, reprints or authenticated copies of relevant pages shall be enclosed. References to pharmacopoeias should be as per the current editions. References should be provided for all in-house processes.

SUBMISSION OF APPLICATION

- An application for the registration of a veterinary medicinal product, either locally manufactured or imported, shall be made in writing via a cover letter.
- The cover letter submitted with the dossier should include a clear statement by the applicant indicating that the information submitted is true and correct.
- If the applicant is a foreign company, it shall appoint a local agent through whom an application shall be submitted.
- The local agent shall be a company registered with the Registrar General of Ghana and appointed as a representative of the foreign company in Ghana.
- The application shall be submitted through the authorized local agent by the regulatory contact person to the following address:

The Chief Executive Officer
Food and Drugs Authority
P. O. Box CT 2783

Cantonment-Accra

For purposes of submission to FDA, applications are classified into three categories as follows:

New applications for registration

This is an application for registration of a veterinary medicinal product that is intended to be placed on the Ghanaian market for the first time.

A new application may only be made by the applicant and he/she shall be the person who signs the declaration portion of FDA application form.

A separate application is required for each product that differs in active ingredient(s), strength, dosage form, proprietary names though containing the same ingredients or is considered to be different products.

However, products containing the same active ingredients and the same strength made by the same manufacturer at the same manufacturing site, to the same specifications and dosage form, but differing only in packing or pack sizes require only one application.

A new application for registration shall include submission of:

- i. Two electronic copies of the dossier (Please refer to the FDA's website for the current version of the application form to be completed and submitted in support of an application).
- ii. Samples of the veterinary medicinal product as per FDA sample schedule. iii.
Reference standard for new chemical entities.
- iv. Non-refundable application fee for registration of medicines (Refer to FDA fee schedule).

Applications for Renewal of Registration

Applications for renewal of registration shall be made at least 3 months before the expiry of existing registration by submitting the following:

- 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. vi. Any other requirements that the FDA may determine from time to time.

Application for Variation of a registered veterinary medicinal product

All applications for variation to a registered product shall be made according to requirements stipulated in the FDA Application Guideline for Variation of Registered Medicinal Products and a non-refundable application fee as specified in the Authority's Fee Schedule.

PART ONE: ADMINISTRATIVE AND LABELLING INFORMATION

1.0 Cover letter

1.1 Table of contents of the application

1.2 Application information

1.2.1 Trade/Proprietary name

Trade/Proprietary name means the (trade or brand) name which is unique to a particular drug and by which it is generally identified. Refer to FDA Guidelines for labeling.

1.2.2 Approved / INN / generic name

Approved / INN / generic name means the internationally recognized non-proprietary name of such a drug.

1.2.3 Strength of the product

Strength of the product shall be given per unit dosage form or per specified quantity: e.g. mg per tablet, mg per capsule, mg per ml, mg per 5ml, mg per gram, etc.

1.2.4 Dosage form of the product

Dosage form of the product shall mean the form in which the drug is presented, eg. emulsion, ointment, suppository, tablet, capsule, solution, suspension, injections.

1.2.5 Pharmacological classification and indication

Specify clinical indication(s) which are supported by relevant information in the application dossier.

1.2.6 Container- Closure System

The container/closure description should include all parts of the primary packaging including desiccant, void filler or adsorbent cotton filler. Dimensions/volume/capacity may be listed. Shape and colour of the bottle and the cap type (including plastic e.g. PP), should be stated. E.g.: Blisters: colour and transparent/opaque.

1.2.7 Commercial presentation

Commercial presentation of the product shall mean the presentation of the product to be registered i.e. list all pack sizes intended for marketing. eg 10 x 1tablets, 10 x 10tablets, 10 x 1 capsules, 200mls, 1ml vial etc.

1.2.8 Category of distribution

Veterinary Medicine- Prescription

Veterinary Medicine- General Dealer's

1.2.9 Proposed Shelf life of the product

Proposed Shelf life of the product means the specified length of time prior to use for which pharmaceutical products are inherently subject to deterioration are deemed to remain fit for use under prescribed conditions.

1.3 Applicant

The name, physical address, telephone number, fax number, and e-mail address of the applicant/license holder.

1.4 Name and complete address(es) of the manufacturer(s) of the product The name, physical address, telephone number, fax number, and e-mail address of the manufacturer shall be provided.

- Where different activities of manufacture of a given product are carried out at different manufacturing sites, the information on the following should be provided.
- Name of the Manufacturer
- Full Physical address of the Manufacturing Site
- Activity at the manufacturing site

- A copy of a valid manufacturing License shall be provided for each site.

1.5 Authorised Local Representative (local agent)

Every applicant who is not resident in Ghana shall appoint one local representative who must be a company incorporated in Ghana and licensed by the Authority to import veterinary products.

1.6 Certificate of Pharmaceutical Product

Attach a valid Certificate of Pharmaceutical Product from the country of origin as per the WHO certification scheme and issued in the name of Ghana or with Ghana included in the list of importing countries.

1.7 International Registration Status

The applicant shall provide the regulatory status of the veterinary medicine in the country of origin and other countries. List of the countries in which product:

- Has been registered. (Attach certificate (s) of registration) Has been withdrawn
- Where an application for marketing in any country has been rejected, suspended, deferred or is pending.

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1.8 Certificate (s) of Suitability of the European Pharmacopoeia (CEP)

Copy of the latest version of Certificate (s) of Suitability of the European Pharmacopoeia (CEP) (including any annexes) should be provided where applicable.

1.9 Product Information for Veterinary Professionals (For all products subject to prescription)

Provide copies of the proposed Summary of Product Characteristics (SmPC) aimed at veterinary practitioners. It should be written in English, should be legible, indelible and comprehensible.

1.9.1 Product Information Leaflet/ Package Insert

Provide four (4) copies of package insert and any information intended for distribution with the product to the user. The package insert should be in conformity with the SmPC. It should be written in English, should be legible, indelible and comprehensible.

Labels (outer and inner labels)

Provide four (4) copies of the proposed outer and inner labels. It should be written in English, should be legible, indelible and comprehensible. The labeling is an essential part of registration and cannot be altered without the prior approval of FDA.

Veterinary Product Samples

Samples of the product and where applicable measuring devices as per the Authority's sample schedule shall be provided.

PART TWO A -QUALITY DOCUMENTATION ACTIVE PHARMACEUTICAL INGREDIENT

Drug Master File of Active Pharmaceutical Ingredient shall be submitted in the Common Technical Document (CTD) format as follows:

2.0 General Information

Information general properties of the API should be included as described in 3.2.S.1

2.1 Manufacture

Information should be included as described in 3.2.S.2:

- Information on the manufacturer
- A brief description of the manufacturing process (including, for example, reference to starting materials, critical steps, and reprocessing) and the controls that are intended to result in the routine and consistent production of material(s) of appropriate quality;
- A flow diagram
- A description of the Source and Starting Material and raw materials of biological origin used in the manufacture of the drug substance, as described in 3.2.S.2.3;
- A discussion of the selection and justification of critical manufacturing steps, process controls, and acceptance criteria. Highlight critical process intermediates, as described in 3.2.S.2.4.
- A description of process validation and/or evaluation, as described in 3.2.S.2.5
- A brief summary of major manufacturing changes made throughout development and
- Conclusions from the assessment used to evaluate product consistency, as described in 3.2.S.2.6.

2.2 Characterisation

A summary of the interpretation of evidence of structure and isomerism, as described in 3.2.S.3.1, should be included.

When a drug substance is chiral, it should be specified whether specific stereoisomers or a mixture of stereoisomers have been used in the nonclinical and clinical studies and information should be given as to the stereoisomer of the drug substance that is to be used in the final product intended for marketing.

2.3 Control of Drug Substance

A brief summary of the justification of the specification(s), the analytical procedures, and validation should be included. Specification from 3.2.S.4.1 should be provided. A tabulated summary of the batch analyses from 3.2.S.4.4, with graphical representation where appropriate, should be provided.

2.4 Reference Standards or Materials

Information from 3.2.S.5 (tabulated presentation, where appropriate) should be included.

2.5 Container Closure System

A brief description and discussion of the information, from 3.2.S.6 should be included.

2.6 Stability

This section should include a summary of the studies undertaken (conditions, batches, analytical procedures) and a brief discussion of the results and conclusions, the proposed storage conditions, retest date or shelf-life, where relevant, as described in 3.2.S.7.1.

The post-approval stability protocol, as described in 3.2.S.7.2, should be included. A tabulated summary of the stability results from 3.2.S.7.3, with graphical representation where appropriate, should be provided.

PART TWO B -QUALITY DOCUMENTATION

2.0 Qualitative and quantitative composition of product (including excipients and their role in the formulation)

A batch formula should be provided that includes a list of all components of the dosage form to be used in the manufacturing process, their amounts on a per batch basis, including overages, and a reference to their quality standards.

2.1 Description of Manufacturing Process and Process Controls

A flow diagram should be presented giving the steps of the process and showing where materials enter the process. The critical steps and points at which process controls, intermediate tests or final product controls are conducted should be identified. A narrative description of the manufacturing process, including packaging that represents the sequence of steps undertaken and the scale of production should also be provided. Novel processes or technologies and packaging operations that directly affect product quality should be described with a greater level of detail. Equipment should, at least, be identified by type (e.g., tumble blender, in-line homogeniser) and working capacity, where relevant.

2.2 Analytical Procedures

The analytical procedures used for testing the finished veterinary product should be provided, where appropriate

2.3 Batch Manufacturing Records

A completed executed batch of the finished product should be submitted

2.4 Release and Shelf Life Specifications

Justification for the proposed specifications for release and shelf life of the product should be provided.

2.5 Stability Data

Results of the stability studies should be presented in an appropriate format (e.g., tabular, graphical, narrative). Information on the analytical procedures used to generate the data and validation of these procedures should be included. The actual stability results/reports used to support the proposed shelf-life should be provided in the dossier. For quantitative tests (e.g. individual and total degradation product tests and assay tests), it should be ensured that actual numerical results are provided rather than vague statements such as “within limits” or “conforms”. Dissolution results should be expressed at minimum as both the average and range of individual results.

PART THREE- SAFETY AND RESIDUE INFORMATION

3.0 Material Safety Data Sheet

A document that contains information on the potential hazards (health, fire, reactivity and environmental) and how to work safely with the chemical product. It is an essential starting point for the development of a complete health and safety program. It also contains information on the use, storage, handling and emergency procedures all related to the hazards of the material should be submitted.

3.1 User Information

Information on the appropriate use of the product, warnings, precautions and cautions that must be taken by the user to prevent accidental poisoning and ensure effective use should be submitted.

3.2 Environmental Risk Assessment

Risk assessment that provides a systematic procedure for predicting potential risks to human health or the environment and chemical risk assessment of the potential to cause detrimental effects to human health or the environment should be submitted.

3.3 Residue Data on Active Ingredients

This Part describes the absorption of the API after administration to animals as well as the Absorption, Distribution, Metabolism and Excretion, ADME, patterns of the API. The extent and duration of persistence of residues of a veterinary drug or its metabolites in edible tissues of treated animals or food products obtained from them determines the withdrawal period (withholding time for milk) needed for the residues to fall below the Maximum Residue Limit (MRL). The summary of the residue-related studies, providing factual, concise descriptions of the test results.

INTERPRETATION

In this guideline, unless the context otherwise states: -

- **“Authority”** means Food and Drugs Authority
- **“Product”** means – a finished veterinary medicine 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

- **“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

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also includes, but is not limited to, a change in the product name, site of manufacture and/or source of ingredients.

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