FOOD AND DRUGS AUTHORITY

GUIDELINES FOR REGISTRATION OF ALLOPATHIC MEDICINES CONSIDERED FOR SMALL SCALE MANUFACTURE

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INTRODUCTION

This guideline applies only to allopathic medicines classified for small scale manufacture. 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 an abridged version of the Common Technical Document (CTD) format as stated below. Part Two which comprise of the Quality Overall Summaries (QOS) and Quality Information Summaries is however not applicable.

I. Part One-: Administrative information

II. Part Two-Not Applicable

II. Part Three-

A: Quality Documentation; Active Pharmaceutical Ingredient

B: Quality Documentation; Finished Pharmaceutical Product

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 allopathic medicines classified for small scale manufacture.

This guideline has been developed to assist in the following;

- Preparation of documentation for the 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 the finished 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 allopathic medicines classified for small scale manufacture.

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.

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 medicinal product, classified for small scale manufacture, 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.

- The application shall be submitted 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 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 medicinal product as per FDA sample schedule.

iii. 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. Samples as specified in the Authority's Sample Schedule. iii. A non-refundable application fee as specified in the Authority's Fee Schedule.
iv. Any other requirements that the FDA may determine from time to time.

Application for Variation of a finished 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 ml, mg per 5ml, 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. lotion, solution, suspension.

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.: 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. 200mls.

1.2.8 Category of distribution

Over the Counter Medicine

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.

1.5.1 Product Information Leaflet/ Package Insert

Provide four (4) copies of package insert and any information intended for distribution with the product to the user.

1.5.2 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 labelling is an essential part of registration and cannot be altered without the prior approval of FDA.

1.5.3 Product Samples

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

PART TWO- NOT APPLICABLE

PART THREE A- QUALITY DOCUMENTATION ACTIVE PHARMACEUTICAL INGREDIENT Active ingredients specification and certificate of analysis

Justification for the proposed specifications for the API and batch analysis report should be provided.

PART THREE B- QUALITY DOCUMENTATION

3.2. P.1.1 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.

3.2.P.3.1 Manufacturer Information

Manufacturer name and site address should be provided.

3.2. P.3.2 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 and working capacity, where relevant.

3.2. P.4 Excipients

The choice of excipients listed in 3.2. P.1.1, their concentration, their characteristics that can influence the drug product performance should be discussed relative to their respective functions. When choosing excipients, those with a compendial monograph are generally preferred. Use of excipients in concentrations outside of established ranges is discouraged and generally requires justification. Ranges or alternates for excipients are normally not accepted, unless supported by appropriate process validation data. Where relevant, compatibility study results should be included to justify the choice of excipients. Specific details should be provided where necessary. Where antioxidants are included in the formulation, the effectiveness of the proposed concentration of the antioxidant should be justified and verified by appropriate studies.

3.2. P.5 Analytical Procedures

All analytical test procedures, including biological and microbiological methods where relevant, must be described in sufficient detail to enable the procedures to be repeated if necessary. Information on the summary of analytical procedures information used for determination of assay of the FPP should be provided in a tabular form.

3.2. P.7 Container Closure System

A description of the container closure systems should be provided, including the identity of materials of construction of each primary packaging component and its specification. The specifications should include description and identification (and critical dimensions, with drawings where appropriate). Non-compendial methods (with validation) should be included, where appropriate. For non-functional secondary packaging components (e.g., those that neither provide additional protection nor serve to deliver the product), only a brief description should be provided. For functional secondary packaging components, additional information should be provided.

3.2. P. 8 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”.

3.2. R.1.1 **Batch Manufacturing Records**

A completed executed batch of the finished product should be submitted

INTERPRETATION

In this guideline, unless the context otherwise states: -

“**Authority**” means Food and Drugs Authority

“Product” means – **Finished Medicinal Products:** Underlisted allopathic medicines classified for small scale manufacture;

- Mist Sennaco
- Mist Expect Sed
- Ferric ammonium citrate
- Methylated Spirit
- Mist Magnesium Trisilicate
- Mist Kaolin

- Eusol Lotion
- Hydrogen Peroxide
- Mist Potassium citrate
- Calamine Lotion
- Gentian Violet
- Isopropyl Alcohol (70%)

- “**Applicant**” means the product owner or license holder. Representatives of license holders may not hold themselves as applicants unless they own the product

- “**Variation**” means - a change in the indication(s), dosage recommendation(s), and classification for a previously registered finished pharmaceutical product 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.