INTRODUCTION

This guideline is prepared based on the mandates given to Drug Administration and Control Authority, which was established by the proclamation number 176/1999 and act number 1 of part one of drugs and cosmetics definition. It is prepared to provide manufacturers with information concerning documentation to be submitted for approval and registration of cosmetics before they are made available to the market.

The guideline consists of three sections: Section I outlines the set of data which should accompany for registration of cosmetic products while section II deals with data that should be submitted along with an application for re-registration of cosmetic products. Section III is concerned with data that should accompany for applications of variation to an existing marketing authorization. After a product is registered, its registration is valid for five years only. It is, therefore, mandatory for manufacturers to apply for re-registration by submitting the required documents within 120 days before the due date.

The requirement for registration of a cosmetic product is as outlined in the guideline and the evaluation and screening of the application is based on the minimum requirements stated in the guideline. However, since all points may not/or can't be addressed in detail and on the fact that science changes and develops every day, the authority has a right to ask the applicant any information related to the product that may need further clarification before document approval or following marketing approval.

The requirements set out in each section of the guideline have general nature. By their very nature, applications have to be considered and assessed individually. Hence, expressions such as ''when applicable'', ''where appropriate'', ''where relevant'', have been frequently used in the guideline.

Samples of various standard formats and a table have been annexed to the three sections of the guideline and applicants are advised to use these standard formats whenever they apply.

Definition

The terms listed below are defined specifically for the purpose of this manual. They may be defined differently in other documentation, including annexes in this manual which were, in certain cases, published some years age.

1. **Cosmetics**- a cosmetic product shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition. However, that the products that defined as drugs are not included under this definition.
2. **Functional Cosmetics**- are cosmetics which that fall in any one of the following category
    a. **Whitening agents**- are cosmetics that are designed to whiten the skin tone
    b. **Ant wrinkling agents**- are cosmetics that are designed to minimize the appearance of the lines in the face and body
    c. **Sun Screen**- are cosmetics that are designed to protect the skin from the UVA and UVB rays of the sun or to develop natural looking tanning of the skin
3. **Cosmetic Drug** - Synonym of "**Medicated cosmetics**", "**border line cosmetics**" - This are products which combines the definition of drugs and cosmetics. Some examples include acne-treatment makeup, antibacterial face wash, antidandruff shampoo, antiperspirant deodorant, and cavity-fighting toothpaste.

4. **Mouth washes**- liquid oral hygiene products for prevention of mouth odor or breath fresheners (liquid and spray).
5. **Body deodorizer**- liquid for external use for prevention of body odor
6. **Heat rashes powder**- powders for external use for prevention of heat rashes
7. **Dentifrice**- Tooth pastes, tooth powders, tooth liquids containing hydrogen peroxide, fluoride, precipitated calcium and silicon dioxide
8. **Bath preparation**- products for external use for bath which may contain soap as body deodrant or a skin disease assisting treatment
9. **Soap products**- products consisting primarily of an alkali salt of fatty acid and making no label claim other than cleansing of the human body
10. **Misbranded cosmetics**- a cosmetic is misbranded if its labeling is false or misleading, if it does not bear the required labeling information or if the container is made or filled in a deceptive manner

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11. **Adulterated cosmetics**- a cosmetics which contains substance which may make the product harmful to consumers under customary conditions of use; if it contains a filthy, putrid, or decomposed substance; if it is manufactured or held under unsanitary conditions whereby it may have become contaminated with filth, or may have become harmful to consumers; or if it is not a hair dye and it contains a non-permitted color additives. Coal tar hair dyes bearing on the label that give "patch test" instruction are exempted from the adulteration even if they

are irritating to the skin or are otherwise harmful to the human body. Eyelash and Eye borrow dyes are not included in this exemption

12. **Labeling**-means all labels and other written, printed, or graphic matter on or accompanying a product
13. **Principal display panel**- the part of the label most likely displayed or examined under customary conditions.
14. **Information Panel**-Folding carton, box wrapping, immediate container, leaflet

Range of Cosmetics

1. **Mouth washes**

Oral hygiene products–Liquid preparation for internal use or mouth washes for prevention of mouth odor

Breath freshners- Liquid and sprays

eg. Mouth spray and gargeles(except the products that exceed 0.75% as hydrogen peroxide)

2. **Body deodorizer**- Liquid for external use for prevention of body odor (deodorants)

-Pudendal detergent

3. **Heat rashes powder**- Powder for external use for prevention of heat rashes (e.g. baby powder)

4. **Dentifrice**

-Tooth pastes, tooth powders, tooth liquids (except the product that exceed 0.75% as a hydrogen peroxide)

This item contains sodium monoflourophosphate, sodium flouride, precipitated calcium carbonate and silicon dioxide etc.

Limits of flouride contents among tooth paste

-Stanousflouride NMT 0.4%
-Sodium flouride NMT 0.22%
-Sodium monoflourophosphate NMT 0.76%
-Amine fluoride NMT 1.31%

If the above mentioned ingredients are mixed , total amount of flouride should be less than 1,000ppm.

5. **Bath preparation**- Bath preparation may contain composition of soap as a body deodorant or a skin disease assistant treatment. The products contain sodium hydroxide, calcium chloride, terpene oil, boric acid etc.

If the product contain hormone, content of the ingredients must be fitted as follows

In 100gm(or 100ml)
-Diethylstilbestrol NMT 2mg
-Hydrocortisone and ester derivatives NMT 1.6MG
-Prednisolone NMT 0.5mg

6. **Cotton and its derivative for reason of sanitary use**

   - Sorbent cotton
   - guaze
   - bandage
   - elastic bandage
   - a plaster of paris bandage
   - sterkint
   - an adhesive plaster and its simillar products

7. **Products for the management of contact lense**

   Preparations for cleaning, preservation, disinfection and washing of contact lens (no instrument or machine)

8. **External disinfector**- The preparation containing hydrogen peroxide, isopropyl alchol, benzalkonium chloride or cresol as active ingredient

9. **Topical aerosol**- The spray of external use, may consist or consists Nicotinic acid benzyl ester, menthol, glycol salicylate, methylsalicylate, camphor, diphenhydramine

10. **Hair care products**- Hair tints and bleaches, waving, straightening and fixing, setting, cleansing products (lotions, powders, shampoos), conditioning products(lotions, creams, oils), hair dressing products (lotions, lacquers, brilliantine),

11. **Make up preparation**- Powders, after bath powders, hygiene powders etc.

12. **Bath and shower preparations**-salts, foams, oils, gels, etc

13. **Tinted bases**-liquids, pastes, powders

14. **Product intended for application to the lips**

15. **Perfumes,toilet waters and eau de cologne, toilet soaps, toilet waters**

16. **Shaving products-** creams, foams, lotions, etc

Section-I Requirement on the registration of Cosmetics

1. Application form

The application form for registration of cosmetics is as indicated in annex I. Therefore, applicants are required to submit the filled in application form together with the registration dossier.

2. Agency Agreement

i. An agency agreement should be made between the manufacturer of the cosmetics in question and the agent responsible for the import, distribution and sale of the cosmetics in Ethiopia. Where the manufacturer manufactures a product at two or more places, the agreement and responsibility of each party made between the manufacturers should be submitted. In such a case the agency agreement between the local agent and the manufacturer should be the site where the file is kept available and product is manufactured.
ii. The agreement should be signed by both parties and such is what is to be presented. The seal/stamp of both parties should also be affixed to the document.
iii. The agreement should specify that the representative chosen is the sole agent for that product in Ethiopia.
iv. The agreement should state that if any fraud or unsuspected and un acceptable adverse event occurs to the consumer under normal utilization, both party will be responsible to collect the product from the community and are responsible to substantiate any event.

3. Data on the Manufacturer

3.1. Background information: year of establishment, development since establishment, organogram, etc (This may omitted if the manufacturer is registered with the authority before or once.)

3.2. The certificate of Good manufacturing practice (GMP) and product certificate and/or free sale certificate which could be combined in one and which is issued by competent Authority in the country of origins and authenticated by Ethiopian Embassy.

4. Chemical and Analytical Data

4.1 Assigned Cosmetic ingredients

Ingredients of the cosmetics should not be in the lists of prohibited cosmetic ingredients. Manufacturer should indicate the reference to each ingredients used for the preparation of cosmetics. Reference can be made to the international cosmetic ingredient Dictionary (ICID), European Union Cosmetic ingredients Compendium (EUCIC), and other Compendium recognized by the Authority. If the reference and /or specification of an ingredient is in-house, the manufacturer should submit the following data for the ingredients under question:

a) Definition of the ingredients
b) Identification (both the method of identification and result obtained by the said method)
c) Method of manufacture (preparation),
d) Analytical Data and test method for the raw materials

4.2 Formulation Report

4.2.1 Data on composition

Indicate all the lists of ingredients, which will present in the final product including both the quantity and quality specification.

The name used for and ingredient shall be identified by its 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 CTFA name, its European pharmaceopeia name, its International Non-proprietary name as recommended by the WHO, its INECS, IUPAC or CAS identification reference or its color index number.

4.2.2 Data on Method of analysis and specification of the finished product

Mention all the relevant control parameter for the finished product and their limit of specification. The final product specification should at least indicate but not limited to the following information:

a. Appearance (clarity, color, homogeneity, odor)
b. Consistency
c. Particle size
d. pH

e. Average weight/Volume
f. Assay (for Border line and functional ingredients for functional cosmetics)
g. Method of analysis for the finished product-Indicate all the test method and specification. The test method should at least mention the equipment, reagent, method, etc.

For toothpaste, which contains fluoride,

1. Total fluoride
2. Available fluoride ion
3. Specific gravity

tests are required among others

4.3 Method of Manufacture (Preparation)

The method of manufacture should show

a) Flow chart for the method of manufacture
b) Concise description of the method of preparation mentioning the quality and quantity of the raw materials used including the final packaging and labeling procedures.
c) Description on the precautions and in-process controls that are made in connection with different stages in cosmetics manufacturing, that is of importance in ensuring the quality of the finished product.

4.2.4. Stability report

The real time stability report data sheet should indicate

4.2.4.1. The Formulation

4.2.4.2. The batch number (minimum two) and the batch type

4.2.4.3. Date of Manufacture

4.2.4.4. Expiry date or any statement which may explain for example, use within two years from the date of manufacture" or "best before '…….' From the date of manufacture

4.2.4.5. Type and chemical nature of the packaging materials

4.2.4.6. Analytical methods that will quantitatively measure the characteristic structural and chemical properties of each active or functional ingredients of a dosage form and distinguish them from their degradation products so that active ingredient content can be measured. If such a method is mentioned elsewhere in the dossier it is enough just to mention the page number.

4.2.4.7. Initial and all subsequent results of chemical, physical and/or biological testing. The frequency of testing must be every 3-month including the initial for the first year and every 6-month for the second year and every year thereafter.

4.2.4.8. Summary of the study and storage recommendations based on the data generated

5. Data Demonstrating Safety and Efficacy

To determine the margin of safety of cosmetics for human use: Relevant toxicity tests should be submitted.

Where applicable the following toxicity data should be submitted

1. Single dose toxicity
2. Primary skin irritation
3. Ocular or mucous membrane irritation test
4. Skin Sensitization
5. Photo toxicity and photosensitivity
6. Repeated human irritation test

For functional cosmetics- The following test should be performed indicating test method and evaluation method

a) Sunscreen product
-SPF test method
-Expression of SPF
-Others

b) Whitening agent
-Invivo tyrosine activity
-Invitro melanin synthesis inhibition assay
-DOPA authoxidation test
-Others

c) Anit-wrinkle product
-Cell proliferation assay
-Collagen synthesis assay
-Elastase inhibition assay

Enamel solubility reduction test or the fluoride enamel uptake test for fluoride containing tooth paste

V. Requirement for Labeling of Cosmetics

Labeling- All labels on cosmetic and personnel care products must contain a list of ingredients. If the container is in an outer package (i.e. a carton) the labeling will be on the carton. If there is no outer packaging it will be on the container. Functional and cosmetic drugs should be accompanied by package insert (leaflet). For products that are small and difficult to label, there are special exceptions. Here the ingredient listing may be on a leaflet, this being indicated by the use of a hand pointing to an open book logo on the outer packaging or as an insert. The labeling statements must appear on the inside (immediate container) as well as any outside container or wrapper. Ingredient labeling and statement of the net quantity of the contents on the principal display panel, only apply to the label of the outer container. Cosmetics bearing false or misleading label statements or otherwise not labeled in accordance with these requirements considered misbranded and may be subject to regulatory systems.

The declaration must be distinct, placed in the bottom area of the panel. All label statements required by regulation is in the English language and must be placed on the label or labeling with such prominence and conspicuousness that they are readily noticed and understood by consumers under customary conditions of purchase. The following statements are prohibited: a) "recommended by doctors" or any other word or words or pictorial representation implying that medical practitioners in general recommend its use, shall be guilty of an offence. b) a claim that conveys that the product possesses health-giving properties shall, unless such word, indication or claim can be scientifically substantiated, be guilty of an offence.

Under customary conditions for sale the principal display must state:

- ✓ Name of the product- The name used for and ingredient shall be identified by its 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 CTFA name, its European pharmaceopeia name, its International Non-proprietary name as recommended by the WHO, its INECS, IUPAC or CAS identification reference or its color index number.
- ✓ Dosage form of the product
- ✓ Use of the product (see annex I)
- ✓ Net quantity of contents of the cosmetic in terms of weight, measuring numerical count, or a combination of numerical count and weight or measure. The net quantity of contents statement of a solid, semi-solid or viscous cosmetic must be in terms of the avoirdupois, pound and ounce, and a statement of liquid measure must be in terms quarts, pints, fluid ounce and subdivisions thereof. If the net quantity of contents is one pound or one pint or more, it must be expressed in ounces. The net quantity of contents may additionally be stated in terms of the metric system or weights or measures.
- ✓ Ingredient declaration- The ingredient declaration must be conspicuous so that it is likely to be read at the time of purchase. It may appear on any information

panel of the package. The ingredient must be declared in descending order of predominance. Color additives and ingredients present at one percent or less may be declared with out regard for predominance. In case where there is confidentiality to list all the ingredients, the manufacturer may use coding system. However, the coding should be defined and submitted to the authority by the responsible person. Cosmetics which are also drugs must first identify the drug ingredient (s) as "active ingredient" before listing the cosmetic ingredients. Cosmetics, which are functional cosmetics, should indicate the functional ingredients and their functionality. For sunscreen ingredients indicate their SPF.

The following are not regarded as ingredients for the purposes of the compilation of the ingredient list:

-Impurities in the raw materials used
-Subsidiary technical materials used in the preparation of the cosmetic product but not present in the final product.
-Perfumes and aromatic composition and their raw materials shall be referred by the words "Perfumes" or "Flavour"

- ✓ Cosmetics, which may be hazardous to consumers when misused, must bear appropriate label warnings. The authority strongly urges cosmetic manufacturer to conduct whatever toxicological or other tests that are appropriate to substantiate the safety of their cosmetics. If the safety of a cosmetic is not adequately substantiated, the product may be considered misbranded and may be subject to regulatory action unless the label bears the following statement. *Warning "The safety of this product has not been determined",*
- ✓ Cosmetics, which might contain an ingredients that may penetrate the skin, should bear the following warning, "Contains ingredients that can penetrate your skin and has been determined to cause cancer"
- ✓ Liquid or oral hygiene products (e.g. Mouth washes, fresheners) and all cosmetic vaginal products (eg. douches, tablets) must be packed in a tamper resistant package. The feature may involve the immediate or outer container or both. The package must also bear a prominently placed statement alerting the consumer to the tamper-resistant feature. This statement must remain un affected if the tamper resistant feature is breached or missing.
- ✓ Hair Dye products- In addition to the general requirement for cosmetic labeling a hair dye product label should indicate: categories of hair dye (Permanent, Semi permanent or temporary hair colors), and coal tar containing hair dye product label should bear direction for patch test and should bear the following caution, "This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.
- ✓ Tooth paste labeling- identify the product as anticavity fluoride (select one of the following as appropriate: dentifrice, toothpaste, tooth polish, or tooth powder;. Warning statement: Keep out of reach of children under 6 years of age. Direction

for use which may vary depending on the total fluoride concentration. The following statement must be prominently placed on the principal display panel

1) For toothpastes with theoretical total fluorine concentration of 850 to 1150 ppm, the directions must read adults and children 2years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Children under 2years or age: Consult a dentist or doctor. If accidentally swallow more than used for brushing, seek professional assistance.
2) For toothpastes with a theoretical total fluorine concentration of 1150ppm, children under 6 years of age: Do not use unless directed by a dentist or doctor.
3) For powdered toothpastes with a theoretical total fluorine concentration of 850 to 1150ppm, the required direction contain much the same age restrictions as the higher-concentration toothpastes as above, along with specific directions on ho to use the powdered pastes.

- ✓ The name of Manufacturer
- ✓ Address of the manufacturer: Street address, City, State, Zip code
- ✓ If the distributor is not the manufacturer this fact must be stated on the label by the qualifying phrase "Manufactured for "....." and distributed by "....." or similar appropriate wording.
- ✓ Batch Number
- ✓ Manufacturing Date
- ✓ Date of expiry (Cosmetic Drug and Functional cosmetics)

Annex I

Label Claims Distinction Across product areas

II. **Baby Powder** -Baby products include Shampoos, Lotions, and powders. The common Cosmetic claims made on these products include: being scented or fragrance-free, cleansing, moisturizing, odour, reducing, softening, and soothing. The claims such as prevention and treatment of diaper rash are antimicrobial, external analgesics, skin protectant, and topical antifungal are considered as drugs

III. **Bath preparation**- Include oils, salts, bubble bath, and capsules. Claims are almost exclusively cosmetic, including being scented or perfumed, bubbling, creating a desirable experience, deodorizing, moisturizing, relaxing, and softening. There are few drug/cosmetic issues.

IV. **Eye makeup preparation**- include eyebrow pencil, eyeliner, eye shadow, eye makeup remover, and mascara. Examples of cosmetic claims include adding luster, beutifying, caoting, coloring, conditioning, curling eyelashes, resisting creases, improving appearane, lasting a long time, lengthening and thickening, resisting smudging and smearing, and being scented/unscented, easy to blend, easy to remove, glamorous, hypoallergenic, waterproof, and water resistant. The common drug claim, which is prohibited, is eye makeup preparation typically should not be marketed as having ophthalmic benefits. Eye makeup preparation especially liquid products such as mascara and eyeliner should bear a warning statement how to avoid an eye injury.

V. **Fragrance preparations**-include perfume, cologne, toilet water, scented powder and sachets. These products primarily lend themselves to cosmetic claims, such as attracting, creating a desirable experience or mood, lasting a long time and perfuming. The claim to prevent or treat disease by means of "aroma therapy" would considered a drug claim

VI. **Hair Care Preparations(Noncoloring)**- include conditioners, sprays, straighteners, permanent waves, rinses, shampoos, tonics, dressings, grooming aids, and wave sets. Cosmetic claim include adding body, adding luster, bleaching, cleansing, containing a protective sunscreen, curling, highlighting, lasting a long time, holding, protecting, removing residue, straightening, styling, and washing as dandruff. Claims that the Authority considers to be drug claims include those relating to prevention of treatment of dandruff, scaling, itching, psoriasis, and similar conditions and claims of prevention or reversal of hair loss. The

presence of pharmacologically active ingredient could make a product a drug even in the absence of explicit drug claims. Even in the absence of antidandruff claims, shampoo products with therapeutic level of antidandruff ingredients are considered as drugs.

VII. **Hair Coloring preparations**- include dyes and colors, tints, coloring rinses, coloring shampoos, lighteners, and bleaches. Cosmetic claims for these products relate to heir bleaching, coloring, and highlighting functions, as well as their secondary functions/benefits such as adding body or luster, cleansing, conditioning, lasting a long time, and protecting.

VIII. **Makeup preparations(Not Eye)** -include blushers, face powders foundations, leg and body paints, and lipstick. Common cosmetic claims include absorbing oil, beautifying, coloring, concealing or covering blemishes and imperfection, controlling shine, covering up the signs of aging, hiding pores, hypoallergenic, improving appearance, lasting a long time, moisturizing, reducing, the appearance of wrinkles, smoothing, and being flavored and/or scented/unscented. Examples of drug claim, which are not recommended under makeup preparations, are acne treatment, skin protectant, and sunscreen. They are also considered to be drug if their labeling contains the term "hormone". These and other drug benefits for makeup product are treated similarly to skin care preparations.

IX. **Manicuring preparations**- manicuring preparations include polish and enamel, basecoats and undercoats, cuticle softeners, nail cremes and lotions, and nail extenders. The general cosmetic claim include beautifying, coating, coloring, conditioning, containing a sunscreen, long-lasting, moisturizing, preventing chipping and cracking, protecting, reinforcing, removing cuticles, softening, and strengthening. The primary drug claim issues in this category relate to the deterrence of nailbiting and thumbsucking. The deterrence of nailbiting and thumbsucking are drug claims and there are no products that are generally recognized as safe and effective for this purpose.

X. **Oral Hygiene products** -include dentifrices, mouthwashes, and breath fresheners.

Examples of cosmetic claims include cleaning teeth and gums, deodorizing, freshening breath, preventing or reducing bad breath, and refreshing. Drug claim include healing wounds, killing bacteria and fungi, preventing cavities or tooth decay, relieving sore throat, sore mouth, and other oral discomfort, and whitening or bleaching teeth, prevention of gingivitis.

XI. **Personal Cleanliness** -include bath soaps and detergents, deodorants, douches, feminine hygiene products, scrubs, and skin cleansers. While

soap sold only for ordinary toilet or household use is exempt from the definition of "cosmetic", soap intended for use other than ordinary toilet or household use and represented, for example, as a beautifying agent, is within the definition of cosmetic. Cosmetic claims for personal cleanliness products include beautifying, being scented or fragrance-free, cleansing, clarifying, conditioning, deodorizing, moisturizing reducing or absorbing odor, refreshing, removing hair, and soothing. Claims such as antifungal, antiperspirant, and/or disinfectant, removing lice, relieving itches removing earwax and treating acne, hemorrhoids, or swimmers ear are drug claims and prohibited.

XII. **Shaving preparations** -include aftershave lotion, beard softeners, shaving cream, and shaving soap. Common cosmetic claims include being scented or fragrance-free, cleansing, lubricating, refreshing, softening beard and skin, soothing, stimulating, tightening pores, and tingling. An example of drug claim that could be made to these products is the treatment of cuts and abrasions from shaving.

XIII. **Skin care preparations**- include creams, lotions, powders, and sprays used for cleansing, depilatories, face and neck, body and hand, foot, moisturizing, night, face masks, skin fresheners, and astringents. As evidenced by the wrinkle remover cases, this category is rife with drug versus cosmetic issues. Cosmetic claim include clarifying, cleansing, clearing pores, controlling shine, conditioning, deflaking, degreasing, hydrating, lasting a long time, lubricating, moisturizing, polishing, refreshing, relieving dryness, smoothing wrinkles, softening, soothing, toning, and being allergy tested, safe for sensitive skin and/or hypoallergenic, as well as having a lower rate to reaction, irritation, or sensitivity. Example of drug claims include prevents aging, acts as an antibacterial, protects from and treats fever blisters and cold sores, protects from and treats insect bites/stings, relieves vaginal irritation and reduces edema, restructures and repairs skin, treats boils, treats skin abrasions, injuries, and bacterial/fungal infections, protects from sun, removes warts and has a transdermal carrier system.

XIV. **Anti-Aging** - claims such as an amazing protein lotion to imply nourishment of the skin, face lift without surgery, super active are drug claim. In contrast pure protein lotion claim is a cosmetic claim. Claims of creating a tingling sensation when at work and tightening the skin implied a therapeutic product whereas tightening and moisturizing tired skin and dramatic astringent activity is allowed as a cosmetic claim.

XV. **Suntan and Sunscreen preparations**- suntan and sunscreen preparations include suntan gels, creams and liquids, indoor tanning preparations, sunscreens, and sun blocks. Because most sunscreen preparations are skin care preparations and makeup preparation, their cosmetic claims will be similar. Because they prevent skin damage by blocking or absorbing ultraviolet light, their action is similar to clothing or other physical sun protection.

XVI. **Toothpaste**- the claim of tooth paste is similar to oral hygiene claim if its main claims were for the beautification of the teeth, and not the prevention of caries. A cosmetic toothpaste would likely have to contain no known therapeutic or drug-like ingredients (such as toothpaste for smokers to whiten the stained teeth with no anticaries indication) can be labeled with claim similar to other oral care products. Anti tartar products should say on the label that the substances only affect supragingival tartar and have no therapeutic effect on gingivitis (gum disease) if the manufacturer wants these claims to have purely cosmetic status.

Annex II

Application form

1. Name of the preparation _____
2. Color of the preparation _____
3. Presentation (Pack size, content) _____
4. Shelf life(months) _____
5. Type of Cosmetics _____
6. Composition of the ingredients per _____

Name of the ingredients	Strength(%)	Function

7. Maine indication _____

8. Manufacturer

Name of the manufacturer _____

Street address _____

Plant address _____

Postal address _____

Tel. number _____

Fax number _____

E-mail _____

9. Local Agent in Ethiopia

Name_____

Street address _____

Plant address _____

Postal address _____

Tel. number _____

Fax number _____

E-mail _____

10. Supporting Documents or Materials Attached(List them and annotate)

_____

_____

_____

_____

_____

_____

Name of Contact person in the Manufacturer

_____

Official designation _____

Profesional status _____

Signature _____

To Be filled in by the Authority

Application Number _____

Date of receipt _____

Registration Number _____

Registration Date_____

Name and Signature of Authority

_____

Date

_____