Doc. No.: TFDA/DMC/CCM/G/001

TANZANIA FOOD AND DRUGS AUTHORITY

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR MARKETING AUTHORIZATION OF COSMETIC PRODUCTS

Made under the Tanzania Food, Drugs and Cosmetics (Control of Cosmetics) Regulations, 2010

Third Edition

September, 2017

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Acknowledgements

This is the third edition of the Guidelines for Submission of Documentation for Marketing Authorization of Cosmetic Products in Tanzania Mainland. It supersedes the second print out which was in use since February, 2015.

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Adam Mitangu Fimbo
Director, Medicines and Complementary Products
Tanzania Food and Drugs Authority

Abbreviations

FIFO	First in First Out
FSC	Free Sales Certificate
GMP	Good Manufacturing Practice
ICID	International Cosmetic Ingredient Dictionary
INCI	International Nomenclature of Cosmetic Ingredient name
TFDA	Tanzania Food and Drugs Authority
TBS	Tanzania Bureau of Standards
UV	Ultra Violet
TZS	Tanzanian Standards

Foreword

The guidelines have been developed to assist applicants who wish to place their cosmetic products in Tanzanian market to provide the required information for marketing authorization. First edition of these guidelines was developed in the year 2009 which was subsequently reviewed into second edition in the year 2015. Since then advanced marketing and development in cosmetic industry has been extensively erupted which led on the need to develop simplified process for marketing authorization of cosmetics to keep pace with the market advancement and stakeholders satisfaction. This third edition has been developed to address those challenges and various concerns from the stakeholders related to cosmetics marketing authorization.

These guidelines have classified cosmetic products into two groups to facilitate marketing authorization process and their regulations as a whole. Marketing authorization process particularly for non special cosmetics has been simplified to improve their access and use. The guidelines have also adopted EU directives on the requirements for composition of a cosmetic product in particular to the list of prohibited ingredients and substances that are permitted to a certain level in order to ensure safe and quality products on the market.

The new guidelines require submission and processing of applications for marketing authorization direct through the online system which will not only shorten approval process but also ensure submission of reliable information from the applicants. Applicants are therefore encouraged to familiarize with these guidelines and follow them. However the requirements stipulated in these guidelines are minimal and whenever there will be additional information regarding products they should be submitted to the Authority.

Adherence to these guidelines will ensure that relevant information are provided for marketing authorization of cosmetics. This will facilitate efficient and effective evaluation and approval processes of the applications. It will also help to avoid queries which results in unnecessary delays of the approval process.

It is anticipated that the guidelines will be revised regularly in response to the knowledge and experiences gathered from time to time. We therefore welcome comments and inputs that will help in improving the guidelines.

Hiiti B. Sillo
Director General
Tanzania Food and Drugs Authority

Introduction

Regulations of cosmetics encompass marketing authorization or registration, premises registration, import and export control, inspection and market surveillance. Marketing authorization is official approval of the cosmetic product to be marketed or distributed in Tanzanian market after assessment of product's scientific and manufacturing information to ensure their safety, quality and performance to users.

All cosmetic products to be manufactured, supplied, distributed or sold in Tanzanian market should prior be registered by the Authority. This is in accordance with provisions of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 and Regulations made there under. The Act further requires person who manufacture, supply, distribute or sell cosmetic products to have their premises registered and licensed to carry out the intended activities.

These guidelines are intended to assist applicants who wish to register their cosmetic products in Tanzania in providing required information thereby facilitating evaluation and subsequently approval. It describes procedures for submission of documentation for registration of new cosmetic products, variation to registered cosmetic products and renewal of registration.

The guidelines are divided in three sections. Section one describes the general requirements, section two processing applications for marketing authorization while section three describe the minimum requirements for cosmetics packaging and labeling.

Assessment of documents submitted for marketing authorization will be based on these guidelines. Applicants are therefore requested to read the guidelines together with the Tanzania Food, Drugs and Cosmetics Act, Cap 219 and Cosmetics Regulations made there under.

Glossary of Terms

The terms listed below are defined specifically for the purpose of these guidelines:

"**Act**" means the Tanzania Food, Drugs and Cosmetics Act, Cap 219;

"**Applicant**" means a person who submits an application for marketing authorization of a cosmetic, an update or amendment to an existing marketing authorization to the Authority who may be a manufacturer or a person to whose order and specifications, the product is manufactured. After the product is registered the applicant shall be "marketing authorization holder";

"**Authority**" means The Tanzania Food and Drugs Authority, or the acronym 'TFDA' established by Section 4 of the Act;

"**Botanical**" means an ingredient that is directly derived from plant and that has not been chemically modified before it is used in the preparation of a cosmetic;

"**Claim**" means any message or representation including pictorial, graphic, symbolic or any form of representation, which states, suggests or implies that a cosmetic has particular characteristics relating to its origin, function, nature, composition or any other characteristics;

"**Colour**" means a substance used as an ingredient of cosmetic product solely to give tonality to the product;

"**Composition of a cosmetic**" means the ingredients contained in a cosmetic product and their proportions;

"**Container**" means a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain a cosmetic;

"**Cosmetic**" means any article intended to be used by means of rubbing, pouring, steaming, sprinkling, spraying on or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as component of a cosmetic, such article exclude articles intended beside the above purposes for use in the diagnosis, treatment or prevention of diseases and those intended to affect the structure or any function of the body;

"**Decorative cosmetics**" means a cosmetic intended to modify the appearance of the area to which they are applied by the use of colour;

"**Flavour**" means a substance used as an ingredient of cosmetic product solely to impart taste to the product;

"**Fragrance**" means a substance used as an ingredient of cosmetic solely to impart odour to the product;

"**Free Sales Certificate**" means a document that indicates that the product is freely sold in that country;

"**Immediate packaging**" means the container or other form of packaging immediately in contact with the cosmetic product;

"**Ingredient of a cosmetic**" means any substance which is a component of a cosmetic and includes colouring agents, botanicals, fragrance and flavour;

"**International Cosmetic Ingredient Dictionary (ICID)**" means the latest edition of a book that gives names of cosmetic ingredients published by the American Cosmetics Toiletries and Fragrance Association;

"**International Nomenclature of Cosmetic Ingredient (INCI) name**" means a name used for listing an ingredient on a cosmetic product label;

"**Labeling**" means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets;

"**Label of a cosmetic**" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any cosmetic;

"**Leaflet of a cosmetic**" means and includes any written information related to a cosmetic;

"**Manufacture of cosmetic**" means and includes all operations involved in the production, processing, compounding, formulating, filling, refining, transforming, packing, packaging, repackaging and labeling of the cosmetics;

"**Manufacturer**" means a registrant (market authorization holder) engaged in the manufacture of cosmetics;

"**Marketing authorization**" means an official approval of the cosmetic product to be marketed or distributed in Tanzania mainland;

"**Name of the cosmetic product**" means the name given to a cosmetic product, which may be an invented name, together with a trademark or the name of the manufacturer;

"**National Standard**" means a Tanzania Standard prescribed by the Tanzania Bureau of Standards (TBS);

"**Outer packaging**" means the packaging into which is placed the immediate packaging;

"**Package**" means 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;

"**Preservative**" means a substance which is added to a cosmetic for the primary purpose of inhibiting the development of micro-organisms in that product;

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

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

"**Prohibited Ingredient**" means a substance which is forbidden to be a component of a cosmetic;

"**Registration certificate**" means a document for official approval of a cosmetic product for circulation in the market;

"**Registrant (market authorization holder)**" means 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 Tanzanian market;

"**Sell or sale**" means 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 cosmetic, whether for a consideration or otherwise;

"Sunscreen" means cosmetic that protects the skin from the harmful radiation of the sun.

SECTION 1: GENERAL REQUIREMENTS

1.1 Language

All applications and supporting documents shall be in Kiswahili or English.

1.2 Classification of cosmetic products

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

1.2.1 Special cosmetics

These are functional cosmetics which offer additional benefit over normal 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) sunscreens or sun blocks,
(b) skin lightening/ spots corrector/spots removals,
(c) antiperspirants,
(d) anti cavity/ anti sensitivity toothpastes,
(e) anti dandruff,
(f) anti-acnes,
(g) anti-aging,
(h) cosmetic products for hair growth, hair removal, hair relaxer, hair waving, hair dyes,
(i) decorative cosmetics etc

Special cosmetics also include:

(a) cosmetics containing components derived from living organisms, microorganisms or produced through biotechnology process,
(b) baby care products,
(c) 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.

1.2.2 Non special cosmetics

These are cosmetics which do not fall under special cosmetics. They normally contain only cosmetics ingredients which are used in products to provide them with appropriate aesthetics, texture, pH, color and smell. They include but not limited to:-

(a) Moisturizing creams and lotions,
(b) Nail polishes and removers,
(c) Shampoo and conditioners,
(d) Body sprays and perfumes,
(e) Make-ups,
(f) Bathing soaps etc

1.3 Marketing authorization

Each category requires marketing authorization from the Authority. All cosmetic products to be marketed in Tanzania shall be subjected to registration process prescribed in these guidelines.

1.4 Who should apply?

1.4.1 For domestic manufactured products

TFDA registered domestic manufacturer or local firm to whose order and specifications of the product is manufactured or any other person authorized by the manufacturer or owner of the product.

1.4.2 For imported products

TFDA registered dealers of cosmetics or overseas cosmetics manufacturers or local firms to whose order and specifications of the cosmetic product is manufactured or any other person authorized by the manufacturer or owner of the product.

1.5 Applicant

Applicant shall be a person who is a resident in Tanzania. If the applicant is not resident in Tanzania then he shall appoint **a local responsible person** who must be residing in Tanzania or a company incorporated in Tanzania. Proof of official appointment shall be submitted to TFDA.

1.6 Responsibility of Applicant

Applicant shall be responsible for facilitating communication with the Authority and when the product is registered he shall assume all responsibilities regarding the safety, quality, performance or efficacy of product on the Tanzanian market as a Registrant.

1.7 **Type of applications**

There are three (3) types of applications as follow:-

1.7.1 New application

1.7.1.1 This is an application for registration of a cosmetic product that is intended to be placed on the Tanzanian market for the first time. New application may only be made by the applicant and he shall be the person who signs application form.

1.7.1.2 A separate application is required for each cosmetic product with exception of the same products with different pack size and shapes. However declaration of the available pack sizes and shapes shall be stated.

1.7.1.3 Request for registration of a product shall be submitted in one application. However variant(s) may be submitted in a separate application and charged half of the prescribed fee.

1.7.1.4 Products with the same formulation and same name but sourced from different manufacturing sites shall be treated as different products hence registered separately.

1.7.1.5 A kit shall be submitted as one application. Categorization of such kit shall base on the components therein. If one of the components is special cosmetic then the whole kit will be categorized as special categorized. If all the components fall are normal cosmetics then the kit will be categorized as normal.

1.7.2 **Variation**

1.7.2.1 If for any reason the applicant changes any matter related to a registered cosmetic product including but not limited to change of packaging, labeling or any other change, shall before selling the changed cosmetic product, notify and obtain approval of the Authority of the change. The notice to the Authority shall be accompanied with the reason(s) for such change.

1.7.2.2 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 registrant will be notified by stating the reasons thereof.

1.7.2.3 All applications for variation to registered cosmetics shall be accompanied by variation fee as prescribed in the Fees and Charges Regulations in force.

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

1.7.3 **Application for renewal**

1.7.3.1 Applications for renewal of registration shall be made at least 30 days before the expiration of registration validity.

1.7.3.2 Application for renewal shall be made by the registrant who shall be responsible for the safety and quality of the product.

1.8 **How to submit an application**

1.8.1 All applications shall be submitted through the online portal link www.tfda.go.tz/portal.

1.8.2 Copy of print out of the same shall be submitted at TFDA offices.

1.8.3 Applicant shall prior to submission of application request for appropriate categorization.

1.9 **Requirements for submission**

Documents and information to be submitted shall depend on category of cosmetic product and type of application as described below.

1.9.1 Submission of application for new and renewal registration of special cosmetic products shall include the following:-

(a) Covering letter.
(b) Applicant's license to deal with cosmetics and/ or company's certificate of incorporation.
(c) GMP certificate and/ or manufacturing license of manufacturing facility.
(d) Free sales certificate and/ or marketing authorization from country of origin.
(e) List of ingredients.
(f) Certificate of conformity from TBS.
(g) Label artwork.

(h) Information to support the claim benefit.
(i) Two (2) samples.
(j) Declaration that information submitted are correct.

1.9.2 Submission of application for new and renewal registration of normal cosmetic products shall include the following:-

(a) Covering letter.
(b) Applicant's license to deal with cosmetics and/ or company's certificate of incorporation.
(c) List of ingredients.
(d) Certificate of conformity from TBS.
(e) Label artwork.
(f) Supplier's name and documents.
(g) Two (2) samples.
(h) Declaration that information submitted are correct.

1.10 Application format

Submission of information for applications shall be in accordance with format available on the TFDA website

(a) Application format for new registration of cosmetic product (**Annex I**)
(b) Application format for variation of registered cosmetic product (**Annex II**)
(c) Application format for renewal registration of cosmetic product (**Annex III**)

1.11 Confidentiality

All information to be submitted to TFDA shall be treated as confidential whether or not it is marked as such by the applicant.

1.12 Composition of a Cosmetic product

A cosmetic product intended to be placed on the Tanzanian market shall not contain substances from the prohibited list and/ or substances that exceeds the level permitted as listed on the following link www.tfda.go.tz/ or any substance determined by the Authority as not safe from time to time.

1.13 **Payment of fees**

1.13.1 Every application shall be accompanied by appropriate fees as specified in the Fees and Charges Regulations in force at the time of application.

1.13.2 The fees shall be paid to following account:-

(a) For foreign currency; Tanzania Food and Drugs Authority, Account No. 100380013 USD, Citibank, Tanzania Ltd. Dar es Salaam – Head office Peugeot House, 36 Upanga Road, P. O. Box 71625, Dar es Salaam Tanzania Swift Code: CITITZTZ.

(b) For local currency; Tanzania Food and Drugs Authority, Account No. 6503900110 National Microfinance Bank, Kariakoo Branch or by banker's draft.

1.13.3 All bank charges shall be borne by the applicant who shall also make sure he sends an advice note giving details of the payment in particular the name of the applicant, the product or products paid for and amount of fees paid. If the product is already registered in addition to the aforementioned details, the registration number of the product must also be quoted.

1.14 **Reporting of adverse reactions**

Marketing authorization holder shall report to the Authority of any adverse event or high incidences of adverse event occurred, regardless of the source of the report (consumer, health care professionals etc).

1.15 **Record keeping**

The company or person responsible for placing cosmetic product in the market shall keep records of the primary distribution of their products for the purpose of traceability.

SECTION 2: PROCESSING APPLICATIONS FOR REGISTRATION

2.1 Receiving of applications

2.1.1 Submission and processing of applications shall be done online.

2.1.2 Applicant shall be informed the outcome by online.

2.1.3 Copy of print out, supporting documents (if any), evidence of payments and samples shall be submitted physically to TFDA headquarters or zone offices.

2.1.4 An application shall only be processed upon payment of application fees as provided in Fees and Charges Regulations in force.

2.2 Processing of applications

2.2.1 Assessment of applications shall be completed within the following working days:-

Type of application	**Category**	**Working days**
Registration	New application	50
	Variation/Alteration	20
	Renewal	20
Approval of Promotion Advert		10

2.2.2 Assessment shall be done against the requirements of these guidelines and in accordance with standard operating procedures. However, the Authority reserves the right to request any additional information (documents and clarification) to establish the quality and safety of cosmetic product(s). Processing of application shall be kept on hold until such requirements are provided.

2.2.3 If the applicant fails to respond to the issues raised within 30 days from the date of query letter, the application shall expire and the marketing authorization of the product may only be considered upon submission of a new application.

2.2.4 Decisions shall be made based on information made available in the submission. Non-compliance to the requirements prescribed in these guidelines shall lead to refusal of marketing authorization of the product(s).

2.2.5 The Authority shall grant marketing authorization of a cosmetic if it is satisfied that:-

2.2.5.1 The cosmetic complies with the National Standards or where there are no National Standards, the International Standards;

2.2.5.2 The cosmetic complies with requirements prescribed in these guidelines.

2.2.6 The Authority after being satisfied that the cosmetic complies with requirements prescribed in these guidelines shall issue the registration certificate to indicate that the product has been granted market authorization.

2.2.7 Registration certificate shall contain a unique number and shall not be used for any other product.

2.2.8 Where the information submitted fails to justify the quality and safety of the product, the Authority will not grant the marketing authorization of a cosmetic product and shall notify the applicant in writing of such decision and the reason(s).

2.3 Application for review of refusal of registration

2.3.1 Any applicant who is not satisfied by the Authority's decision of not grant marketing authorization may, within 30 days after the date of being notified of the refusal, apply for review of the decision to the Authority. The Authority may review, reject or vary its own decision.

2.3.2 Where the Authority still refuses to approve the marketing authorization of a cosmetic it shall notify the registrant in writing of such decision and the reason(s) thereof, and if still aggrieved of the decision, the applicant may appeal to the responsible Minister

2.4 Validity of registration

2.4.1 Registration of a cosmetic product shall be valid for three (3) years subject to comply with requirements and payment of annual retention fee as prescribed under the Fees and Charges Regulations made under the Act.

2.5 Termination of registration

2.5.1 Authority may by giving reasons suspend, cancel or revoke marketing authorization or amend the conditions of marketing authorization based on the following conditions:-

2.5.1.1 Evolution of new requirements of the law or standards.

2.5.1.2 Payment of the annual retention fee per product is not made to the Authority as prescribed under the Fees and Charges Regulation made under the Act.

2.5.1.3 The Authority receives 30 days notice in writing from registrant informing the intention of withdrawing from dealing with the approved cosmetic product (s).

2.5.1.4 New scientific developments or laboratory testing reveal that the product or ingredient(s) used are proved to have a significant health effect to the consumer.

2.5.1.5 The applicant provided false information related to the product that may pose negative impact on safety or quality of the product.

SECTION 3: PACKAGING AND LABELING OF COSMETICS

3.1 Packaging requirements

3.1.1 The product shall be packaged in suitable well containers that protect the content(s)

3.1.2 Immediate packaging or containers shall not cause any contamination or react with product.

3.2 Labeling requirements

3.2.1 Every immediate container of any cosmetic shall be labeled in English or Kiswahili or both.

3.2.2 The labeling of cosmetic product shall comply with requirements of the current TZS 774.

3.2.3 All containers or packages packed with cosmetic products shall be labeled and marked with the following information in indelible, easily legible and visible lettering:-

3.2.3.1 name of the cosmetic product

3.2.3.2 type of the cosmetic product

3.2.3.3 intended use of the cosmetic product unless it is clear from the presentation of the product

3.2.3.4 instructions of use of the cosmetic product unless it is clear from the product name or presentation

3.2.3.5 net contents given by weight or volume, in either metric or both in metric and imperial system

3.2.3.6 name and address of the manufacturer, including country of origin

3.2.3.7 manufacturer's batch/lot number

3.2.3.8 precautions and warnings; where applicable
example declaration of ingredients from animal parts must be declared, in this case there must be a statement (of any format) on

the product label that declares the presence of bovine and/or porcine parts (the exact animal must be declared).

3.2.3.9 storage condition; where applicable

3.2.3.10 manufacturing date in the form of "mm/yyyy"

3.2.3.11 expiry date/ best before date in the form of "mm/yyyy"

(a) products that have shelf life of 30 months and less shall be marked with the expiry date

(b) products with a shelf life greater than 30 months the best before date may be labeled

3.2.3.12 list of ingredients

(a) list of ingredients present in the final product shall be declared in descending order of predominance, in their concentration by weight

(b) ingredients shall be identified by their common name as provided for in the common ingredients nomenclature or, in the absence of nomenclature or of a common name, by its chemical name, its International Non-proprietary name as recommended by the WHO, its IUPAC or CAS Identification reference or its colour index number

(c) in case of decorative 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) botanicals must be listed by specifying at least genus and species portions

(e) ingredients that are present at a concentration of 1% or less and all colouring agents, regardless of their concentration may be listed in random order after the ingredients that are present at a concentration of more than 1%

3.2.4 In case where the size, shape or nature of the container or package does not permit the above particulars to be displayed, the use of label, tag, tape or card

attached to the product or an enclosed leaflets or pamphlets shall be allowed. However at least the following particulars shall appear on small immediate packaging:-

3.2.4.1 name of the cosmetic product

3.2.4.2 name of the manufacturer

3.2.4.3 manufacturer's batch/lot number

3.2.4.4 manufacturing and expiry dates as indicated above

3.2.5 Cosmetic products should not make claims that are regarded as medicinal in nature.

SECTION 3: ANNEXES

Annex I: Application format for registration of cosmetic product

TANZANIA FOOD AND DRUGS AUTHORITY

APPLICATION FOR REGISTRATION OF A COSMETIC PRODUCT

(For official use only)
Application Reference No:

1.0 Product Particulars

1.1 Name of product:

_____

1.2 Form: (refer *Annex IV*)

_____

1.3 Physical description:

_____

_____

1.4 Intended use: (refer *Annex V*)

_____

1.5 Contraindication:

_____

_____

1.6 Method of use:

_____

1.7 Pack size(s):

_____

1.8 Unit composition:

S/N	common name	Chemical name	% proportion	Reason for inclusion

1.9 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.

_____

_____

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

_____

_____

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

_____

1.12 Proposed shelf-life*:

_____

2.0 Particulars of Applicant/Registrant

Name: _____

Physical Address: _____

Postal Address: _____

Country: _____

Phone: _____ Fax: _____Email: _____

Status of applicant (tick where appropriate)

Manufacturer _____ Importer _____

3.0 Particulars of Manufacturer

Name: _____

Physical address: _____

Postal address: _____

Country: _____

Phone: _____Fax: _____E-mail: _____

4.0 Particulars of Local agent/Distributor

Name: _____

Physical address: _____

Postal address: _____

Country: _____

Phone: _____Fax: _____E-mail: _____

5.0 Declaration by the Applicant/Registrant

I, the undersigned certify that all the information in this form and accompanying documentation is correct and true to the best of my knowledge.
Name: _____
Position: _____
Signature: _____
Official stamp:
Date: _____

Annex II: ***Application format for variation of registered cosmetic product***

TANZANIA FOOD AND DRUGS AUTHORITY

APPLICATION FOR VARIATION OF A REGISTERED COSMETIC PRODUCT

1.0 Name of cosmetic product:	
2.0 Cosmetic form:	
3.0 Type of change(s) (*State type(s) of Variation)*	
4.0 Reason(s) and justification for change(s)	

5.0 Present *(Please specify precise present wording or specification)*	**Proposed** *(Please specify precise proposed wording or specification)*

6.0 Particulars of Registrant

Name: _____

Physical Address: _____

_____

Postal Address: _____

Country: _____

Phone: _____ Fax: _____Email: _____

7.0 Declaration

I hereby submit an application for the above Marketing Authorization to be varied in accordance with the proposals given above.

I declare that (Please select the appropriate declarations):

☐ There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel; such parallel variations have to be specified under 'Other Application(s)');

☐ Variation fees have been paid;

Name:
Qualification:
Position in the company:
Signature:
Date: Official stamp:

Annex III: ***Application format for renewal of registration of cosmetic product***

TANZANIA FOOD AND DRUGS AUTHORITY

APPLICATION FOR RENEWAL OF REGISTRATION OF 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 Form: (refer *Annex IV*)

_____

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 TFDA

_____

_____

1.7 Are there any reported adverse reactions?

No ☐

Yes ☐

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

_____

_____

2.0 **Particulars of Registrant**

Name: _____
Physical Address: _____
_____
Postal Address: _____
Country: _____
Phone: _____ Fax: _____Email: _____
Status of applicant (tick where appropriate)
Manufacturer _____ Importer _____

3.0 **Particulars of manufacturer**

Name: _____
Physical address: _____
Postal address: _____
Country: _____

4.0 **Particulars of local agent or importer**

Name: _____
Physical address: _____
Postal address: _____
Country: _____
Phone: _____Fax: _____E-mail: _____

Phone: _____Fax: _____E-mail: _____

5.0 **Declaration by the registrant**

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

Name: _____
Position: _____
Signature: _____
Official stamp:
Date: _____

Annex IV: FORMS OF COSMETICS

EXPLANATORY NOTES

Aerosol: A product that is packed under pressure and contains various ingredients that are released upon activation of an appropriate valve system example some hair sprays, body sprays, perfumes.

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

Cream: A semisolid emulsion with medium viscosity. It is more viscous than a lotion, but less viscous than an ointment.

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.

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

Granules: bath pellets, crystals, pearls, etc

Kit: If the product consists of two or more components of different forms which are mixed before use, then insert "Kit" and write in brackets the forms of the various components.

Liquid Suspension: Solids in liquid.

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

Lotion: A low-viscosity liquid emulsion.

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

Paste: A very thick semisolid dosage form containing a high amount of solids finely dispersed in the vehicle, e.g. dentifrice.

Pressed powder: A solid dosage form that contains a freely flowing mixture of different dry solid ingredients in a compressed form, e.g. blush, eye makeup.

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.

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.

Other (Please specify) - Product which does not fall into one of the general categories above. Please provide the rationale as to why the form is unique.

Annex V: INTENDED USES

EXPLANATORY NOTES

Ant wrinkle Preparation: Product applied as a makeup or moisturizer generally to the face to mask or reduce the appearance of fine lines or wrinkles. (See also, Eye Lotion and Eye Makeup).

Baby Product: Product labeled for use on infants 2 years old or less.

Barrier Cream: Product which protects the hands from dirt, grease, solvents, etc.

Bath Preparation: Product added to the bath water, it includes bath oils, tablets, salts, bubble baths, etc.

Body Makeup: Product applied as makeup to the body excluding the hair, eyes or face. Includes leg and body paints. (See also, Eye Makeup and Face makeup.)

Dentifrice: Product which cleans and/or polishes the teeth.

Deodorant: Product which modifies, reduces, or prevents the development of body odors, excludes genital deodorants and products which claim to reduce perspiration.

Douche: Product used for personal feminine hygiene. (See also, Genital Deodorant.)

Eye Lotion: Non-makeup product specifically indicated for use in the area of the eye, it includes lotions and moisturizers.

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.

Face Makeup: Product for use in the area of the face, it includes blushes, face powders, foundations, rouges, makeup fixatives, etc. (See also, Anti wrinkle Preparation, Eye Lotion, Eye Makeup, Lipstick and Skin Moisturizer.)

Fragrance: Includes perfumes, colognes, toilet water, dusting and talcum powders.

Genital Deodorant: Deodorant/Cleanser intended for use in the genital area, it includes non-douche feminine hygiene products.

Hair Bleach: Product which bleaches the hair excluding hair lighteners with colours.

Hair Conditioner: Non-shampoo product which increases the suppleness or body of the hair, facilitates combing, adds gloss or texture to the hair, etc. (See also, Hair Shampoo.)

Hair Dye: Product which changes the colour of the hair.

Hair Grooming: Product which improves the appearance or is used to shape/style the hair. Includes mousses, gels, pomades, sprays etc. (See also, Hair Straightener and Hair Waving Preparation).

Hair Removal: Depilatory/epilatory product which facilitates the removal of hair by chemical or mechanical means. Includes wax treatments. (See also, Shaving Preparation.)

Hair Shampoo: Product which cleanses the hair. Product is washed off after use.

Hair Straightener: Product which contain agents which chemically soften the hair to facilitate straightening of the hair.

Nail lacquer (Nail polish): Products which changes the colour of the nail.

Nail polish remover: Products which removes the colour from the nail.