RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF MEDICATED COSMETIC PRODUCTS

JULY, 2020

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GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO BY COUNSULTANTS	25 September 2019
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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 medicated cosmetics in order to improve access to medicated cosmetic s in Rwanda.

Considering the provisions of the technical regulation N° CBD/TRG/011 of 20th April 2020, governing the control of medicated cosmetics products especially in its articles 6, 7, 8, 9, 12 and 47, the authority has to issue these *Guidelines N° DHT/GDL/023 on submission of documentation for registration of medicated cosmetics.*

These guidelines provide guidance to applicants to make sure that the products they manufacture or produce and apply for registration meet Rwandan requirements.
Applicants are encouraged to familiarize with the guideline and follow it when preparing and submitting applications for registration of medicated cosmetics.

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

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

Dr. Charles KARANGWA
Ag. Director General

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ABBREVIATIONS AND ACRONYMS

DOMD	Date of minimum durability
GMP	Good manufacturing practice
ICID	International Medicated Cosmetic Ingredient Dictionary
INCI	International Nomenclature of cosmetic ingredients.
PAO	Period After Opening
PDP	Principal display panel
WHO	World Health Organization

DEFINITIONS

In these regulations, unless the context otherwise requires:

1. **Address"** means where the business of manufacture or sale or distribution or storage or display of medicated cosmetic product is carried out which includes the house number, plot number, street name, Town/City, State, Country, website, email, phone number etc.
2. **"Advertisement"** is a form of communication through the media about products, services or ideas paid for by an identified sponsor. It is used to encourage, persuade or manipulate an audience (viewers, readers or listeners) to continue with or take some new action.
3. **"Advertising"** means the publicity of goods and description of all products; this includes any form of notices in circulars, handouts, label wrappers, catalogue and price lists, newspaper, magazines and many other documents made orally or otherwise or by means of projected light, sound recording, Radio, presenter mentions, television, bill boards, mobile vans and writings.
4. **Anti-perspirant:** is a substance that is applied to the skin, especially under the arms, to prevent or reduce perspiration.
5. **"Applicants"** means a person or company manufacturing medicated cosmetics or their representatives applying for inspection for suitability of premises and licensing of registering the medicated cosmetics.
6. **"Appropriate fee"** means the fee prescribed in the Ministerial Order
7. **"Approve" or "approval"** means official consent by the Authority as an acceptance of a registration of the medicated cosmetics or practices related to that in the Rwandan market;
8. **"Authority"** means the Rwanda Food and Drugs Authority or the acronym "Rwanda FDA" established by Law N° 003/2018 of 09/02/2018
9. **"Batch number or Lot"** means the number or a combination of numbers and letters specifically given to a medicated cosmetics product which is linked to the manufacturing history of the product;

10. ***"Botanical"*** refers to an ingredient that is directly derived from plant and that has not been chemically modified before it is used in the preparation of a medicated cosmetic
11. ***"Claim"*** refers to any message or representation including pictorial, graphic, symbolic or any form of representation, which states, suggests or implies that a medicated cosmetic has particular characteristics relating to its origin, function, nature, composition or any other characteristics
12. **Colour"** means a substance used as an ingredient of a medicated cosmetic product solely to give tonality to the product
13. ***"Composition of a medicated cosmetic "*** refers to the ingredients contained in a medicated cosmetic product and their proportions.
14. "**Container"** means any form of packaging of medicated cosmetics for sale as a single item whether by completely or partially enclosing the medicated cosmetics and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.
15. **"Contract manufacturer"** means any person who manufactures any product on the order of another person to whom a manufacturer's licence has been issued under these Regulations;
16. **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.
17. **Cream** is a preparation usually for application to the skin. Creams are semisolid dosage forms containing more than 20% water or volatile components and typically less than 50% hydrocarbons, waxes, or polyols as vehicles.
18. ***"Decorative medicated cosmetics"*** refers to a medicated cosmetic intended to modify the appearance of the area to which they are applied by the use of colour;
19. **Deodorant**: is a substance which removes or conceals unpleasant smells, especially bodily odours.

20. **Depilatories**: Depilatory in singular, is a cream or lotion for removing unwanted hair
21. **"Distributor"** means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a medicated cosmetic product available on the Community market;
22. **Emulsions:** In the world of medicated cosmetics, "emulsion" is a common term. Most lotions and creams are emulsions. Mix two fluids that usually don't mix together well and you have an emulsion. Think oil and water getting along happily.
23. **Face masks**: is a creamy or thick pasted mask applied to clean or smoothen the face. It often contains minerals, vitamins, and fruit extracts, such as cactus and cucumber.
24. **"Fragrance"** means a substance used as an ingredient of a medicated cosmetic product solely to impart odour to the product;
25. ***"Flavour"*** refers to a substance used as an ingredient of medicated cosmetic product solely to impart taste to the product;
26. ***"Free Sales Certificate"*** refers to a document that indicates that the product is freely sold in that country;
27. ***"Importer"*** means any person or body corporate permitted and authorized under the laws and regulation in Rwanda pertaining to medicated cosmetics to import medicated cosmetic products
28. **"Immediate packaging"** refers to the container or other form of packaging immediately in contact with the medicated cosmetic product;
29. **Ingredients** means any substance that is one of the components of a medicated cosmetic and includes colouring agents, botanicals, fragrance and flavour, but does not include substances that are used in the preparation of the medicated cosmetic but that are not present in the final product as a result of the chemical process
30. **"Inner label"** means primary packaging material label;
31. ***"International Medicated cosmetic Ingredient Dictionary (ICID)"*** refers to the latest edition of a book that gives names of medicated cosmetic ingredients published by the American Medicated cosmetics Toiletries and Fragrance Association;

"International Nomenclature of Medicated cosmetic Ingredients" refers to a name used for listing an ingredient on a medicated cosmetic product label;

32. **Label of medicated 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 medicated cosmetic product
33. "**Law"** means Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning
34. **"Leaflet of a medicated cosmetic "** refers to a printed paper and includes any written information related to a medicated cosmetic ;
35. **"License"** means permission from Authority to manufacture and sell one or more of its products.
36. **"Licenced importer**" means a person to whom an import licence has been issued under ***Regulations N^{o} CBD/TRG/011 governing the control of medicated cosmetic***
37. **"Licenced manufacturer"** means a person to whom a manufacturer's licence has been issued under these Regulations, and includes a contract manufacturer;
37. **"Licensed wholesaler"** means a person to whom a wholesaler's licence has been issued under these Regulations;
38. **Lotions:** lotion in singular is a low-viscosity topical preparation intended for application to the skin, while a lotion may be used as a medicine delivery system, many lotions, especially hand lotions and body lotions are meant instead to simply smooth, moisturize, soften and perhaps perfume the skin
39. **"Manufacture"** means any operation that includes of:

    a) the making or assembling of the product;

    b) enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling of the container; and
40. **manufacturer'** means any natural or legal person who manufactures, assembles medicated cosmetic product or has such a product designed or manufactured, and markets that medicated cosmetic product under his name or trademark;
41. **"Marketing authorization"** refers to an official approval of the medicated cosmetic product to be marketed or distributed in Rwanda mainland;

42. "**marketing communications**" includes "advertising as well as other techniques, such as promotions, sponsorships and direct marketing, and should be interpreted broadly to mean any communications produced directly by or on behalf of marketers intended primarily to promote products or to influence consumer behavior".
43. **Media":** means newspaper, magazine, medical/journal, television, radio, the internet; Out of home, vehicle branding, posters, handbills, cinema, point of sale material; online, digital and social media, any form of projected light and sound recordings or any of such means of communication.
44. **"Medicated cosmetics "or "cosmeceuticals"** are products that have both cosmetic and therapeutic (cosmetic or drug-like) effects, and are intended to have a beneficial effect on skin health and beauty. Like medicated cosmetics, they are applied topically as creams or lotions but contain active ingredients that have an effect on skin cell function. In some cases, their action is limited to the skin surface (such as exfoliants), while others can penetrate to deeper levels, either enhancing or limiting normal skin functions
45. ***"Name of the medicated cosmetic product"*** refers to the name given to a medicated cosmetic product, which may be an invented name, together with a trademark or the name of the manufacturer;
46. "**Registered product"** means a product currently registered in accordance with the provisions of these Regulations
47. **"Outer label"** Outer label" means secondary packaging material label;
48. ***"Outer packaging/* outer container*"*** refers to the packaging into which is placed the immediate packaging/inner container
49. ***"Package"*** refers to any box, packet or any other article in which one or more containers of medicated cosmetics are to be enclosed in one or more other boxes, packets or article in question, the collective number thereof;
50. "**Package labelling**" includes the label on the immediate container plus all other printed matter such as outer wrapper, carton or leaflet associated with the package;
51. "***patch test"*** is a way of seeing how sensitive you are to certain products, including medicated cosmetics. To do the test, wash a small area of the skin behind

your ear or on your inner forearm, then apply a small amount of the medicated cosmetic and let it dry.

52. **"Premises"** means any place that includes a vehicle, vessel, railway carriage, aircraft and building

53. ***"Product"*** for the purpose of these guidelines, means a medicated cosmetic ;

54. ***"Product Variant(s)"*** For the purpose of this guideline product variants shall mean, items in a range of medicated 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;

55. **"Prohibited Ingredient"** refers to a substance which is forbidden to be a component of a medicated cosmetic ;

56. "**Principal display panel"** means the part of a package or label that is most likely to be displayed, presented, shown or examined under customary conditions of display for display for retail sale;

57. **'recall'** means any measure aimed at achieving the return of a medicated cosmetic product that has already been made available to the end user;

58. ***"Registrant (market authorization holder)"*** refers to the holder of the authorization for the medicated 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;

59. **Responsible person** is defined in the Regulations as a locally or foreign registered company who is instrumental in causing the medicated cosmetic product to be available for sale in Rwanda which may be Manufacturer in Rwanda,Person designated by a manufacturer from outside of Rwanda.The key responsibilities of the person responsible include the following:Submitting product notifications, ensuring product safety, performing recall of unsafe products, reporting product defects and adverse effects, submitting safety & technical information when requested by Authority.

60. ***"Sell or sale"*** refers to sell by wholesale or retail and include import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for the purposes of sale, and

barter or exchange supply or dispose of medicated cosmetic , whether for a consideration or otherwise;

61. ***"Sunscreen"*** refers to medicated cosmetic that protects the skin from the harmful radiation of the sun
62. **withdrawal'** means any measure aimed at preventing the making available on the market of a medicated cosmetic product in the supply chain;

CHAPTER 1: INTRODUCTION

1.1 Scope

These guidelines shall be used on submission of documentation for registration of medicated cosmetics. It describes procedures for dossier applications for registration of new medicated cosmetic products, variation to registered medicated cosmetic products, renewal of registration as well as labelling.

1.2 Classification of medicated cosmetic products

For the purpose of these guidelines cosmetic products are classified into two (2) categories namely medicated cosmetics and non-medicated cosmetics.

Rwanda FDA classify cosmetics product according to their **Active ingredient**(s) and **intended uses** (For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An Antidandruff shampoo is both cosmetic and medicated, because it is intended to cleanse the hair and treat dandruff)

1.2.1 Medicated cosmetics

These are functional medicated cosmetics which offer additional benefit over non-medicated cosmetics. They contain bioactive ingredients that although are not drugs have visible and measurable short- and long-term effects on the body.

They include but not limited to:

(a) anti-acnes, /Anti-Eczema/anti-pimple

(b) anti-aging/anti-wrinkles,

(c) Sensitive skin protection/skin repair/Oily skin (Mattifying)

(d) skin lightening/ spots corrector/spots removals,

(e) sunscreens or sun blocks

(f) Anti-irritant/Anti-inflammatory and Exfoliators /Anti-redness/ Anti-itching,

(g) Ultra moisturize for dry skin and Anti crack,

(h) Toothpastes: anti cavity/ anti sensitivity, mouthwash/anti-gingivitis

(i) Anti dandruff,

(j) Antiperspirants,

(k) medicated cosmetic products for hair growth, hair inhibitor, hair removal, hair relaxer, hair waving, hair dyes

(l) medicated cosmetics powder

(m) Pain relief/Aromatherapy fragrance oil

(n) medicated cosmetic products for skin growth removal

(o) Scars / Marks removal

(p)Special cosmetics also include:

a) cosmetics containing components derived from living organisms, microorganism produced through biotechnology process,
b) baby care products,
c) medicated cosmetics which have potential to be absorbed through the mucous membrane such as products for application in the area around the eyes (except eyebrow products), intimate areas, lips/and oral cavity.

CHAPTER 2: GENERAL REQUIREMENTS FOR REGISTRATION

2.1 Submission of application

An application for product registration for either locally manufactured or imported, shall be made in writing via a cover letter and application form dated and signed by the applicant. If the applicant is a foreign company, the applicant shall appoint a local technical representative through whom an application shall be submitted. The local agent shall be a registered wholesale company or an accredited manufacturer's representative. All application document shall be in English

The application should be submitted to Rwanda FDA through the authorized local technical Representative to the following address:

Director General
Rwanda Food and Drugs Authority
P. O. Box 84
Kigali- Rwanda

2.2 Types of Applications

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

1. **New applications for registration:** an application for registration of product that is intended to be placed on the Rwanda market for the first time or product which was on the market without registration certificate.
2. **Renewal of product registration:** Applications for renewal of a registered product. The application shall be made at least 3 months before the expiry of existing registration.
3. **Variation of a registered product:** an application for any change in the registered products. All applications for variation to a registered product shall be made according to requirements as stipulated in the Rwanda FDA Guideline for Variation of Registered medicated cosmetic.

2.3 Application requirements

An application for registration of medicated cosmetics in Rwanda shall include the following:

1. Signed and dated original hard-copy of cover letter ***(refer to the annex I, document N° DHT/FMT/31)***
2. Signed and dated application form for new registration of medicated cosmetics products ***(refer to the annex II, document N° DHT/FOM/45)***
3. Proof of payment of non-refundable registration fee at the time of submission
4. Two CD-Rom or external driver virus free containing all information on safety, quality and efficacy of the product. (where applicable)
5. Two commercial samples of the products with certificate of analysis.
6. A separate and complete application for registration of medicated cosmetic products shall be submitted for each product or product variant.
7. A separate and complete application for registration of products shall be submitted for each medicated cosmetic with different ingredients and formulation, intended use, forms and site of manufacture.
8. A separate and complete application for registration of products shall be submitted for product with the same ingredients and formulation but with different colours and/or fragrance

2.4 Receiving of applications for medicated cosmetics registration

An application consists of electronic copies, online submission or specified hard copies where applicable. The application of product registration is only received by the Authority when the payment of prescribed registration fees is made. After receiving a product registration application, a reference number is assigned according to SOP for assigning reference number for product registration and it will be used in all subsequent correspondences relating to the application. An acknowledged receipt will be issued.

2.5 Data requirements for new application

2.5.1 Administrative requirement

a. Applicants should include a cover letter with all applications. The cover letter for product registration shall be dated and signed by the applicant (***Refer to the annex-I document N^{o} DHT/FMT/031***) downloadable from Authority's website
b. An application to register a medicated cosmetic must be accompanied by a completed product application form ***(refer to the annex II, document N^{o} DHT/FOM/045)*** downloadable from Rwanda FDA website. The application form should be duly filled with relevant information and attachments, dated signed and stamped appropriately.
c. Contract Manufacturing Agreement (where applicable)
d. Manufacturing license
e. A valid GMP Certificate or other applicable internationally recognized Management System certification
f. Two (2) commercial samples of the product(s) and two (2) coloured artwork/Label of the product and leaflet insert of the product (where applicable). Where necessary additional samples may be requested depending on tests or parameters to be carried out.
g. Appointment letter of the local technical representative with original copy of Power of attorney from the product manufacturer (if imported)
h. Proof of payment of non-refundable registration application fee

2.5.2 Technical requirements

2.5.2.1 chemical analytical data of raw materials

The applicant shall indicate the following for raw materials:

a. Name for each ingredients and their CAS (Chemical Abstract Service) number
b. Name and address of manufacturer for each ingredients
c. Specifications: The basic and minimum specifications active ingredient of medicated cosmetic shall include: chemical identity, physical form, purity of the chemical,

characterization of impurities, Heavy metals, solubility and melting point, pH, moisture content microbiological test and additional relevant physical, and chemical specifications.

d. Copies of certificate of analysis for each ingredient should be submitted
e. Material Safety Data Sheet for each ingredients

2.5.2.1 Data on final product

Applicant shall submit the following information on final products:

a. Description of final product and its intended use

b. Data Composition of product and active ingredient: Composition data shall indicate all the lists of ingredients, quantity, role in tabular format.

c. Manufacturing process

1. The applicant shall provide flow chart and narrative of manufacturing process, mentioning the quality and quantity of the raw materials used including the final packaging and labelling procedures.
2. Description on the precautions and in-process controls that are made in connection with different stages of manufacturing shall be indicated

d. Method of analysis and specification of the finished product

1. The applicant shall mention relevant control parameter for the finished product and their acceptance limits. The final product specification may indicate the basic and minimum specifications include: appearance (clarity, color, homogeneity and odor), consistency, particle size, pH, average weight or volume, microbiological limit and assay of active ingredient.
2. Method of analysis for the finished product shall indicate all the test method and specification. The test methods shall be including the equipment, reagent and analytical method.

e. Packaging and labelling information

1. The applicant shall provide information on packaging material. This shall be made of substances/materials which are safe and suitable for its intended use and which shall preserve its hygienic, safety and quality.
2. Medicated cosmetic product labels should be clearly legible, indelible letters and written in one of the official languages used in Rwanda bearing the following information: brand name, common name of the product, Manufacturer's name and physical address, lot or batch number, Manufacturing date and Expiry date, Net content (weight/volume), List of ingredients used, intended use medicated cosmetic product, Instructions for use, Country of origin, Storage conditions, Warnings and cautions if any.

f. Stability data

The applicant shall provide stability data supporting the proposed shelf life for at least two batches. The stability studies shall be conducted in the container closure system in which it will be marketed in Rwanda.

The applicant shall provide stability data supporting the proposed shelf life for at least two batches. The stability studies shall be conducted in the container closure system 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 and Duration:

Storage conditions	**Duration**	**Testing interval (Months)**
Long term stability studies at $4^{o}C$	Shelf life	0, 3,6,9,12,18,24,36,48
Long term stability studies at $25^{o}C$ / ambient Relative Humidity	Shelf life	0, 3,6,9,12,18,24,36,48
Accelerated stability studies at $37^{o}C$/ ambient Relative Humidity	6months	0,3,6
Accelerated stability studies at $37^{o}C$ /	6 months	1

80 % Relative Humidity		

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

iv. Parameters to be tested should be those susceptible to change and are likely to influence the quality and safety of the finished product. They shall at least cover appearance (clarity, color, homogeneity and odor) for product form, levels of characteristic ingredients, physicochemical properties (such as pH, purity, and consistency), average weight or volume, assay of active ingredient and microbial limits depending on the nature of the product.

v. Test results from item (iv) above.

2.6. Data requirement for Variation

a. If for any reason the applicant changes any matter related to registered medicated cosmetic including but not limited to change of packaging, labeling or any other change, shall before selling the changed medicated cosmetic product, notify and obtain the Authority'approval of the change. The application shall be accompanied by:

1. A duly signed covering letter
2. Documentation in support of variation
3. Product samples reflecting the variation
4. A non – refundable variation fee as specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff and fees

b. The Authority will evaluate reasons provided in the notice and if satisfied with such reasons it will approve the changes by issuing approval notice and if it is not satisfied the applicant will be notified by stating the reasons thereof.

c. Changes involving product(s) composition and manufacturing sites shall be treated as new application.

2.7. Retention of medicated cosmetics on the register

The registered medicated cosmetic is retained on the register annually. The medicated cosmetic shall be removed from the register if application and payment of fees is not effected

Application for retention on the register shall be submitted thirty (30) calendar days before the due date.

The application shall be accompanied by:

a. A covering letter
b. Non-refundable fees as specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service fee tariff and fines

2.8. Renewal of product registration

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

The application shall be accompanied by:

a. A covering letter
b. Supporting documentation for any variations since the product was last registered
c. Samples of the product in the final package
d. Non-refundable application fee as specified in Rwanda FDA regulation CDB/TRG/004 related to regulatory service tariff and fees
e. The registration renew shall be approved by the Authority

ENDORSEMENT OF THE GUIDELINES

	Author	Authorized by	Approved by
Title	Division Manager of Drugs and Health Technologies	Head of Food and Drugs Assessment and Registration	Director General
Names	**IRASABWA Clarisse**	**KABATENDE Joseph**	**Dr. KARANGWA Charles**
Signature			
Date	**29/07/2020**	**29/07/2020**	**29/07/2020**

ANNEXES

ANNEX I – COVER LETTER

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

<Rwanda FDA>
<P.O.BOX 84> <Kigali>
< Rwanda >

Dear Sir/Madam,

Subject: Submission of Application for registration of Medicated cosmetics <Brand Name(s), Common Name(s) and product form(s)

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

Name of the medicated cosmetic product as follow:
Brand name (s):
……..……..…….
Common Name (s):
……
Active ingredient(s) INCI name:
…….....
……
…
Product form :
…….……..……
Intended use(s):
……..……..……..
Manufacturer:
…….

You will find enclosed the submission dossier as specified hereafter:

- ☐ The relevant fees for this applicantion have been paid.
- ☐ Two CD rom/external driver that contains product information in word format and in PDF
- ☐ Two commercial samples of the product

- ☐ The electronic submission contains the following sections:

Section 1: Administrative requirement informations

Section 2: Technical 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>

ANNEX II: APPLICATION FORM FOR NEW REGISTRATION OF MEDICATED COSMETICS PRODUCTS

(For official use only)

Application Reference No:

Requirements for new registration of medicated cosmetics

1. Signed and dated original hard-copy of cover letter ***(refer to the annex I, document* DHT/FMT/031*)***
2. Signed and dated application form for new registration of medicated cosmetics products (refer to the annex II, document No DHT/FOM/045)
3. Proof of payment of non-refundable registration fee at the time of submission
4. Two CD-Rom or external driver virus free containing all information on safety, quality and efficacy of the product. (where applicable)
5. Two commercial samples of the products with certificate of analysis.
6. A separate application shall be submitted for each product or product variant.

1.0. Product Particulars

1.1 Brand name of Prouct……

1.2 Common Name of Product……

1.3 Product Form (tick the appropriate form)

Aerosol	☐	Capsule	☐	Cream	☐	Emulsion	☐	Gel	☐
Granules	☐	Kit	☐	Liquid Suspension	☐	Loose powder	☐	Lotion	☐
Ointment	☐	Paste	☐	Pressed powder	☐	Pressed Cake	☐	Solution	☐
Stick	☐	Other (Please specify):……							

1.4 Physical Description:……

..……..……

1.5 **Area of application of cosmetic *(tick the appropriate)*:**

Oral cavity ☐ Hair system ☐ Face ☐ Lips ☐

Body ☐ External genital ☐ Nail ☐ Eyes ☐

Other…

1.6 Intended use (tick the appropriate):

Anti-Acnes ☐ Anti- Eczema ☐ Anti-pimple ☐ Anti-Aging ☐

Anti- Wrinkles ☐ Sensitive Skin ☐ Skin repair ☐ Mattifying ☐

Skin lightening ☐ Spot Corrector ☐ Spot removals ☐ Suscreens ☐

Anti-irritant ☐ Ani-inflammatory ☐ Hair conditionners ☐ 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 ☐ Powder ☐

Hair Removal ☐ Antidundruff ☐ Hair strenghthener ☐ Pain Relief ☐

Aromatherapy oil ☐ Hair Inhibitor ☐ Scars Removal ☐

1.7 Contraindication

……

……

1.8 Application method:

……

1.9 Pack size(s):

……..

1.10 Unit Composition:

S/N	Chemical Name	INCI name	% Proportion	Reason for Inclusion

Note:1 Add row(s) if required

2 If the formula is considered to be confidential seal in an envelope and mark confidential and then attach.

1.11 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.

……

…...……

…….……

1.12 Brief description of the method used to determine the shelf life.

……..

……..

……

1.13 Recommended storage conditions (where applicable) including any relevant information after the product is opened for use or reconstituted:

1.14 Proposed shelf-life:

……

…….

2. Particulars of Applicant/ Registrant

Name: …….

Physical Address: ……

Postal Address: ……

Country: ……

Phone: ……..……. Fax: ……

Email: …….

Status of applicant (tick where appropriate)

Manufacture ☐ Importer ☐ Exoporter ☐

Other……

3. Particulars of Manufacturer

Name: …….

Physical Address: ……

Postal Address: ……

Country: ……

Phone: ……..……. Fax: ……

Email: …….

4.0 Particulars of Local agent/ Distributor

Name: …….
Physical Address: ……
Postal Address: ……
Country: ……
Phone: ……..……. Fax: ……
Email: …….

5.0 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 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 reliable for appropriate action under the provisions of the Rwanda FDA regulation
Name:
……..…….
Position in the company:……
Signature:
…….…… Official stamp:……..
Date:……..

* Note: If fees have been paid, attach proof of payment

6.0 Fees/ Charges payment (For Official Use only)

Fees to be Paid …….

Name and Signature of Authorized Officer…….

Name and Signature of Cashier ……...

Receipt Number ……...

Date …….. Stamp……..

NB: Cashier should attach copy of receipt

ANNEX III:APPLICATION FORM FOR RENEWAL OF PRODUCT REGISTRATION OF MEDICATED COSMETIC PRODUCT

(For official use only) Application Reference No:

1.0 Product Particulars

1.1 Registration number:

……..

1.2 Date of expiry of current registration:

……..

1.3 Name of Product:……..

1.4 Product Form:…..……..

1.5 Physical description: ……..

……..

1.6 Are there any changes since product was registered?

No ☐

Yes ☐

If yes, give descriptions of the changes and if were approved by Rwanda FDA

……..

…….

1.7 Are there any reported adverse reactions?

No ☐ Yes ☐

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

……..

……..

2.0 Particulars of Registrant

Name: ……

Physical Address: ……

……

Postal Address: ……

Country……..

Phone: ……Fax: ……Email: ……

Status of applicant (tick where appropriate)

Manufacturer ☐ Importer ☐

2.0 Particulars of manufacturer

Name: ……

Physical Address: ……

……

Postal Address: ……

Country……..

Phone: ……Fax: ……Email: ……

4.0 Particulars of local agent or importer

Name: ……

Physical Address: ……

……

Postal Address: ……

Country……..

Phone: ……Fax: ……Email: ……

5.0 Declaration by the Applicant

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 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 reliable for appropriate action under the provisions of the Rwanda FDA regulation

Name:

……..…….

Position in the company:……

Signature:…….……..

Official stamp:……

Date:……..

ANNEX IV: PACKAGING AND LABELLING OF MEDICATED COSMETICS

All written information, printed or graphic material on or accompanying a product, this includes labels, inserts, risers, display packs, leaflets, promotional literature or any other written or printed information distributed with a product. This information appears in PDP and IP

1. Placement of Information on Labels

1.1 Outer Container

A label may consist of more than one panel. It may consist of a front panel, side panels and a back panel. Back and side panels are generally called information panels. PDP must be large enough to accommodate all required label information with clarity and conspicuousness

The information below must appear on the label of the outer container holding the inner container. The immediate container holding the medicated cosmetic product also is the outer container if it is not displayed in a box, folding carton …etc.

Principal Display Panel	**Information Panels**
Name of product	Directions for safe use
Identity	Name and place of business
Warning	Ingredient declaration
Net quantity of contents	Warnings
	Any other required information

1.2 Inner Container

The information below must appear on the label of the inner container holding the medicated cosmetic product.

The inner container is packaged and displayed in a non-transparent box, folding carton etc. If the outer container is removed and the product displayed for sale without it, the label of the immediate container becomes a label of an outer container.

Front Panel	Information Panels
	Directions for safe use
	Warnings
Name of Product	Name and Place of Business
	Net Quantity of Contents
	Any Other Required Information

2 Labelling requirements

Medicated cosmetic product labels should contain truthful and accurate information about the medicated cosmetic product, its intended use and application method. They are required to be labelled in accordance with these guidelines before they can be sold or supplied in Rwanda and to make claims that will NOT mislead the consumer about the product's contents, quality or safety.

The following information must appear on the outer packaging or immediate container of the medicated cosmetic products:

1. The brand name
2. Name of the product
3. Manufacturer's name and physical address
4. lot or batch number
5. Manufacturing date and Expiry date
6. Net content (weight/volume)
7. List of ingredients used
8. intended use of medicated cosmetic product,
9. Instructions for use
10. Country of origin
11. Registration number assigned to it in a manner as prescribed by the authority
12. Storage conditions

13. Warnings and cautions if any

2.1 Product name or identity

2.2 Name and address of Local Technical Represetative

The name and business address appearing on the label may be that of the Responsible If you have a question or a problem with a product you should contact manufacturer, packer or distributor. If the name and address is not that of the manufacturer, the name must be preceded by phrases such as

a. Manufactured for
b. Distributed by
c. or other appropriate wording

2.3 An ingredients list

The name used for and ingredient shall be identified by its common name as provided for in the common ingredients nomenclature INCI.or, in the absence of nomenclature or of a common name, by its chemical name

All medicated cosmetic products must be labelled with all the ingredients contained in the product. The quantity or percentage of each ingredient in the medicated cosmetic product need not be disclosed on the labelling. The ingredients should be listed in descending order by weight, except

for:

a) Ingredients in concentrations of less than 1% (by weight or by volume) which may be listed in any order after ingredients present in concentration of 1% or more;
b) Colouring agents which may be listed in any order, after the other ingredients`
c) in case of decorative medicated cosmetics marketed in a range of colour shades, all colouring agents used in the range may be listed if they are preceded by the symbol¨+/-¨ or ¨±¨ or the phrase ¨may contain¨
d) Perfume and aromatic compositions and their raw materials may be referred to by the word “perfume”, “fragrance”, “aroma” or any other similar term. Likewise, flavoring may be referred to as “flavor” or any other similar term.
e) Botanicals must be listed by specifying at least genus and species portions

f) All toothpastes containing sodium fluoride must be labelled with the following wording: "contains sodium fluoride"

i. any toothpaste containing 0.1 to 0.15% fluoride, unless it is already labelled as contraindicated for children (e.g. "for adult use only") the following labelling is mandatory: "Children under 6 years and younger: use a pea-sized amount for supervised brushing to minimize swallowing.

ii. In case of intake of fluoride from other sources consult a dentist or doctor".

g) The following shall not, however, be regarded as ingredients:

i. Impurities in the raw materials used;

ii. Subsidiary technical materials used in the preparation but not present in the final products;

iii. Materials used in strictly necessary quantities as solvents, or as carriers, for perfume and aromatic compositions.

2.4 Net content of medicated cosmetic product

(1) The contents given by weight or volume, in either metric or both metric and imperial system;

(2) The accurate average net content of every medicated cosmetic product shall be

(3) declared on the inner and outer label in the metric system.

(4) Products that have only an inner label shall meet the same requirements as those for the outer labels of products having both an outer and inner label.

(5) The declaration of the average net content of the medicated cosmetic product shall be required to be made in the case of:

(a) liquid medicated cosmetic in volume;

(b) solid medicated cosmetic by weight and number or count (where applicable); and

(c) semi-solid or viscous medicated cosmetic by weight or volume.

(6) The declaration shall accurately reveal the quantity of medicated cosmetic in a package exclusive of wrappers and other material packed therewith, provided that:

(a) in the case of medicated cosmetics packed in containers designed to deliver the medicated cosmetic under pressure, the declaration shall state the net quantity of the

contents that will be expelled when the instructions for use as shown on the container are followed and the propellant is included in the net quantity declaration;

(b) in the case of a package which contains the integral components making up a complete kit, and which is designed to deliver the components in the manner of an application, the declaration may state the net quantity of the contents in non-deceptive terms of the number of applications available in the kit when the instructions for use as shown on the container are followed; and

(c)the declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of Good Distribution Practice or by unavoidable deviations in Good Manufacturing Practice will be recognized along with variations from stated quantity of contents which shall not be unreasonably large.

In cases where the size, shape or nature of the container or package does not permit the particulars laid down in (2-4) to be displayed, the use of leaflets, pamphlets, hang tags, display panel, shrink wrap, etc. shall be allowed. However, the following particulars at least shall appear on small immediate packaging:

a) The name of the medicated cosmetic product;

b) The manufacturer's batch number;

2.5. Batch number or lot

The batch number /code allows responsible person or supplier identifying the batch in which product was produced. If the product is not made in a batch, then the code should enable the date and place of manufacture to be identified.

The batch number is a combination of letters and/or figures. The Regulation does not specify the format for the batch number; the decision belongs to the responsible person. The purpose of the batch number is to ensure identification of a certain batch of a medicated cosmetic product throughout the whole supply chain, in particular in the rare case of a recall.

The batch number has to be printed on both the container and the packaging. Where this is impossible for practical reasons because the products are too small, it can be printed only on the packaging.

2.6 Date of minimum durability (DOMD) and period after opening (PAO)

On the basis of finished product physicochemical and microbiological stability studies on DOMD and PAO, two different situations have to be considered:

1. The finished product has a minimum durability of less than or equal to 30 months, the date of minimum durability shall be clearly expressed and preceded by the mention "best used before the end of" (or by the abbreviation "Exp." or the letter "E) or by the following symbol(Image 1)

Image 1

a. The date consists either of the month and year (MMYYYY or MMYY) or the day, month and year (DDMMYYYY or DDMMYY), in that order. If the date is not located next to the symbol or next to the "best used before the end of" sentence, its location has to be clearly explained. If necessary, the information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

b. Manufacturing date in the form as of "mm/yyyy"

2. The finished product has a minimum durability of more than 30 months, a date of minimum durability is not required. However, an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer must be labelled using the symbol representing an open cream jar shown in image 2

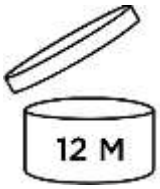

Image 2

The symbol must be accompanied by an indication of the period of time in months or years shown as a number, which can be located inside or outside the symbol. The indication is usually given in months as "x M".

3 Particular Requirements for labelling Certain Medicated cosmetics

I. **A hair dye**

A hair dye that contains paraphenylene-diamine or other coal tar dye base or coal tar intermediate must

a. carry the following warning on both the inner and outer labels:

"CAUTION: This product contains ingredients that may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows. To do so may cause blindness.

b. be accompanied by instructions to the following effect:

1. the preparation may cause serious inflammation of the skin in some persons, and a preliminary test should always be made to determine whether special sensitivity exists, and

2. to make the test, a small area of skin behind the ear or on the inner surface of the forearm should be cleansed, using either soap and water or alcohol, and a small quantity of the hair dye as prepared for use should be applied to the area and allowed to dry. After 24 hours, the area should be washed gently with soap and water.

If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should be made before each application. The hair dye should never be used for dyeing eyebrows or eyelashes, as severe inflammation of the eye or even blindness may result.

II. **A deodorant**

A deodorant that is intended for use in the genital area and that is sold in a pressurized container shall carry the following information on both its inner and outer labels

"**Directions:** For external use only. Use sparingly and not more than once daily. Spray external skin surface while holding nozzle at least 20cms from the skin"

"**Caution:** Do not apply internally or to broke, irritated or itching skin. Do not use when wearing a sanitary napkin. Discontinue use immediately if a rash or irritation develops. Consult a physician if the rash or irritation persists or if there is any unusual odour or discharge at any time"

III. Soap

1. Where soap is supplied in a container or wrapper, it shall comply with the labelling requirements set forth in these Regulations.
2. Where soap is not supplied in a container or wrapper, the name and address of the manufacturer and the batch number shall be given on either:
   - the soap itself;
   - or the packaging in which it is exposed for supply;
   - or the container in which it was packed before being exposed for supply.
   - And the remaining information, that is:-
   - minimum durability date;
   - warning statements and precautionary information;
   - product function (where applicable); and
3. Ingredient listing shall be provided on a leaflet supplied with the soap

4 Prominence and Conspicuousness

This guideline offers detailed information on how to comply with the requirement for prominent and conspicuous placement of information on medicated cosmetic labels or labelling.

4.1 Panel display:

A warning statement must appear on the label prominently and conspicuously as compared to other words, statements or designs so that it is likely to be read by ordinary consumers at the time of purchase and use. This eliminates placement of required information on a bottom panel of a medicated cosmetic unless it is very small and customarily picked up by hand where inspected for possible purchase.

4.2 Panel Size:

The label must be large enough to provide sufficient space for prominent display of the required information.

4.3 Style and Size of Letters

The type must be of such size, and at least of the required minimum size and may in no case be less than 1.6 mm in height, and of such style that the required label statements are easily readable

4.4 Background Contrast

The contrast must be sufficient to make the required label statements conspicuous and easily readable.

4.5 Obscuring Designs, Vignettes

The required statements must not be obscured by vignettes or other designs or by crowding with other printed or graphic matter.

5 Language

All label or labelling statements required by regulation must be in Kinyarwanda, English or French language.

6 Prohibition

- No person shall manufacture, import, export, distribute, advertise, display for sale, offer for sale, sell, or use a medicated cosmetic , unless The product shall be packaged in suitable well containers (container made of suitable packaging materials) that protect the content(s) and not cause any contamination or reacts with product
- No person shall manufacture, import, export, distribute, advertise, display for sale, offer for sale, sell, or use a medicated cosmetic , unless a label has been affixed thereto with the information required by these guideline appearing on both the inner and outer container.

Suppliers of medicated cosmetic products, such as wholesalers or retailers, must ensure that the medicated cosmetic products comply with the Regulations before they supply the product.

7 Sanctions and penalties

Any person who contravenes any of the provisions of these guidelines shall be guilty of an offence and liable on conviction to a fine

a. The authority shall cancel, suspend, or withdraw the registration of medicated cosmetics
b. Order the recall of medicated cosmetic products
c. Suspension or revocation of issued license and certificate
d. Adverse publicity
e. Seize and destruction of medicated cosmetics determined not to be in compliance with the requirement of provisions of this regulations.

The authority may impose additional fine depending on the nature of non-compliance

ANNEX V: EXPLANATORY NOTES ON FORMS OF COSMETICS

Aerosol products: are a mixture of liquefied gas, propellant, solvent(s) and active ingredients that are packaged under pressure in a container with a valve. When the valve is opened, typically by pressing a button on the top of the can, the internal pressure forces the aerosol up the dip tube and out of the valve. Many aerosol products require shaking before use to completely mix the ingredients prior to spraying. Failure to do this can mean the propellant (part that helps push the ingredients out of the can) would be used first, which would then trap the remaining ingredients in the can.

Capsule: A solid dosage form consisting of a shell and a powder or liquid filling example bath oil capsules.

Cream: Cream is a preparation usually for application to the skin. Creams are semisolid dosage forms containing more than 20% water or volatile components and typically less than 50% hydrocarbons, waxes, or polyols as vehicles.

Emulsion: Usually a white, opaque system that consists of at least two immiscible liquids, one of which is dispersed as droplets (internal phase) in the other (external phase). The system is generally stabilized with emulsifiers.

Foam: A suspension of gas in a liquid.

Gel: A clear semisolid dosage form that contains a gelling agent, which provides stiffness to the product.

Liquid suspension: A solid suspended in a liquid. For example, some moisturizers and some skin cleansers.

Liquid oil :A substance which is not miscible with water, and is generally slippery, viscous and liquid at room temperatures (for example mineral oil).

Liquid non-oily: A non-oil based, low viscosity fluid form that can be poured. For example, solutions and milky lotions.

Lotion: A low-viscosity liquid emulsion.

Ointment: A highly viscous, usually greasy, semisolid dosage form. It is more viscous than a cream.

Solution: A clear, homogeneous liquid dosage form that contains one or more chemical substances dissolved in a solvent or mixture of mutually miscible solvents.

Stick: A solid dosage form that is made of waxes and a smaller amount of oils and is prepared in a relatively long cylindrical form, e.g. lipsticks, eyebrow pencil.

Solid powder – Loose: A solid dosage form containing a freely flowing mixture of different dry solid ingredients, e.g. dusting powder,makeup and talcum

Solid powder - Pressed: A solid dosage form that contains a freely flowing mixture of different dry solid ingredients in a compressed form, e.g. blush, eye makeup/shadow.**Solid - Cake/Pressed Cake:** A solid dosage form that consists of primarily dry solid particles mixed and/or pressed together, or waxy ingredients molded into a specific shape, e.g. soap, bath bar.

Solid granules: A small particle or grain that is usually dissolved or dispersed in water or another liquid. For example, bath salts, crystals and pearls.

Semi-solid cream: A viscous liquid or semi-solid emulsion. For example, some hair grooming products and makeup.

Semi-solid gel:A viscous, usually clear, jelly-like semi-solid. For example, some hair grooming products and dentifrices.

Semi-solid lotion:A liquid emulsion that is usually applied to the skin. For example, some moisturizers and makeup.

Semi-solid ointment/balm: A thick, viscous preparation based on a fatty material.

Scars removal: medicated cosmetics used to improve the condition or appearance of a **scar** anywhere on your body

Other (Please specify) - Product which does not fall into one of the general categories above.

ANNEX VI: EXPLANATORY NOTES ON INTENDED USES

1. **Anti-acnes:** Anti-acne are the medicated cosmetics that help clear up the pimples, blackheads, whiteheads, and more severe forms of lesions that occur when a teen has acne.
2. **Anti-aging creams**: are predominantly moisturizer-based cosmeceutical skin care products which making the consumer look younger by reducing, masking or preventing signs of skin aging.
3. **Anti-dandruff**: cosmetics tending to prevent dandruff
4. **Anti-irritant:** describe a diverse group of topical product ingredients, which were able to reduce the irritation potential of other more irritating ingredients in the same product and they are being added to cosmetic formulations in order, allegedly, to benefit tolerability of the products and allow claims such as 'soothing' and 'healing' ingredients therefor reduce skin irritation.
5. **Anti-inflammatory**: medicated cosmetics acting to reduce certain signs of inflammation, as swelling, tenderness, fever, and pain.
6. **Anti-itching**:
   preventing or alleviating itching/ are medications that inhibit the itching often associated with sunburns, allergic reactions, eczema, psoriasis, chickenpox fungal infections
   insect bites and stings like those from mosquitoes, fleas, and mites
7. **Antiperspirants:** cosmetics product put on the skin, especially under the arms, in order to prevent or reduce sweating typically by blocking sweat glands
8. **Anti-wrinkles** : cosmetics that are intended to reduce the appearance of wrinkles in the skin, or intended to reduce or remove wrinkles from the skin against sunburn.
9. **Baby Product**: Product labelled for use on infants 3 years old or less.
10. **Bath Preparation**: Product added to the bath water, it includes bath oils, tablets, salts, bubble baths, etc.
11. **Breath freshener** :Product that is used in the oral cavity to mask or reduce mouth odours. Includes breath freshening drops, sprays and strips. Excludes lozenges and gum.
12. **Deodorant:** Product which modifies, reduces, or prevents the development of body odors, excludes genital deodorants and products which claim to reduce perspiration.

13. **Eye Lotion:** Non-makeup product specifically indicated for use in the area of the eye, it includes lotions and moisturizers.
14. **Eye Makeup:** Product specifically indicated for use in the area of the eye, it includes eyebrow pencils, eyeliners, eye shadows, eye makeup removers, mascara, etc.
15. **Face Makeup:** Product for use in the area of the face, face powders, foundations, rouges, makeup fixatives, etc.
16. **Exfoliant – Chemical:** Product that chemically removes dead cells from the surface of the skin, such as a facial peel.
17. **Exfoliant – Mechanical:**Product that mechanically removes dead cells from the surface of the skin, such as a body scrub.
18. **Hair Bleach:** Product which make hair whiter or lighter especially by physical or chemical removal of color excluding hair lighteners with colors
19. **Hair growth** Medicated cosmetic products used for promotion of *hair growth*, prevention of *hair loss*
20. **Hair inhibitor:** Medicated cosmetic products used for prevention of *hair loss*
21. **Hair Conditioner:** Non-shampoo product which increases the suppleness or body of the hair, facilitates combing, adds gloss or texture to the hair, etc. **Hair Dye:** Product which changes the color of the hair.
22. **Hair Grooming**: Product which improves the appearance or is used to shape/style the hair. Includes mousses, gels, pomades, sprays etc.
23. **Hair Removal**/ Depilatory/ EpilatorCosmetics product which facilitates the removal of hair by chemical or mechanical means such as hair removal wax.
24. **Hair Shampoo:** Product which cleanses the hair. Product is washed off after use.
25. **Hair Straightener:** Product which contain agents which chemically soften the hair to facilitate straightening of the hair.
26. **Genital Deodorant/intimate**: Deodorant/Cleanser intended for use in the genital area, it includes non-douche feminine hygiene products.
27. **Lubricant (personal, non-spermicidal):** Product used to lubricate the genital area.
28. **Massage product:** Product used for massaging purposes.

29. **Moisturizer** :Product applied to the skin to soften or maintain skin suppleness by reducing water loss or increasing the water content of the skin. Includes emollients and humectants.
30. **Mouth wash** Product to freshen or deodorize the mouth and breath. Usually a liquid that is swished in the mouth and spat out (not swallowed).
31. **Nail product:** Product applied to the nails. Includes nail polish, nail cream, nail lotion, cuticle softener and nail hardener.
32. **Shaving product:**Product used to care for the hair or skin during and after shaving. Includes shaving cream, pre-shave lotion, after shave lotion, beard softener and shaving soap.
33. **Shampoo:** Product which cleanses the hair.
34. **Straightening, waving and curling products (permanent/semi-permanent):**Product which chemically softens the hair to facilitate straightening or curling. This is generally followed by a neutralization step.
35. **Styling product:**Product which is used to shape or style the hair. Includes mousse, gel, pomade and spray.
36. **Sunless tanning product :**Product which is used to give the appearance of a tan. Excludes products which protect the skin from sun damage or enhance or accelerate the tanning process.
37. **Skin lightening**: or ***skin bleaching***, is a cosmetic product aims to lighten dark areas of skin or achieve a generally paler skin tone. It's usually used to improve the appearance of blemishes such as birthmarks and dark patches (melasma).
38. **Skin repair :** medicated cosmetics which Protected skin from mechanical injury, chemical hazards, and bacterial invasion is provided by the skin because the epidermis is relatively thick and covered with keratin.
39. **Spots corrector**: spot corrector refers to a skin care product (generally with a serum or moisturizer-like consistency) that can help fade the appearance of dark spots with continued use over time for brighter and more even-looking skin
40. **Sunscreen**/**sunblock**, is a cosmetics product that absorbs or reflects some of the sun's ultraviolet (UV) radiation and thus helps protect against sunburn. Diligent use of sunscreen can also slow or temporarily prevent the development of wrinkles, dark spots and sagging skin.

41. **Toothpaste** is a paste or gel dentifrice used with a toothbrush to clean and maintain the aesthetics and health of teeth.
42. **Tooth whitener:** Product used to whiten teeth.

ANNEX VII: EXPLANATORY NOTES ON AREA OF APPLICATION

The table below describes the area(s) of application of the product-choose the most appropriate

Area of application	Description
Body	Applied externally to the human body. Does not include the eyes or the oral cavity.
Eyes	Primarily applied to the area of the eyes. In other words, the area bounded by the supraorbital and infraorbital ridges, including the eyebrows.
Face	Primarily applied to the skin of the face.
Genitals	Primarily applied to the genital area.
Hair	Primarily applied to the body or facial hair, except eyelashes and eyebrows.
Lips	Primarily applied to the lips.
Nails	Applied to the nails only.
Oral Cavity	Applied to the teeth or the mucous membrane of the oral cavity (mouth) only.

ANNEX VIII:ARRANGEMENT OF DOCUMENTS REQUIRED TO APPLY FOR REGISTRATION

This arrangement is subdivided in three different parts such as: administrative requirement, raw materials technical data requirements and finished product technical data requirements according to the requirements state in these guidelines:

a) The application and supporting document should be submitted in CD-ROM or External driver addressed to Rwanda FDA

b) The application form should be typed in English. Any document which is in any language other than English must be accompanied by a certified or notarized English translation.

c) Application Form and part three should be in both PDF and word format

d) The PDF documents should be selectable and searchable

e) All pages of the application should be numbered in the style: ***page x of y***.

Therefore, the applicant shall prepare and present the product dossier information in the following format

PART I: ADMINISTRATIVE REQUIREMENT

1.1 Table of content

1.2 Dated and signed cover letter

1.3 Completed application form (dated, signed and stamped)

1.4 Manufacturing sites and responsibility

1.5 Contract Manufacturing Agreement (where applicable)

1.6 A valid marketing authorization certificate

1.7 A valid manufacturing license.

1.8 A valid GMP Certificate (ISO 22716 Cosmetic GMP Certifications) or other applicable internationally recognized Management System certification

1.9 Two commercial samples

1.10 Two (2) colored Label of the product

1.11 Leaflet insert of the product (where applicable)

1.12 Appointment letter of the local technical representative with original copy of Power ofattorney from the product manufacturer

1.13 Two CD- Rom or external driver virus free containing all information

1.14 Proof of payment of non-refundable registration application fee

PART II: RAW MATERIALS TECHNICAL DATA REQUIREMENTS

2.1 Table of content

2.2 INCI Name for each ingredients

2.3 CAS (Chemical Abstract Service) number of ingredients

2.4 Name and address of manufacturer for each ingredients

2.5 Certificate of Analysis(COA) for each ingredient

2.6 Specifications of raw materials

2.7 Storage conditions and shelf life for each ingredients

2.8 Active ingredient(s) stability studies

2.9 Material Safety Data Sheets (MSDS) for each ingredient

PART III: FINISHED PRODUCT TECHNICAL DATA REQUIREMENTS

3.1 Table of content

3.2 Description of finished product and its intended use

3.3 Data Composition (ingredients, quantity, role) of product in tabular format.

3.4 Manufacturing process

3.5 Method of analysis and specification of the finished product

3.6 Packaging and labelling information

3.7 Stability data

3.7.1 Study design (protocol)

3.7.2 Test conditions, testing interval and Duration, Type of container used and Parameters to be tested

3.7.3 Test results

3.8 Material Safety Data Sheets of finished product (MSDSFP)