

**DRUG**  
**NATIONAL AUTHORITY**



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**GUIDELINES for REGULATION of COSMETIC PRODUCTS  
In UGANDA**

**VERSION 1, JULY 2009**

## LIST OF ACRONYMS

NDA	National Drug Authority
WHO	World Health Organisation
INN	International Non-proprietary Name
UNBS	Uganda National Bureau of Standards

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## **GUIDELINES FOR REGULATION OF COSMETIC PRODUCTS IN UGANDA (Version 1, July 2009)**

### **1.0 GENERAL**

These guidelines apply to all Cosmetic Products other than Conventional Pharmaceutical Products, Biological Products, Traditional medicinal products, diagnostic aids, medical appliances and public health chemicals.

**Definition:**

'**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 a component of a cosmetic, such article excludes 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.

- 1.1 All documents are to be submitted typewritten or computer printed in ENGLISH. Where originals are in another language, copies shall be presented together with certified English translations.
- 1.2 Each complete application must contain a complete index to the various appendices and each page of the application dossier must be numbered.
- 1.3 A prescribed application fee shall accompany each complete application form. Subsequent applications to amend any part of the application shall be accompanied by a prescribed fee per change and guidelines on submission of amendment applications shall be followed.

A fee shall be charged annually to retain the cosmetic product on the notification list.

- 1.4 Notification procedures shall commence only if the application form with its appendices has been properly completed. Only the information required in the appendices should be furnished.
- 1.5 All documents shall be addressed to:

The Executive Secretary / Registrar,  
National Drug Authority, Plot 46–48 Lumumba Avenue  
PO Box 23096, Kampala, UGANDA

Phone: (+256) 41-255665 / 347391/ 347392

Fax: (+256) 41-255758

E-mail: [ndaug@nda.or.ug](mailto:ndaug@nda.or.ug)

- 1.6 Payment of fees can be made by Bank Transfer to:

National Drug Authority Account no: 0240060034201  
Stanbic Bank Uganda Limited, Kampala

or by bank draft in favour of National Drug Authority

- 1.7 All cosmetic products marketed in Uganda have to be notified before they are sold and distributed.

## 2.0 APPLICANT

- 2.1 Application for the notification of a cosmetic product shall be made only by:
- the patent holder
  - the manufacturer
  - a distributor authorised by the manufacturer or patent holder
  - an authorised Local Technical Representative (LTR) of the manufacturer or patent holder

The name, physical address, telephone number, fax number, and e-mail address of the applicant shall be provided.

## 3.0 PARTICULARS OF THE COSMETIC PRODUCTS

- 3.1 **Proprietary name** means the (trade or brand) name which is **unique** to a particular Cosmetic Product and by which it is generally identified (and by which it is registered in the country of manufacture).
- 3.1.1 All cosmetic products shall be notified as per their proprietary Name. The Proprietary Name should not be derived from INN name and should not have an INN stem.
- 3.1.2 If derived from Generic Name should not be similar to the Generic Name.
- 3.1.3 Each cosmetic form will require a unique Proprietary Name.
- 3.1.4 Each Name used should be distinctive in sound and in writing not to be confused with Names of other Products.
- 3.1.5 The Name should not be misleading. Names which lead to self-diagnosis in conditions requiring professional diagnosis will be considered as misleading.
- 3.1.6 The use of "Umbrella/Brand Naming" is not acceptable, each product type should have its own unique Name.
- 3.1.7 Any Phrase that implies superiority, speed or better performance over other products shall not be allowed.
- 3.1.8 Meaning of abbreviations, symbols, alpha-numerals must be explained in a covering letter.
- 3.1.9 A proprietary name should not carry prescription information unless otherwise backed with a strong scientifically proven report that supports the connotation.
- 3.1.10 When the Name being applied for is identical or very close to already registered Name, applicant shall be advised to change to another Name.
- 3.2 **Approved / INN / generic name** in relation to a cosmetic product means the internationally recognised non-proprietary name of such a product .
- 3.3 **Form of cosmetics** shall mean the form in which the Cosmetic product is presented, e.g; creams, oils, kits, gels, lotions, powders (pressed or loose), sprays, sticks, pencils etc.
- 3.4 **Description of the Product** shall mean a full visual description of the cosmetic product including colour, size, shape and other relevant features, e.g; pink lotion, white cream etc.
- 3.5 **Botanical** means an ingredient that is directly derived from plants and that has not been chemically modified before its used in the preparation of a cosmetic

- 3.6 **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.
- 3.7 **Composition of a cosmetic** means the ingredients contained in a cosmetic product and their proportions.
- 3.8 **Cosmetic promotion** means and includes advertising and any other activity undertaken to increase the supply, sale, or consumption of a cosmetic.
- 3.9 **Decorative cosmetics** means a cosmetic intended to modify the appearance of the area to which they are applied by the use of colour.
- 3.10 **Fragrance** means any substance used as an ingredient of a cosmetic solely to impart odour to the product.
- 3.11 **Ingredient of a cosmetic means** any substance which is a component of a cosmetic and includes colouring agents, botanicals, fragrance and flavour.
- 3.12 **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
- 3.13 **International Nomenclature Cosmetic Ingredient (INCI) name** means a name used for listing an ingredient on a cosmetic product label.
- 3.14 **Label of a Cosmetic** means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, or impressed on or attached to a container of any cosmetic.
- 3.15 **Leaflet of a cosmetic** means and includes any written information related to a cosmetic.
- 3.16 **Manufacture of a Cosmetic** means and includes all operations involved in the production, processing, compounding, formulating, filling, refining, transforming, packing, packaging, repackaging and labelling of the cosmetics.
- 3.17 **Manufacturer** means a company, facility, or factory engaged in the manufacture of cosmetics.
- 3.18 **National Standard** means a Ugandan Standard prescribed by the Uganda National Bureau of Standards (UNBS)
- 3.19 **Package** means any box, packet or any other article in which one or more containers of cosmetics are to be enclosed.
- 3.20 **Preservative** means a substance which is added to a cosmetic for the primary purpose of inhibiting the growth of micro-organisms in that product
- 3.21 **Product** for the purpose of these guidelines means a cosmetic.
- 3.22 **Product variants** means a range of cosmetics produced by the same manufacturer in the same site, similar in composition and intended for the same use but available in different colours, fragrances, flavours, and container shapes.
- 3.23 **Prohibited Ingredient** means a substance which is forbidden to be a component of a cosmetic.

- 3.24 **Sell or Sale** means sell by wholesale retail and include import, offer, advertise, keep, expose, display, transmit, consign, convey, or deliver for sale or authorize, direct or allow a sale, and barter or exchange supply or dispose of a cosmetic, whether for a consideration or otherwise.
- 3.25 **Ultra Violet (UV) filter** means a substance which is added to a sunscreen cosmetic for the purpose of filtering ultra violet rays to protect the skin.
- 3.26 **Market Authorisation Holder** means any person / company who may either be the trademark owner or person authorised by him, who has rights to sell the product and is responsible for placing the product on the Ugandan market.

#### 4.0 COMPOSITION OF COSMETICS

4.1 For a product to qualify as a cosmetic, should conform to the definition of a cosmetic stated in this guideline and in addition, should meet the following requirements;

- (a) There should not be any medicinal or therapeutic claims in relation to use of the product.
- (b) The product should not contain any substance of known pharmacological activity.

4.2 A cosmetic intended to be placed on the Ugandan market should not contain any of the following:

- (a) A Prohibited ingredient as provided in *Annex II* of these guidelines.
- (b) Any substance listed in column b of *Annex III* of these guidelines unless the requirements in column c, d, e and f of that Annex in relation to that substance are satisfied.
- (c) Any colouring agent which is not listed in *Annex IV* of these guidelines.
- (d) Any preservative listed in column 2 of *Annex V* of these guidelines unless the requirements in column 3, 4, and 5 of that Annex in relation to that preservative are satisfied.
- (e) Any preservative which is not listed in *Annex V* of these guidelines.
- (f) Any UV filter listed in column 2 of *Annex VI* of these guidelines unless the requirement in column 3 and 4 of that Annex are satisfied

#### 5.0 LABELLING OF COSMETICS

**5.1 Labelling:** The applicant shall ensure that the primary (immediate) packaging of the product is labelled according to the law applicable in Uganda. The following minimum information shall be required in English on the label of the immediate packaging:

- (i) Brand name where appropriate
- (ii) International non-proprietary name/generic name where it is applicable
- (iii) Quantity of active ingredient per dosage unit where applicable
- (iv) Total packed quantity in a unit pack.
- (v) Date of manufacture
- (vi) Date of expiry
- (vii) Batch number
- (viii) Storage conditions
- (ix) Name and address of manufacturer

The name of the manufacturer may be substituted with a trade-mark or any other symbol, however these details shall appear in full on the secondary packaging.

- 5.2 Information leaflet:** Applicants should be encouraged to include Scientific Package Inserts in product Packs where applicable. Package Inserts will ensure that cosmetics are safely and effectively used under normal conditions.

Package inserts should not carry exaggerated promotional statements and make comparison of its product to other products.

In case of changes in the scientific package information leaflet after product has been notified, NDA should be informed.

**The leaflet shall include the following minimum information:**

- i) Proprietary Name
- ii) Approved INN/Generic Name where applicable
- iii) Form of cosmetic
- iv) Composition of product, including the preservatives used
- v) Cosmetic benefit of the product
- vi) Mode of application and directions for use
- vii) Storage instructions
- viii) Shelf life
- ix) Name and address of the manufacturer

**6.0 PARTICULARS OF THE MANUFACTURER(S) AND ACTIVITY**

The name, physical address, telephone number, fax number, and e-mail address of the manufacturer shall be provided.

Where different activities of manufacture of a given product are carried out at different manufacturing sites, the above particulars shall be provided for each site and the activity carried out at the particular site shall be stated as in the examples below.

	<b>Name</b>	<b>Address</b>	<b>Activity</b>
1.	Goodman Limited	GLN, 13LT, London, UK Tel: 235 898 491	Packing, Pressing e.g. for eye makeup, soap

A copy of a valid manufacturing licence shall be provided for each site.

**7.0 AUTHORISED REPRESENTATIVE IN UGANDA**

A body corporate (company) authorised to handle cosmetics, shall be the applicant’s local representative in Uganda with legal authorisation to take full responsibility for the product on behalf of the applicant, and will be answerable to NDA.

This body corporate shall be called the **Local Technical Representative (LTR)**. A copy of the legal authority given to the representative or agent shall be enclosed. Such a body may be:

A business entity dealing in cosmetics, supervised by a scientist with an appropriate qualification as may be defined by NDA.

**8.0 SIGNATORY**

The signatory shall be a qualified personnel working for and/or authorised by the manufacturer / applicant. The designation and qualification of the qualified personnel shall be stated.

## 9.0 NOTIFICATION OF COSMETICS

- 9.1 An application for notification of a cosmetic will be made by an applicant. Such an Applicant shall be a person resident in Uganda or a company incorporated in Uganda. All application documents must be in English.
- 9.2 Every Applicant who intends to sell any cosmetic in Uganda shall;  
Apply for notification of the cosmetic to NDA by submitting a duly filled form as provided in Annex I of these guidelines accompanied with two samples of the product plus all the necessary information as indicated in these guidelines.  
Submit separate application for each product or product variant.  
Notification fee of US\$..... for imported and US\$.....for locally manufactured cosmetics
- 9.3 An application shall only be accepted and processed if all the conditions hereunder are complied with:  
Submission of duly filled in application form,  
Payment of notification fees,  
Application filled in a spring A4 size file.
- 9.4 The authority shall grant notification of a cosmetic if it is satisfied that:  
The cosmetic intended to be notified complies to national standards or where there are no national standards, complies with International standards;  
The cosmetics complies with requirements in these guidelines and;  
The cosmetic complies with the criteria for 'total viable count' and absence of 'specific organisms' as prescribed in the Annex VIII of these guidelines.
- 9.5 The Authority may during assessment of the application require the applicant to submit samples, documents and information and give clarification as the case may be. The processing of an application shall be put on hold until such samples, documents, information or clarification is provided.
- 9.6 The authority after being satisfied that the cosmetic complies with the requirements, it will inform the applicant in writing that the cosmetic has been granted a marketing authorisation.
- 9.7 Where the authority refuses to approve notification of a cosmetic, it shall notify the applicant in writing of such decision and the reason(s).
- 9.8 The Authority after considering the submitted documents may grant notification to the cosmetic.
- 9.9 The notification of a cosmetic shall be valid for one year unless suspended, cancelled, or revoked by the authority or withdrawn by the applicant.
- 9.10 If for any reason the applicant changes any matter related to a notified cosmetic including but not limited to change of composition, packaging, labelling, or any other change ,shall, before selling the changed cosmetic ' notify and obtain approval of the authority of the change.
- 9.11 Every applicant shall be responsible for:  
(a) All information supplied in support of the application for notification and variation thereof;  
(b) Ensure safety and quality of the notified cosmetics and that the product complies with all requirements in these guidelines;  
(c) Effect voluntary and compulsory product recall whenever necessary;  
(d) Observation of sanitation and hygiene in the manufacturing premises and

Guidelines on Notification of COSMETIC PRODUCTS for Human Use in Uganda  
equipment.

## **10.0 APPENDIX 1 (Specifications of Packaging Materials & Product Composition)**

### **10.1 SPECIFICATIONS OF THE PACKAGING MATERIAL**

The following information shall be provided:

- a) A general description of the container and closure system including primary (inner) and secondary (outer) packaging materials used.
- b) Specifications for primary (immediate) packaging components such as: glass containers, plastic containers, rubber closures.
- c) Evidence of suitability of the container and closure system for the finished product and proof of compatibility of primary packaging components with finished product.

## **11.0 APPENDIX 2 (Chemistry and manufacturing aspects)**

### **11.1 Raw material specifications**

Raw material specifications and certificates of analysis shall be given.

**11.2 Details of the procedures involved in the various stages of manufacture,** including packaging shall be given. This shall be in the form of a detailed flow diagram.

**11.3 Summarised specifications of the final product** shall be given, i.e. The acceptable limits of all the physical, chemical, biological and (where applicable) microbiological parameters.

**The Finished product specification should include the following tests;**

- 1) **Tests for all forms of cosmetics**
  - a) Description
  - b) Identity - test method should be specific for active ingredient(s)
  - c) Assay - for active ingredient(s)
  - d) Impurity limits - to determine the level of degradation products
  - e) Ph
  - f) Microbial limits
  - g) Water content

## **12.0 APPENDIX 3 (Registration Status in other countries)**

**12.1** Applicant should provide a registration certificate or authorization to market the product as Cosmetic in the country of manufacture. (If a cosmetic is not registered in country of manufacture, a valid explanation must be given)

**12.2** A copy of the manufacturing licence of the manufacturer shall be provided.

## **13.0 APPENDIX 4 (of Form NDA: R1)**

**13.1** References to literature shall be precise, quoting the year of publication and the relevant page(s). Photocopies of relevant literature may be attached.

**13.2** A minimum of two samples of the final product for each package size being applied for must be provided in the form in which it shall appear on the market.

#### **14.0 MONITORING AND CONTROL OF COSMETIC PRODUCTS**

14.1 Each consignment of cosmetics that is imported into Uganda shall be inspected at the port of entry by NDA Inspectors for physical attributes and only notified cosmetics shall be accepted.

14.2 Each batch of every consignment shall be accompanied by an authenticated certificate of analysis that states;

- i). Name of the COSMETIC PRODUCT
- ii). Batch Number
- iii). Manufacturing date
- iv). Packaging Date if different from Manufacturing date
- v). Expiry date
- vi). Identification for each ingredient
- vii). Assay for each ingredient
- viii). Impurity tests
- ix). Specific tests applicable to form e.g. pH, viscosity,
- x). Tests for microbial limits

14.3 The inspector at the port of entry shall ensure that cosmetics are properly labelled with the following minimum labelling requirements.

- Name of the Cosmetic.
- Quantity per pack.
- Date of manufacture
- Date of expiry
- Batch number
- Storage conditions
- Name and address of manufacturer
- Direction for usage

11.4 Consignments that are of suspected quality shall be sampled for testing at the National Drug Quality Control laboratory (NDQCL) or UNBS and tested at the Importer's cost. Product batches that fail tests of analysis shall be rejected.

#### **15.0 REFERENCES AND RESOURCE LIST:**

1. *Guidelines for the registration of Cosmetic products (www.tfda.or.tz)*
2. *Guidelines for regulation of dietary Supplements in Uganda (www.nda.or.ug)*

**1. Fees for cosmetics notification:**

<b>Description</b>	<b>Amount (US\$)</b>
1. New application – Imported cosmetics	\$.....
2. Annual retention – Imported cosmetics	\$.....
5. New application – Local cosmetics	\$.....
6. Annual retention – Local cosmetics	\$.....

**2. Amendment Fees (Cosmetics):**

<b>Description</b>	<b>Amount (US\$)</b>
A. Amendments for imported cosmetics	
1. Change in formulation	\$.....
2. Extension of shelf life	\$.....
3. New scientific information /literature	\$.....
4. Finished product specification	\$.....
5. Trade name change	\$.....
6. Change in name of manufacturer	\$.....
7. Additional pack size	\$.....
8. Pack design	
- Primary pack	\$.....
- Secondary pack	\$.....
9. Change in packing material	\$.....
10. Additional accessories	\$.....
11. Change of label design	\$.....
12. Change of licence holder	\$.....
B. Amendments for locally produced cosmetics	Can be exempted but the authority should be informed