



**GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR
REGISTRATION OF COSMETIC PRODUCTS**

AUGUST, 2025

FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and efficacy of cosmetics in order to improve access to quality and safe cosmetic products on Rwandan Market.

Considering the provisions of the technical regulation N° CBD/TRG/011 of 20th April 2020, governing the Control of Cosmetics, the authority has to issue this Guidelines DD/CHCR/GDL/002 on submission of documentation for registration of cosmetics.

These guidelines have been developed to provide guidance to the applicants and the authority in managing applications for registration of cosmetics products.

Applicants are encouraged to familiarize with the guidelines and follow it when preparing and submitting applications for registration of cosmetics products.

Adherence to these guidelines will ensure that all relevant information is provided for registration of cosmetics products. This will facilitate efficient and effective evaluation as well as approval process. It will also help to avoid queries which result in unnecessary delays in approving documents.

The Authority acknowledges all the efforts of key stakeholders who participated in development and validation of these guidelines.

Prof. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

| | |
|--------------------------------|----------------------------|
| First issue date | 01/08/2020 |
| Effective date of this version | Refer to the approval date |

DOCUMENT REVISION HISTORY

| Date of revision | Revision number | Changes made and/or reasons for revision |
|----------------------------|-----------------|---|
| 01/01/2020 | 0 | First version |
| Refer to the approval date | 1 | <ol style="list-style-type: none"> 1. Time line for new application dossier processing has been reduced from 6 months to 3 months. 2. Application for renew has been fixed to 2 months 3. Application form for new products registration and renew of a registered product have been revised and harmonized with IRIMS 4. Information required for packaging material have been revised and improved 5. Some of the definitions in the guidelines has been improved 6. Documents requirements for variation are removed and referred to the guideline for variations 7. Abbreviation and acronyms have been updated 8. Statement for reliance have been added in guidelines 9. The manufacturing process data for foreign manufacturers has been waived as a result of relying on international standards compliance or being subject to Rwanda FDA GMP when it is deemed necessary due to quality and safety concern. 10. Annual Retention on the Register has been removed 11. Requirements for new products registration have been revised in |

| Date of revision | Revision number | Changes made and/or reasons for revision |
|-------------------------|------------------------|--|
| | | favor of local and foreign manufactured products |

DRAFT

TABLE OF CONTENTS

| | |
|---|----|
| FOREWORD | 2 |
| GUIDELINES DEVELOPMENT HISTORY | 3 |
| DOCUMENT REVISION HISTORY | 3 |
| TABLE OF CONTENTS..... | 5 |
| ACCRONYMES AND ABBREVIATIONS | 7 |
| GLOSSARY | 8 |
| CHAPTER I: INTRODUCTION..... | 10 |
| I.1 Background..... | 10 |
| I.2 Scope | 10 |
| I.3 Submission of applications | 10 |
| I.3.2 Submission of commercial samples for registration..... | 10 |
| I.4 Types of applications | 11 |
| I.4.1 New applications for registration | 11 |
| I.4.2 Renewal application for registration..... | 11 |
| I.6 Timelines for product dossier assessment | 12 |
| I.7 compliance to Good Manufacturing Practices (GMP) | 12 |
| I.9 Rwanda FDA Peer Review Committee for CHC product registration..... | 12 |
| CHAPTER II: GENERAL REQUIREMENTS FOR REGISTRATION | 13 |
| II.1 requirements for new application | 13 |
| II.1.1 Requirements for local manufactured products | 13 |
| II.1.1.1 Section A: Administrative requirements | 13 |
| II.1.1.1.1 Cover letter | 13 |
| II.1.1.1.2 Application form | 13 |
| II.1.1.1.3 Manufacturing license | 13 |
| II.1.1.1.4 Contract Manufacturing Agreement (where applicable)..... | 13 |
| II.1.1.1.5 Samples of the product..... | 13 |
| II.1.1.1.6 One coloured artwork/Label of the product | 13 |
| II.1.1.2 Section B: Technical data requirements..... | 14 |
| II.1.1.2.1 Data on raw materials..... | 14 |
| II.1.1.2.2 Data on final product..... | 14 |
| II.1.1.2.2.1 Certificate of analysis (CoA)..... | 14 |
| II.1.1.2.2.2 Packaging and labelling information..... | 14 |
| II.1.1.2.2.3 Commitment letters | 14 |
| II.1.2 Requirements for foreign manufactured products..... | 14 |
| II.1.2.1 Section A: Administrative requirements | 14 |
| II.1.2.1.1 Cover letter | 15 |
| II.1.2.1.2 Application form | 15 |
| II.1.2.1.3 Contract Manufacturing Agreement (where applicable)..... | 15 |
| II.1.2.1.4 Valid Manufacturing license. | 15 |
| II.1.2.1.5 Valid GMP Certificate or ISO certificate or other applicable internationally recognized management system certification..... | 15 |

| | |
|--|----|
| II.1.2.1.6 Appointment letter of the Local technical representative (LTR) | 15 |
| II.1.2.1.7 Samples of the product | 15 |
| II.1.2.1.8 One coloured artwork/Label of the product | 15 |
| II.1.2.1.9 Commitment letter (where applicable)..... | 16 |
| II.1.2.1.10 Market Authorization or Registration Certificate/ status in other countries (If applicable) | 16 |
| II.1.2.2 Section B: Technical data requirements..... | 16 |
| II.1.2.2.1 Data on raw material | 16 |
| II.1.2.2.2 Data on final product..... | 16 |
| II.1.2.2.2.1 Certificate of analysis (CoA)..... | 16 |
| II.1.2.2.2.1.2 Method of analysis | 16 |
| II.1.2.2.2.3 Packaging and labelling information..... | 16 |
| II.1.2.2.2.4 Stability data..... | 17 |
| II.1.2.2.2.5 Materials safety data sheet | 17 |
| CHAPTER III: REQUIREMENTS FOR RENEWAL OF PRODUCT REGISTRATION | 18 |
| III.1 Cover letter..... | 18 |
| III.2 Application form..... | 18 |
| III.3 Copy of previous registration certificate..... | 18 |
| III.4 Supporting documentation for any variations since the product was last registered | 18 |
| III.5 Samples of the product in the final package | 18 |
| ENDORSEMENT OF THE GUIDELINES | 19 |
| ANNEX I: COVER LETTER..... | 20 |
| ANNEX II: APPLICATION FORM FOR NEW REGISTRATION OF COSMETICS..... | 22 |
| ANNEX III: APPLICATION FORM FOR RENEW OF REGISTRATION OF COSMETIC, VECTOR CONTROL PRODUCTS, PUBLIC HEALTH ANTISEPTIC AND DISINFECTANT AND PUBLIC HEALTH LABORATORY CHEMICAL PRODUCTS | 27 |

ACCRONYMES AND ABBREVIATIONS

| | |
|-------------------|---|
| CoA | Certificate of Analysis |
| CHC | Cosmetics and Household Chemicals |
| CHCR | Cosmetics and Household Chemicals Registration |
| DOMD | Date Of Minimum Durability |
| GMP | Good Manufacturing Practice |
| IP | Information Product |
| IRIMS | Integrated Regulatory Information Management System |
| ICID | International Cosmetic Ingredient Dictionary |
| INCI | International Nomenclature of Cosmetic Ingredients |
| ISO | International Organization for Standardization |
| LTR | Local Technical Representative |
| PRC | Peer Review Committee |
| PAO | Period After Opening |
| PDP | Principal Display Panel |
| Rwanda FDA | Rwanda Food and Drugs Authority |
| SDS | Safety Data Sheet |
| WHO | World Health Organization |

GLOSSARY

In these regulations, unless the context otherwise requires:

Active ingredients: are those found in cosmetic products that have an intended purpose

Anti-perspirant: is a substance that is applied to the skin, especially under the arms, to prevent or reduce perspiration.

Applicant: means a person by or on whose behalf, an application for, an update or amendment to an existing registration, is made. After the product is registered, the applicant shall be the ‘Marketing Authorization Holder’.

Approve or approval: means official consent by the Authority as an acceptance of a registration of the cosmetics.

Authority: means the Rwanda Food and Drugs Authority or the acronym “Rwanda FDA” established by Law N° 003/2018 of 09/02/2018

Colour: means a substance used as an ingredient of a cosmetic product solely to give tonality to the product.

Composition of a cosmetic: refers to the ingredients contained in a cosmetic product and their proportions.

Container: means any form of packaging of cosmetics for sale as a single item whether by completely or partially enclosing the cosmetics and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.

Contract manufacturer: means any person who manufactures any product on the order of another person to whom a manufacturer's license has been issued.

Cosmetic: means any substance or preparation intended to be placed in contact with the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance or correcting body odours, protecting them or keeping them in good conditions.

Fee: means the fee prescribed in Regulations No. ODDG/RES/TRG/001 Version 5 governing tariff/fees and charges on services rendered by Rwanda food and Drugs Authority.

High Risk products: high risk products are products classified by the department as having an implication to health and safety when exposed to humans. These are products when used have an ability of causing an adverse reaction to the body if not used per the manufacturer’s instructions.

Ingredients: means any substance that is one of the components of a cosmetic and includes but not limited to colouring agents, botanicals, fragrance/flavour, but does not include substances obtained in the final product as a result of the chemical process

Label of cosmetic: means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a package (container) of a cosmetic product

Leaflet of a cosmetic: refers to a printed paper and includes any written information related to a cosmetic;

Low Risk products: Low risk products are products classified as having limited risk on exposure to the skin/body due to the product composition, mode of application and usage,

Manufacturer: means any natural or legal person who manufactures, assembles cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark;

Package: refers to any box, packet or any other article in which one or more containers of cosmetics are to be enclosed in one or more other boxes, packets or article in question, the collective number thereof;

Product Variant(s): for the purpose of this guideline product variants shall mean, items in a range of cosmetic products, which are produced by same manufacturer, similar in composition and are intended for the same use but are available in different colours, fragrances or flavours;

Prohibited Ingredient: refers to a substance which is forbidden to be a component of a cosmetic as defined in the *Ministerial Order N°20/38 du 26/02/2016 determining the list of cosmetics ingredients whose use is prohibited in Rwanda.*

Registrant (market authorization holder): refers to the holder of the authorization for the cosmetic products, means any person who may either be the trademark owner or person authorized by him, who has rights to sale the product and is responsible for placing the product on the Rwanda market;

Reliance: Regulatory reliance is the act whereby the regulatory Authority in one jurisdiction may take into account and give significant weight to regulatory work performed by another regulatory or trusted institution for purposes of reaching its own regulatory decisions.

DRAFT

CHAPTER I: INTRODUCTION

I.1 Background

These guidelines are applicable to registration of Cosmetic products as specified in the Law n° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, Organisation, and functioning and Ministerial Order N°20/38 of 26/02/2016 determining the list of cosmetics whose use is prohibited in Rwanda and Regulations No CBD/TRG/011 governing control of cosmetics in Rwanda.

Generally cosmetic products are classified into two (2) categories namely medicated cosmetics and non-medicated cosmetics. For the purpose of these guidelines, Rwanda FDA classifies cosmetics products according to their **Active ingredient(s)** and **intended uses** (For example, a shampoo is a non-medicated cosmetic because its intended use is to cleanse the hair. Anti-Dandruff shampoo is medicated cosmetics because it is intended to cleanse the hair and treat dandruff).

The Authority has developed these guidelines to assist applicants who wish to register their cosmetic products in Rwanda FDA by providing required information and procedures for submission of documentation for registration of new cosmetic products and renewal of registration thereby facilitating assessment and subsequently approval.

Adherence to these guidelines by the manufacturers/importers/applicants will timely facilitate assessments and approvals of the concerned cosmetics products application dossiers by the authority for pre-marketing evaluation, marketing authorization/registration and post-marketing review.

I.2 Scope

These guidelines shall be used on submission of documentation for registration of cosmetics.

I.3 Submission of applications

I.3.1 Submission of technical dossier

An application for product registration for either locally manufactured or imported, shall be submitted along with a dated and signed letter of application addressed to Rwanda FDA. If the applicant is a foreign company, the applicant shall appoint a local technical representative through whom an application shall be submitted. The LTR shall be a wholesale company registered in Rwanda FDA or manufacturer's representative company registered in Rwanda.

All application documents shall be in one of the official languages used in Rwanda. Any document which is in any language other than official language must be accompanied by a certified or notarized document translated in official language. The application dossier shall be submitted to Rwanda FDA through Integrated Regulatory Information Management System (IRIMS) available at <https://irims.rwandafda.gov.rw/portal/#/public/app-home>.

I.3.2 Submission of commercial samples for registration

The submission of samples for registration shall be in the final package proposed for marketing of the product in Rwanda and shall have 60% of its shelf-life remaining. This notwithstanding, products with

a shelf life of less than 24 months shall have at least 80% of its shelf life remaining at the time of submission. Two commercial samples must be submitted directly to Rwanda FDA headquarter on the addresses below:

Rwanda Food and Drugs Authority
P. O. Box 1948 Kigali
Nyarutarama Plaza, KG 9 Avenue

The additional samples may be requested once deemed required during the registration process. Where it's not possible due to big pack size (above 5L or 5kg), the applicant shall be requested to avail the necessary commercial sample size simulated and equivalent (1L or 1Kg) to the big commercial samples for further assessment procedures. The simulated and equivalent commercial samples shall never be placed on the market. A hard copy of the latter should be brought with samples for reception acknowledgement by the Authority.

I.4 Types of applications

For the purpose of submitting the cosmetic product dossier application for registration to Rwanda FDA, applications are categorized into three distinct groups as outlined below:

I.4.1 New applications for registration

An application for registration of a product that is intended to be placed on the Rwanda market for the first time or product which was on the market without a registration certificate.

I.4.2 Renewal application for registration

Applications for renewal of the marketing Authorization of product that has been registered previously. The application dossier shall be submitted to the Authority at least 3 months before the expiry of existing marketing Authorization Certificate.

I.4.3 Variation application

Variation application refer to the application for any change in the registered products. An application for variation shall be submitted as per the requirements set out in the guidelines for variation of registered cosmetics, vector control products and laboratory reagents for public health.

I.5 Receiving of applications for cosmetic products registration

An application is electronically submitted through IRIMS accessible via this link: <https://www.irims.rwandafda.gov.rw/portal/>. The application of product registration is screened through the system and the applicant is queried for any document that is not fulfilling the application requirements. The reference number assigned to a product during the application is used in all subsequent correspondences relating to the application. An acknowledged receipt of application will be issued by the system. A separate and complete application for registration of products shall be submitted for each cosmetic product with different commercial name, ingredients, formulation, intended use, forms and/or site of manufacture.

I.6 Timelines for product dossier assessment

Product dossiers shall be scheduled for assessment according to the First in First out (FIFO) basis upon compliance of the requirements. For new applications, assessment process shall be processed within three (3) months from the date of submission, with feedback provided to the applicant. Regarding the renewal and variation application of the registered products, the assessment shall be processed within two (2) months from the date of submission, with feedback provided to the applicant. The applicant will be required to provide any requested additional data within sixty (60) calendar days. Assessment of submitted additional data or query responses shall be processed within thirty (30) calendar days from the day of submission with feedback provided to the applicant.

I.7 Compliance to Good Manufacturing Practices (GMP)

The applicant shall submit a valid GMP Certificate or ISO certificate or other applicable internationally recognized Management System certification for foreign manufacturers. Regarding to the quality and safety concern of the product, the applicant may be requested to apply for GMP inspection to Rwanda FDA. More information on GMP requirements and application for GMP inspection is detailed in the Rwanda FDA Guidelines on Good Manufacturing Practice and its annexes accessible via Rwanda FDA Website.

I.8 Reliance

The Authority may rely on other regulatory agencies from regional, international and other Stringent Regulatory Authorities' decisions in regard to product market authorization when it deems necessary. The Authority may apply reliance procedures for granting Marketing Authorization in the following situations:

1. The product should have been evaluated and listed on register of EAC countries, WHO and other Stringent Regulatory Authorities or Regulatory Authorities with ML3/4 with signed MoU with Rwanda FDA.
2. The product should have been evaluated through work sharing (Joint) or regional reliance mechanisms.

I.9 Rwanda FDA Peer Review Committee for CHC product registration

A final dossier assessment report shall be presented to CHCR Peer Review Scientific Committee before making final decisions for granting or refusing Market Authorization.

When there are deficiencies related to safety, quality and/or efficacy to be resolved as per the decision of the CHCR Peer Review Scientific Committee, the application shall remain pending until the raised queries are resolved.

I.10 Validity of issued registration certificate

The Market Authorization issued by Rwanda FDA shall be valid for five (5) years from the date of its approval and it is renewed.

CHAPTER II: GENERAL REQUIREMENTS FOR REGISTRATION

This chapter provides guidance of components expected in the application for registration of cosmetics.

II.1 Requirements for new application

Data required for a new application contains two parts with each part having administrative requirements and technical data requirements. Part 1 relates to the requirements for local manufacturers while part 2 relates to the requirements for foreign manufacturers.

II.1.1 Requirements for local manufactured products

II.1.1.1 Section A: Administrative requirements

All administrative documents should be provided in part of administrative requirements as follow:

II.1.1.1.1 Cover letter

Applicants should include a cover letter within the dossier applications. A dated and signed copy of the cover letter should be uploaded using the cover letter format (Refer to the Annex-I).

II.1.1.1.2 Application form

A Dossier application must include a completed application form (refer to the annex II, document No DD/CHCR/FOM/002) available on Rwanda FDA website. The application form should be duly filled with relevant information and dated, signed and stamped appropriately.

II.1.1.1.3 Manufacturing license

The applicant should submit a valid manufacturing license issued by Rwanda Food and Drugs Authority.

II.1.1.1.4 Contract Manufacturing Agreement (where applicable)

An agreement between two parties (the party who manufactures any product on the order of another party). If a product is manufactured on contract, evidence of the contract shall be included in the documentation submitted. And this shall be clearly stated on the label of the product.

II.1.1.1.5 Samples of the product

Two (2) samples of the product(s) shall be submitted. Where necessary additional samples may be requested depending on tests or parameters to be carried out.

II.1.1.1.6 One coloured artwork/Label of the product

The applicant should submit one coloured artwork/Label of the product.

II.1.1.2 Section B: Technical data requirements

A technical data requirement is a document that includes various pieces of information about the raw materials and the final product.

II.1.1.2.1 Data on raw materials

The applicant should submit the SDS for each raw material (ingredients) describing all sections.

II.1.1.2.2 Data on final product

II.1.1.2.2.1 Certificate of analysis (CoA)

The dated and signed CoA should include the batch number tested, parameters tested, test results, manufacture date and expiry date along with the standards testing used for quality control.

II.1.1.2.2.2 Packaging and labelling information

The applicant shall provide information on packaging material such as primary and or Secondary (e.g. PVC, HDPE, PE...). This shall be made of substances/materials which are safe and suitable for its intended use. Cosmetic product labels should be clearly legible, indelible letters and written in one of the official languages used in Rwanda bearing the following information:

- a) Brand name,
- b) Manufacturer's name and physical address,
- c) lot or batch number,
- d) Manufacturing date and Expiry date,
- e) Net content (weight/volume),
- f) List of ingredients used,
- g) intended use of cosmetic product,
- h) Instructions for use,
- i) Country of origin,
- j) Storage conditions,
- k) Warnings and cautions if any.

II.1.1.2.2.3 Commitment letters

For ongoing stability studies, applicant must submit the commitment letter indicating when the final data on stability will be available. The authority reserves its total rights to request the applicant to submit the commitment letter wherever it is applicable.

II.1.2 Requirements for foreign manufactured products

II.1.2.1 Section A: Administrative requirements

All administrative documents should be provided in part of administrative requirements as follow:

II.1.2.1.1 Cover letter

Applicants should include a cover letter within the dossier applications. A dated and signed copy of the cover letter should be uploaded using the cover letter format (*Refer to the Annex-I*).

II.1.2.1.2 Application form

A Dossier application must include a completed application form (*refer to the annex II, document No DD/CHCR/FORM/002*) available on Rwanda FDA website. The application form should be duly filled with relevant information and dated, signed and stamped appropriately.

II.1.2.1.3 Contract Manufacturing Agreement (where applicable)

An agreement between two parties (the party who manufactures any product on the order of another party) are required. If a product is manufactured on contract, evidence of the contract shall be included in the documentation submitted. And this shall be clearly stated on the label of the product.

II.1.2.1.4 Valid Manufacturing license.

The applicant shall submit valid Manufacturing License from the manufacturer granted by competent authorities.

II.1.2.1.5 Valid GMP Certificate or ISO certificate or other applicable internationally recognized management system certification

For all foreign products, all key manufacturing and/or processing steps in the production of finished products must be performed in plants that comply with GMP or ISO. Regarding to the quality and safety concern of the product, the applicant may be requested to apply for GMP inspection to Rwanda FDA.

II.1.2.1.6 Appointment letter of the Local technical representative (LTR)

Appointment letter of the LTR with original copy of Power of attorney must be enclosed in the product dossier. The LTR shall be a wholesale company registered in Rwanda FDA or manufacturer's representative company registered in Rwanda.

II.1.2.1.7 Samples of the product

Two (2) samples of the product(s) shall be submitted. Where necessary additional samples may be requested depending on tests or parameters to be carried out.

II.1.2.1.8 One coloured artwork/Label of the product

The applicant should submit one coloured artwork/Label of the product.

II.1.2.1.9 Commitment letter (where applicable)

For ongoing stability studies, the applicant must submit the commitment letter indicating when the final data on stability will be available.

II.1.2.1.10 Market Authorization or Registration Certificate/ status in other countries (If applicable)

Applicant shall submit Market Authorization or Registration Certificate/ registration status in other countries (If applicable).

II.1.2.2 Section B: Technical data requirements

A technical data requirement is a document that includes various pieces of information about the raw materials and the final product.

II.1.2.2.1 Data on raw material

The applicant should submit the SDS for each raw material (ingredients) that include all sections.

II.1.2.2.2 Data on final product

II.1.2.2.2.1 Certificate of analysis (CoA)

The dated and signed CoA should include the batch number tested, parameters tested, test results, manufacture date and expiry date along with the standards testing used for quality control.

II.1.2.2.2.1.2 Method of analysis

Method of analysis for the finished product shall include the equipment, reagent and analytical method.

II.1.2.2.2.3 Packaging and labelling information

The applicant shall provide information on packaging material such as primary and or Secondary (e.g. PVC, HDPE, PE...) packaging. This shall be made of substances/materials which are safe and suitable for its intended use. Cosmetic products labels should be clearly legible, indelible letters and written in one of the official languages used in Rwanda bearing the following information:

- a) Brand name,
- b) Manufacturer name and physical address (all manufacturers involved in the manufacturing processes should appear on the label if applicable)
- c) Lot or batch number,
- d) Manufacturing date and Expiry date/best before,
- e) Net content (weight/volume),
- f) List of ingredients used,
- g) intended use of cosmetic product,
- h) Instructions for use,
- i) Country of origin,
- j) Storage conditions,
- k) Warnings and cautions if any.

II.1.2.2.2.4 Stability data

The proposed shelf life should be justified by submission of stability data. Applicant shall provide stability data supporting the proposed shelf life. The stability studies shall be conducted in the container in which it will be marketed in Rwanda. Stability study report critically examine the method used to determine the established product shelf life including:

1. Study design (protocol);
2. Test conditions (humidity and temperature), testing interval;
3. Duration:

| Storage conditions | Duration | Testing interval (Months) |
|--|------------|---------------------------|
| Long term stability studies at 25±5°C/60% RH | Shelf life | 0, 3,6,9,12,18,24,36,48 |
| Accelerated stability studies at 40°C/75% RH | 6 months | 0,3,6 |

4. Type of container used (Testing should be conducted using containers and closures intended for marketing of products);

5. Parameters to be tested should be those susceptible to change and are likely to influence the quality and safety of the finished product.

II.1.2.2.2.5 Materials safety data sheet

The applicant should submit the SDS that include **all sections** (Human health data sheet, Environmental safety information and Toxicity...).

CHAPTER III: REQUIREMENTS FOR RENEWAL OF PRODUCT REGISTRATION

An application for registration renewal shall be made ninety (90) calendar days before expiration of the last registration.

III.1 Cover letter

Signed and dated cover letter addressed to the DG of Rwanda FDA must be submitted.

III.2 Application form

Signed and dated application form for renewal of registered cosmetic product (*refer to the annex III, document No. DD/CHCR/FORM/005*)

III.3 Copy of previous registration certificate

The applicant shall submit the copy of previous registration certificate issued by Rwanda FDA.

III.4 Supporting documentation for any variations since the product was last registered

During the renewal of the product, the applicant must submit the data for any variations that have been reported and also the variations which were not reported yet (variation that happened in the last year of certificate validity).

III.5 Samples of the product in the final package

The applicant must submit two samples of the product supporting along with the artwork/label.

ENDORSEMENT OF THE GUIDELINES

| | Prepared by | Checked by | | Approved by |
|------------------|----------------------------------|-------------------------------------|--|-------------------------|
| Title | Division Manager/CHCR | Head of Drugs Department | Division Quality Assurance Management | Director General |
| Names | Dr. Janvier MUKIZA | Dr. Védaste HABYALIMANA | Mrs. Marie Ange UWASE | Prof. Emile BIENVENU |
| Signature | | | | |
| Date | | | | |

DRAFT

ANNEX I: COVER LETTER

Letter header of the applicant/manufacturer/LTR

< Applicant>
< Address>
<Postal Code>
< Town>
<Country>
<Date>

<Rwanda FDA>
<P.O.BOX 1948> <Kigali>
< Rwanda >

Dear Sir/Madam,

Subject: Submission of application for registration of cosmetic product <Brand Name(s), Common Name (s) and product form(s)

We are pleased to submit our Application Dossier(s) for a registration of cosmetic product that details are as follows:

Name of the cosmetic product as follow:

Brand name (s):

Proprietary (Common Name (s):

Name and strength/purity of active ingredient(s):

Product form:

Intended use(s):

Manufacturer:

You will find enclosed the submission dossier as specified hereafter:

- The relevant fees for this application have been paid.
- Two commercial samples of the product
- The electronic submission contains the following sections:

Section 1: Administrative information and product information requirement

Section 2: Technical data requirements

We confirm that the electronic submission has been checked with up-to-date and state-of-the- antivirus software.

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>

DRAFT



ANNEX II: APPLICATION FORM FOR NEW REGISTRATION OF COSMETICS

| | |
|--|---------------------------|
| 1. ADMINISTRATIVE INFORMATION | |
| 1.1. Name(s) and complete physical address(es) of the manufacturer(s): | |
| Company name: | |
| Physical address: | |
| Postal address: | |
| Country: | |
| Telephone: | |
| Fax: | |
| Email: | |
| 1.2. Particulars of Applicant/ Registrant | |
| Name: | |
| Physical Address: | |
| Postal Address: | |
| Country: | |
| Phone: | |
| Fax: | |
| Email: | |
| Status of applicant (tick where appropriate): | |
| Manufacture: Importer: Exporter: Other: | |
| 1.3 Particulars of Local Technical Representative/Distributor (if applicable) | |
| Physical Address: | |
| Postal Address: | |
| Country: | |
| Phone: | |
| Fax: | |
| Email: | |
| 2. PRODUCT DETAILS | |
| 2.1 | Brand name of the product |

| | | |
|-----|--|--|
| 2.2 | Proprietary name of the product/Generic name | |
| 2.3 | Name and strength of active ingredient (s) | |
| 2.4 | Form of the product: (Powder, Liquid, Gel, Cream, Lotion, Spray, Aerosol, Gaseous, Emulsion, Cream, ointment, Solution, ...) | |
| 2.5 | Intended use | <p>Anti-Acnes Anti-Wrinkles, Anti-Eczema Sensitive Skin, Skin repair, Anti-pimple, Anti-Aging Mattifying, Skin lightening, Spot Corrector, Spot removals, Sunscreens, Anti-irritant, Anti-inflammatory, Hair conditioners, Hair Dye, Anti-itching, Anti-redness, Exfoliators, Moisturizer, Anti-crack, toothpastes, Mouth wash, anti-dandruff, antiperspirants, Hair growth, hair removal, hair relaxer, Hair Waiving, Hair Dyes, Hair Conditioner, Hair Removal, Antidandruff,</p> |

| | | |
|-------------|---|---|
| | | Hair strengthener, Pain Relief, Aromatherapy oil, Hair Inhibitor, Scars Removal Other (Specify)..... |
| 2.6 | Area of application of cosmetic (Oral cavity, hair system, Face, Body, External genital, nails, eyes. ...) | |
| 2.7 | Contraindication (where applicable) | |
| 2.8 | Do you hold Marketing Authorization (s) of this product from other regulatory authorities? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes state; Market Authorization Number: Market Authorization issuance date: Name of Regulatory Authority issued the Market Authorization: Country: | |
| 2.9 | Application method | |
| 2.10 | Physical description | |
| 2.11 | Packing Material/pack size: | |
| 2.12 | Description of container closure | |
| 2.13 | Proposed shelf life (in months): | |
| 2.14 | Proposed shelf life after reconstitution or dilution (if applicable) | |
| 2.15 | Proposed shelf life (after first opening container): | |
| 2.16 | Proposed storage conditions: | |
| 2.17 | Proposed storage conditions after first opening (where applicable): | |

| 2.18 | <p>LABELLING</p> <p>Brief description of the type and properties of packaging material and the seal and its liner (if any) and provide justification for the suitability of the packaging material and the seal and its liner used.</p> <p>.....</p> <p>.....</p> <p>.....</p> | | | | | | | | | | | | | | | | | | | | |
|---|---|---------------------|----------------------------------|---------|------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| 2.19 | <p>List the qualitative and quantitative composition per unit pack (Please, add or delete as many rows and columns as needed).</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 30%;">Name of ingredients</th> <th style="width: 30%;">Chemical Abstract service number</th> <th style="width: 20%;">Purpose</th> <th style="width: 20%;">Amount (%)</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table> | Name of ingredients | Chemical Abstract service number | Purpose | Amount (%) | | | | | | | | | | | | | | | | |
| Name of ingredients | Chemical Abstract service number | Purpose | Amount (%) | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |
| 3. Details on administrative & Technical documents submitted with the application | | | | | | | | | | | | | | | | | | | | | |
| Technical documents | Annex, Page number, etc. | | | | | | | | | | | | | | | | | | | | |
| Quantitative and qualitative composition of the formulation (Introduction of active ingredients and their functions) | | | | | | | | | | | | | | | | | | | | | |
| Manufacturing Process | | | | | | | | | | | | | | | | | | | | | |
| Certificate of analysis | | | | | | | | | | | | | | | | | | | | | |
| Product specifications and test methods | | | | | | | | | | | | | | | | | | | | | |
| Toxicity data | | | | | | | | | | | | | | | | | | | | | |
| Antimicrobial efficacy data | | | | | | | | | | | | | | | | | | | | | |

Declaration by the Applicant/ Registrant

I, the undersigned, certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.

I also agree that I shall carry out vigilance to monitor the safety of the product in the market and provide safety update reports to Rwanda Food and Drugs Authority.

It is hereby confirmed that fees have been paid according to the Rwanda Food and Drugs Authority fees and regulations.

I understand that if any information given here above is found false or incorrect, I will be reliable for appropriate action under the provisions of the Rwanda Food and Drugs Authority regulations.

Name:

Position in the company:

Signature:

Official stamp:

Date:



ANNEX III: APPLICATION FORM FOR RENEW OF REGISTRATION OF COSMETICS, VECTOR CONTROL PRODUCTS, PUBLIC HEALTH ANTISEPTIC AND DISINFECTANT AND PUBLIC HEALTH LABORATORY CHEMICAL PRODUCTS

1. Product information

1.1 Registration number.....

1.2 Date of issue of current Market Authorization.....

1.3 Date of expiry of current registration.....

1.4 Brand Name of Product:

1.5 Product category:.....

1.6 Physical description.....

1.7 Product Form:

1.8 Name and Strength of the Active ingredient(s):.....

1.9 Intended use of the product.....

1.10 Are there any changes since product was registered? No Yes

If yes, give descriptions of the changes and if such variation was approved by Rwanda FDA

.....
.....

2. Are there any reported adverse reactions?

No Yes

If yes, give descriptions of the adverse reactions and if were reported to Rwanda FDA

.....
.....

3. Particulars of Applicant/ Registrant

Name of company:

Physical Address:

Postal Address:

Country:

Phone:

Fax:

Email:

Status of applicant (tick where appropriate)

Manufacturer Importer Other

If other, please specify:.....

4. Particulars of manufacturer

Name:

Physical Address:

Post Address:.....

Country.....

Phone: Fax: Email:

5. Particulars of Local Technical Representative (if applicable)

Name:

Physical Address:

Postal Address:

Phone Number..... Fax: Email:

Declaration by the Applicant

I.....undersigned certify that all the information filled on this form and accompanying documentation are correct, complete and true to the best of my knowledge. I also agree that I shall carry out vigilance to monitor the safety of the product on the market and provide safety update reports to Rwanda FDA. It is hereby confirmed that fees have been paid according to the Rwanda FDA fees and regulation. I understand that if any information given here above is found false or incorrect, I will be liable for appropriate action under the provisions of the Rwanda FDA regulations.

Name:.....

Position:.....

Signature:.....

Officials Stamp:.....

Date:.....