



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

**APRIL, 2026**

## **FOREWORD**

Rwanda Food and Drugs Authority (Rwanda FDA) 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 20<sup>th</sup> April 2020, governing the Control of Cosmetics, Rwanda FDA 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 Rwanda FDA 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.

Rwanda FDA 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**

<b>Date of revision</b>	<b>Version number</b>	<b>Changes made and/or reasons for revision</b>
01/01/2020	1	First version
Refer to the approval date	2	<ol style="list-style-type: none"> <li>1. Time line for new application dossier processing has been reduced from 6 months to 3 months;</li> <li>2. Timeline for submitting addition data has been increased for three (3) months to six (6) months;</li> <li>3. Timeline for processing addition data has been increased from one (1) month to two (2) months;</li> <li>4. Timeline for renewal application has been fixed to 2 months;</li> <li>5. Application form for new products registration and renew of a registered product have been revised and harmonized with IRIMS;</li> <li>6. Information required for packaging material have been revised and improved;</li> <li>7. Some of the definitions in the guidelines has been improved;</li> <li>8. Documents requirements for variation are removed and referred to the guideline for variations;</li> <li>9. Abbreviation and acronyms have been updated;</li> <li>10. Statement for reliance have been added in guidelines;</li> <li>11. 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;</li> <li>12. Annual Retention on the Register has been removed;</li> <li>13. Requirements for new products registration have been revised in favor of local and foreign manufactured products.</li> </ol>

## **TABLE OF CONTENTS**

FOREWORD.....	2
GUIDELINES DEVELOPMENT HISTORY.....	3
DOCUMENT REVISION HISTORY.....	3
TABLE OF CONTENTS.....	4
ACRONYMS AND ABBREVIATIONS.....	6
GLOSSARY.....	7
CHAPTER I: INTRODUCTION.....	9
I.1 Background.....	9
I.2 Scope.....	9
I.3 Submission of applications.....	9
I.3.1 Submission of technical dossier.....	9
I.3.2 Submission of commercial samples for registration.....	10
I.4 Types of applications.....	10
I.4.1 New applications for registration.....	10
I.4.2 Renewal application for registration.....	10
I.5 Receiving of applications for cosmetic products registration.....	10
I.6 Timelines for product dossier assessment.....	11
I.7 compliance to Good Manufacturing Practices (GMP).....	11
I.8 Reliance.....	11
I.9 Rwanda FDA Peer Review Committee for CHC product registration.....	12
I.10 Validity of issued registration certificate.....	12
CHAPTER II: GENERAL REQUIREMENTS FOR REGISTRATION.....	12
II.1 Requirements for local manufactured products.....	12
II.1.1 Section A: Administrative requirements.....	12
II.1.1.1 Cover letter.....	12
II.1.1.2 Application form.....	12
II.1.1.3 Manufacturing license.....	13
II.1.1.4 Contract Manufacturing Agreement (where applicable).....	13
II.1.1.5 Samples of the product.....	13
II.1.1.6 One coloured artwork/Label of the product.....	13
II.1.2 Section B: Technical data requirements.....	13
II.1.2.1 Data on raw materials.....	13
II.1.2.2 Data on final product.....	13
II.2 Requirements for foreign manufactured products.....	14
II.2.1 Section A: Administrative requirements.....	14
II.2.1.1 Cover letter.....	14
II.2.1.2 Application form.....	14
II.2.1.3 Contract Manufacturing Agreement (where applicable).....	14
II.2.1.4 Valid Manufacturing license.....	14
II.2.1.5 Valid GMP Certificate or ISO certificate or other applicable internationally recognized management system certification.....	14
II.2.1.6 Appointment letter of the Local technical representative (LTR).....	15
II.2.1.7 Samples of the product.....	15
II.2.1.8 One coloured artwork/Label of the product.....	15
II.2.1.9 Commitment letter (where applicable).....	15

*Guidelines on Submission of Documentation for Registration of Cosmetic Products*

II.2.1.10 Market Authorization or Registration Certificate/ status in other countries (If applicable).....	15
II.2.2 Section B: Technical data requirements.....	15
II.2.2.1 Data on raw material .....	15
II.2.2.2 Data on final product.....	15
CHAPTER III: REQUIREMENTS FOR RENEWAL OF PRODUCT REGISTRATION .....	17
III.1 Cover letter .....	17
III.2 Application form.....	17
III.3 Copy of previous registration certificate .....	17
III.4 Supporting documentation for any variations since the product was last registered.....	17
III.5 Samples of the product in the final package .....	17
ENDORSEMENT OF THE GUIDELINES .....	18
ANNEX .....	19
ANNEX: COVER LETTER.....	20

**ACRONYMS AND ABBREVIATIONS**

<b>CoA</b>	Certificate of Analysis
<b>CHC</b>	Cosmetics and Household Chemicals
<b>CHCR</b>	Cosmetics and Household Chemicals Registration
<b>GMP</b>	Good Manufacturing Practice
<b>IRIMS</b>	Integrated Regulatory Information Management System
<b>ISO</b>	International Organization for Standardization
<b>LTR</b>	Local Technical Representative
<b>SDS</b>	Safety Data Sheet
<b>WHO</b>	World Health Organization

## **GLOSSARY**

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

**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 Rwanda FDA as an acceptance of a registration of the cosmetics.

**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 manufacturing:** refer to a contract for manufacturing any product from another person to whom a manufacturing 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 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** 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.

**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.

## *Guidelines on Submission of Documentation for Registration of Cosmetic Products*

**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.

**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.

## **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).

Rwanda FDA 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 Rwanda FDA 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>. Applicant shall consequently have account in IRIMS.

### **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 is 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 Rwanda FDA.

### **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 Rwanda FDA 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.

After receiving the product application, Rwanda FDA shall proceed with screening of the dossier for completeness. In the event that the dossier is incomplete, it will not be scheduled for assessment and the applicant will be notified within 30 calendar days and requested to comply with requirements in writing. In case of a positive outcome during the screening, the application will be scheduled for assessment according to the First in First out (FIFO) rules.

### **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 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 six (6) months. Assessment of submitted additional data or query responses shall be processed within sixty (60) calendar days from the day of submission with feedback provided to the applicant.

Once a query has been issued to the applicant, the assessment process stops until Rwanda FDA receives a response to the raised queries. Further processing of the application may only be undertaken if responses to issued queries, contain all outstanding information requested in one submission. If the queries have been reissued for a third time and the applicant provides unsatisfactory responses, the application shall be rejected. In the event that the responses to the queries are not submitted within specified timeline from the date they were issued, it will be considered that the applicant has withdrawn the application unless the applicant has requested for extension of deadline to Rwanda FDA. Thereafter, registration of the product may only be considered upon submission of a new application.

### **I.7 Compliance with 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 Rwanda FDA Guidelines on Good Manufacturing Practice and its annexes accessible via Rwanda FDA Website.

### **I.8 Reliance**

Rwanda FDA 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. Rwanda FDA may apply reliance procedures for granting Marketing Authorization in the following situations:

- a. 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.
- b. 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.

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 Requirements for local manufactured products**

#### **II.1.1 Section A: Administrative requirements**

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

##### **II.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.1.1.2 Application form**

Dossier application must include a completed application form N° DD/CHCR/FOM/002 for new registration of Cosmetics available on Rwanda FDA website. The application form should be duly filled with relevant information and dated, signed and stamped appropriately.

### **II.1.1.3 Manufacturing license**

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

### **II.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.1.1.5 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.1.1.6 One coloured artwork/Label of the product**

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

## **II.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.1.2.1 Data on raw materials**

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

### **II.1.2.2 Data on final product**

#### **a. Certificate of analysis (CoA)**

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

#### **b. 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:

- i. Brand name,
- ii. Manufacturer's name and physical address,
- iii. Lot or batch number,
- iv. Manufacturing date and Expiry date,
- v. Net content (weight/volume),

- vi. List of ingredients used,
- vii. Intended use of cosmetic product,
- viii. Instructions for use,
- ix. Country of origin,
- x. Storage conditions,
- xi. Warnings and cautions if any.

**c. Commitment letters**

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

**II.2 Requirements for foreign manufactured products**

**II.2.1 Section A: Administrative requirements**

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

**II.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.2.1.2 Application form**

Dossier application must include a completed application form No DD/CHCR/FORM/002 for new registration of Cosmetics available on Rwanda FDA website. Application form should be duly filled with relevant information and dated, signed and stamped appropriately.

**II.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.2.1.4 Valid Manufacturing license**

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

**II.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.2.1.6 Appointment letter of the Local Technical Representative**

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 or importer of cosmetics or household chemicals or pharmaceutical products licensed by Rwanda FDA or any manufacturer's representative company registered in Rwanda.

In case the LTR is not wholesale or importer of cosmetics or household chemicals or pharmaceutical products licensed by Rwanda FDA, a contract with company owning Rwanda FDA licensed premise for cosmetics or household chemicals or pharmaceutical products together with valid premise license shall be submitted, and this contract shall highlight that the imported cosmetics will be stored in the above-mentioned premise.

### **II.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.2.1.8 One coloured artwork/Label of the product**

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

### **II.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.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.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.2.2.1 Data on raw material**

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

### **II.2.2.2 Data on final product**

#### **a. 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.

## **b. Method of analysis**

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

## **c. 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:

- i. Brand name,
- ii. Manufacturer name and physical address (all manufacturers involved in the manufacturing processes should appear on the label if applicable)
- iii. Lot or batch number,
- iv. Manufacturing date and Expiry date/best before,
- v. Net content (weight/volume),
- vi. List of ingredients used,
- vii. intended use of cosmetic product,
- viii. Instructions for use,
- ix. Country of origin,
- x. Storage conditions,
- xi. Warnings and cautions if any.

## **d. 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:

- i. Study design (protocol);
- ii. Test conditions (humidity and temperature), testing interval;
- iii. Duration:

<b>Storage conditions</b>	<b>Duration</b>	<b>Testing interval (Months)</b>
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

- iv. Type of container used (Testing should be conducted using containers and closures intended for marketing of products);
- v. Parameters to be tested should be those susceptible to change and are likely to influence the quality and safety of the finished product.

**e. 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. Rwanda FDA foresees a grace period for renewal of ninety (90) days after the specified expiry date. Failure to renew the marketing authorization within the grace period, the application shall be considered as new.

**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 N°: DD/CHCR/FORM/006 for renew of registration of cosmetic, vector control products, public health antiseptic and disinfectant and public health laboratory chemical products available on Rwanda FDA Website.

**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**

	<b>Prepared by</b>	<b>Checked by</b>		<b>Approved by</b>
<b>Title</b>	<b>Division Manager for Cosmetics and Household Chemicals Registration</b>	<b>Head of Drugs Department</b>	<b>Division Manager for Quality Management System</b>	<b>Director General</b>
<b>Names</b>	Dr. Janvier MUKIZA	Dr. Védaste HABYALIMANA	Ms. Marie Ange UWASE	Prof. Emile BIENVENU
<b>Signature &amp; Date</b>				

**ANNEX**

**ANNEX: 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,

*Guidelines on Submission of Documentation for Registration of Cosmetic Products*

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>