Palestinian National Authority
Ministry of Health

General Directorate of Pharmacy
Drug Control and Registration Dept

PART III

GUIDELINES FOR COSMETIC PRODUCTS REGISTRATION IN PALESTINE

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1 Introduction

These guidelines are prepared to provide manufacturers and importers with information concerning documentation to be submitted for approval and registration of cosmetics in Palestine before they are made available to the market.

The guidelines consist of three sections: Section I outlines the requirements on the registration of cosmetics while section II deals with data that should be submitted with an application for re-registration of cosmetic products. Section III is concerned with data that should accompany the 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 to apply for re-registration by submitting the required documents 120 days before the re-registration validity due date.

The requirement for registration of a cosmetic product is as outlined in the guidelines and the evaluation and screening of the application is based on the minimum requirements stated in them. However, since all points cannot be addressed in detail and since science changes and develops every day, the DDCR has the right to ask the applicant for 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 these guidelines provide general guidance. 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 guidelines.

2 Definitions

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, products defined as drugs are not included under this definition.
2. **Functional Cosmetics:-** are cosmetics which fall in any one of the following category:
   a. **Whitening agents:-** are cosmetics that are designed to whiten the skin tone
   b. **Anti-wrinkling agents:-** are cosmetics that are designed to minimize the appearance of the lines in the face and body
   c. **Sun Screens-** 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.
   d. **Antidandruff preparations**.
   e. **Anti-perspirant deodorants**.
   f. **Cavity fighting tooth paste**.
3. **Mouth washes:-** liquid oral hygiene products for prevention of mouth odor or breath fresheners (liquid and spray).
4. **Body deodorizer:-** liquid for external use for prevention of body odor
5. Heat rash powder- powders for external use, for prevention of heat rashes
6. **Dentifrice:-** Tooth pastes, tooth powders, tooth liquids containing hydrogen peroxide, fluoride, precipitated calcium and silicon dioxide
7. **Bath preparation:-** products for external use for bath which may contain soap as body deodorant or a skin-disease-assisting treatment
8. **Soap products:-** products consisting primarily of an alkali salt of fatty acid and making no label claim other than cleansing of the human body
9. **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

10. **Adulterated cosmetics:-** cosmetics which contain a substance which may make the product harmful to consumers under customary conditions of use; if they contain a filthy, putrid, or decomposed substances; if they are manufactured or held under unsanitary conditions whereby they may have become contaminated with dirt, or may have become harmful to consumers; or if they are not a hair dye and they contain non-permitted colour additives. Coal tar hair dyes bearing a label that gives "patch test" instructions are exempt from the adulteration category even if they are irritating to the skin or are otherwise harmful to the human body. Eyelash and eyebrow dyes are not included in this exemption
11. **Labeling:-** means all labels and other written, printed, or graphic matter on or accompanying a product.

3 General Registration Provisions:

1. Any pharmaceutical product of any dosage form intended to be used on humans or animals, whether internally or externally, is required to be registered with the Department of Drug Control and Registration (DDCR).
2. All required applications and file documents shall be submitted in original hard copies. Authenticated copies may be accepted if submitted with a clear statement from the original owner allowing the use of the copied documents.
3. All information and documents must be in English/Arabic and legible. Where documents are not originally in English/Arabic, a copy in the original language and a full legalized translation should be submitted.
4. All application forms shall be filled by a competent qualified person (i.e. responsible pharmacist). He or she shall ensure that all information provided to the department (DDCR) is true and correct to the best of his/her knowledge. The applicant shall be aware that if he/she makes any false statement, representation or declaration in connection with an application to the DDCR, he/she shall be guilty of an offence.
5. All the registration conditions and requirements shall be fulfilled by the applicant. If the applicant wishes to waive any condition, he/she shall apply for a waiver together with supporting documents.
6. Authentication (or legalization) of documents, wherever required, shall be done by the relevant health authority, the Ministry of Foreign Affairs and the Palestinian embassy in the country where the document was issued.
7. The applicants should notify the DDCR of any change in the particulars submitted in the application and of any new significant information during the course of evaluation and as long as the product remains on the Palestinian market.
8. The marketing authorization holder shall notify the department if the product is no longer registered by another country, as long as the product remains on the Palestinian market.

9. The marketing authorization holder shall ensure that the product will be sold, supplied and recommended for use in accordance with the approved and in compliance with all license conditions, applicable legislation and guidelines.
10. Product registration shall be only through authorized agent, exclusive distributor, scientific office or local manufacturer.
11. The registration documents shall be submitted in bound files, pages shall be numbered and the file should have protruding dividers, each bearing the name of the relevant section.
12. The registration of a product shall be valid for five years or such period as specified in the registration certificate (unless sooner suspended or cancelled by the DDCR).
13. Renewal of product registration can be done six months prior to the expiry of the validity period of the product registration.
14. Application for renewal of registration shall be submitted to the department not later than four months prior to the expiry of the validity of registration.
15. Upon expiry of the validity period of registration, the renewal of product registration will no longer be accessible and application for new registration of product can be submitted.
16. The DDCR shall reject, cancel or suspend the registration of any product, if there are deficiencies in safety, quality or efficacy of the product or failure to comply with the conditions of registration.
17. Any applicant or marketing authorization holder aggrieved by the decisions of the DDCR may make a written appeal to the head of the department. All appeals must be made within thirty days from the date of the DDCR notification. The director of the DDCR department shall submit the appeal and the supporting data or documents to the Drug Technical Committee. The decision of the DTC made on any appeal is final.
18. Every application for registration and renewal of registration shall be accompanied by the registration fees, which is to be determined by the Minister of Health.

19. The DDCR will charge the applicant any costs for carrying out laboratory testing relating to the registration or renewal of the registration of any product.
20. Any payment made is not refundable once an application has been submitted and payment confirmed.
21. Letters of authorization and certifications should be valid and current at the time of submission.
22. Where a product is contract-manufactured, letters of authorization of contract manufacturer and acceptance to register from the manufacturer and each sub-contractor, if applicable (e.g. repacker).
23. The letter of authorization should be on the product owner's original letterhead and be dated and signed by the managing director, president, or equivalent person who has overall responsibility for the company organization.
24. The letter of acceptance from the manufacturer shall comply with similar requirements as stated above.
25. The letters of authorization and acceptance should state the name of the product(s) concerned and the name and actual site address of the manufacturer(s) involved in the manufacturing of the product(s).
26. A separate application is required for each product i.e. products containing the same ingredient(s) but made to different specification (in terms of strength/content of ingredient(s), dosage form, description, etc.) or by a different manufacturer shall require separate applications for product registration.
27. Different primary packing (materials) or pack sizes (quantity or volume) of a product made by the same manufacturer to the same specifications, formulation and dosage form, shall require only one application for product registration. The product registration shall be for the packing and pack sizes stated in the registration documents only.
28. An application for a second source shall be considered where deemed necessary. This second source product shall be the same as the first product in all aspects except for the site of manufacturing.

29. A decision on the approval or rejection of an application shall be made based on the outcome of the evaluation of the submitted documentation. The decision will be sent to the marketing authorizations holder by the DDCR within the stipulated time as stated in the DDCR notification.
30. A registration number will be given when a product application is found to have satisfied the registration requirements of quality, safety and efficacy and is granted registration approval by the DDCR. The registration number is specific for the products registered with the name identity, composition, characteristic, origin (manufacturer) and marketing authorization holder as specified in the registration documents. It must not be used for any other product.
31. A certificate of registration with the provisions, conditions, limitations etc of the registration, shall be issued for the registered product.
32. No change in product name, product specifications, packaging, indications, contents of product label, package insert, or product literature, or any relevant particular of the registered product shall be made without the prior approval of the DDCR. Similarly, prior approval of the DDCR is required for changes in excepients, such as any change in lubricant, preservative, solvent, etc to improve product formulation. Explanation/reason for the changes requested should be given. All relevant supporting data related to the above changes such as finished products specifications, certificate of analysis, stability data, raw materials specifications, etc should be updated accordingly. The registration of the products may be cancelled if changes are made without prior approval of the DDCR.
33. All necessary documents in accordance to the specified conditions laid for each type of variation (amendment) should be submitted. The marketing authorization holder is responsible for ensuring that all the necessary validation has been conducted to demonstrate that the change does not reduce the quality, safety or efficacy of the product

34. Any change which affects the composition or characteristics of the products such as, colour/ shade, flavour/ fragrance, shape, change of vehicle shall require a new application for registration.
35. The product marketing authorization holder should inform the DDCR of any adverse reaction to the product.
36. The product registration can be cancelled if the marketing authorization holder fails to inform the DDCR of any serious adverse reactions upon receipt of such reports.
37. All labels and package insert must be amended to include any new adverse reactions, warnings, precaution etc.
38. Samples of products registered by the DDCR may be taken and tested for compliance with official pharmacopoeial standards or specifications agreed by the manufacturer.
39. If a sample fails to meet adequate specifications, the marketing authorization holder will be issued a warning. Unless the failure is serious enough to justify recall of the product, the marketing authorization holder has up to thirty (30) days to identify the source/cause of quality defect and actions to be taken to improve quality.
40. The marketing authorization holder should notify the DDCR of any product quality related problems (with registered products) that the holder is aware of. It is also the responsibility of the prescribers, the pharmacists, as well as other health professionals who come into contact with the product to report.
41. The marketing authorization holder is responsible for conducting recalls of defective or unsafe products. It is also his responsibility to notify the DDCR of any recall decision. No recall should take place without first consulting/informing the DDCR.
42. The marketing authorization holder shall inform the DDCR of any decision to terminate the registration of a product before the end of the validity of such registration. The marketing authorization holder must return the product registration certificate immediately to the DDCR.

43. The registration of a product once terminated shall not be re-registered. A new application must be submitted .
44. A product registration (marketing authorization) may be transferred from the existing product marketing authorization holder (MAH) to another holder using a transfer procedure..
45. The DDCR will register a product for any marketing authorization holder only once for the same active ingredient(s).
46. A product will be registered only if it satisfies all requirements of the DDCR, especially with respect to safety, efficacy and quality of the product. other criteria that may be taken into consideration include:
    - Either that the product is needed or not. Aspects like potential for abuse, number of registered products, different dosage form, products containing forbidden excipients, etc are considered.
    - Therapeutic advantage.
47. The DDCR may register locally manufactured products for export only that is to be sold in a different colour (formulation), shape and strength.
48. Registration of product for export purposes is not necessary if there is no change in the formulation or appearance of the product. An "export notification" procedure allows an applicant to apply for free sale certification for the product where by the applicant need only declare to the DDCR the differences in the product for export compared to the registered product marketed in Palestine (such as a product being exported under a different name).A Free Sale Certificate(FSC)/ a certificate of a pharmaceutical product (CPP) will be issued to the applicant for the registered product together with an explanation of any difference(s) to the importing country.
49. Products which are packed together in combination for a therapeutic regimen (example for the treatment of helicobacter pylori, hepatitis C, etc) will be classified as a combination pack. Product shall be registered as a single product.
50. A product which is packed together with diluent(s) is not considered as combination pack product.

51. A combination pack product must consist of registered products only.
52. The use of halal and certification logos (i.e. ISO, GMP. etc) on the labels of drug products will not be allowed.
53. However use of the mentioned logos will be considered for traditional products, food supplements, and also cosmetics, for both local and export market, provided that such products have been certified and approved as halal or ISO or GMP by DDCR. The use of the logos is based on application to DDCR and is not a mandatory requirement.
54. All the registration data submitted to the DDCR shall be considered confidential and shall be kept in safe manner.

4 Range of Cosmetic Products

1. **Mouth washes:-**
   Oral hygiene products-Liquid preparation for internal use or mouth washes for prevention of mouth odor

   Breath fresheners- Liquid and sprays (e.g. Mouth spray and gargles (except the products that exceed 0.75% as hydrogen peroxide)

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

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 fluoride should be less than 1,000ppm (<1500ppm, <1000ppm for children).

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.

6. **Products for the management of contact lenses:-**
   Preparations for cleaning, preservation, disinfection and washing of contact lens (no instrument or machine)

7. **Topical aerosol:-** The spray for external use, may contain Nicotinic acid benzyl ester, menthol, glycol salicylate, methylsalicylate, camphor.

8. **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),

9. **Make up preparations:-** Powders, after-bath powders, hygiene powders etc.

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

11. **Tinted bases:-** liquids, pastes, powders

12. **Products intended for application to the lips**

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

14. **Shaving products:-** creams, foams, lotions, etc

5 Section1: Requirements on the registration of Cosmetics

1. Application form

The application form for registration of cosmetics is as indicated in appendix (2). Therefore, applicants are required to submit the filled in application form together with the registration dossier.

2.Agency Agreement

i. An authenticated 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 Palestine. 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. 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 or exclusive distributor authorized to register the cosmetic product in Palestine.

iv. The agreement should state that if any fraud or suspected and unacceptable adverse event occurs to the consumer under normal utilization, both parties will be responsible for removing the product from the market.

3. Data on the Manufacturer

3.1. Background information: year of establishment, development since establishment.

3.2. The authenticated 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 the competent Health Authority in the country of origin.

3.3. Types of products produced, quality system in brief and countries to which the product(s) are exported.

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 DDCR. If the reference and /or specification of an ingredient is in-house, (i.e. not mentioned in any recognized compendium), 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) Analytical Data and test method for the raw materials

4.2. Unapproved and restricted components:

4.2.1. A cosmetic product license will not be granted for a product containing a component listed in *Annex II* – List of substances which must not form part of the composition of cosmetic products

4.2.2. A cosmetic product license will not be granted for a product containing a component at a higher concentration than listed in *Annex III*

4.2.3. A cosmetic product containing a colouring agent will contain only colours listed in *Annex IV* and shall not exceed the maximal concentrations listed therewith.

4.2.4. A cosmetic product containing a preservative will contain only preservatives listed in *Annex V* and shall not exceed the maximal concentrations listed therewith.

4.2.5. A cosmetic product containing synthetic UV filters will contain only UV filters listed in *Annex VI* and shall not exceed the maximal concentrations listed therewith.

4.2.6. For cosmetic products containing ingredients that do not appear in the ICID or a known pharmacopoeia (one of the following: European, British, American) the applicant must submit basic data pertaining to the safety of the ingredient, its purity level (microbial if relevant) and test methods.

4.3. Formulation Report

4.3.1 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 an 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 colour index number.

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

Mention all the relevant control parameters for the finished product and their specification limits. The finished product specification should include but not be limited to:

a. Appearance (clarity, colour, homogeneity, odor)
b. Consistency
c. pH
d. Average weight/Volume
e. Assay (for Border line and for functional cosmetics) as required in addition to other tests.
f. Method(s) of analysis for the finished product. The test method should at least mention the equipment, reagent, method, etc.

For each dosage form refer to (*Appendix (3*)) for the required testing parameters.

4.4. Method of Manufacture (for local manufacturers only)

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 of 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.

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

- SPF test method
- Expression of SPF
- Others

6. Requirement for Labeling of Cosmetics

Labeling- All labels on cosmetic 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. The labeling statements must appear on the inside (immediate container) *as* well *as* any outside container or wrapper. Cosmetics bearing false or misleading label statements or otherwise not labeled in accordance with these requirements are considered misbranded.

The following statement is prohibited: "recommended by doctors" or any other word or words or pictorial representation implying that medical practitioners in general recommend its use.

The following shall appear on the container:

- Name of the product.
- Dosage form of the product
- Use of the product.
- Net quantity of contents of the cosmetic in terms of weight, measuring numerical count, or a combination of numerical count and weight or measure.
- 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. Colour additives and ingredients present at one percent or less may be declared without regard for predominance cosmetics, which are functional cosmetics, should indicate the functional ingredients and their functionality. For sunscreen ingredients, indicate their SPF.
- Cosmetics, which may be hazardous to consumers when misused, must bear appropriate label warnings. Warning "The safety of this product has not been determined",
- 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 colours), 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 be 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 anti cavity fluoride.
- 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 principle package:

a. For toothpastes with theoretical total fluorine concentration of 850 to 1150 ppm, the directions must read adults and children 2years of age and older as directed by a dentist or doctor.

b. For toothpastes with a theoretical total fluoride concentration of 1150ppm, children under 6 years of age: Do not use unless directed by a dentist or doctor.

c. For powdered toothpastes with a theoretical total fluoride 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 how to use the powdered pastes.

- The name of Manufacturer.
- Address of the manufacturer: Street address, City, State, Zip code.
- Name and address of the agent/distributor in Arabic.
- Batch Number .
- Manufacturing Date.
- Date of expiry (Functional cosmetics)

7. Sufficient samples for analysis accompanied by a reference standard material from functional ingredient (when applicable). For the required sample quantities see appendix (7).

6 Section 2: Renewal of the Registration of cosmetic products

1. Application for renewal of registration shall be submitted to the Drug Control and Registration Department every five years not later than four months prior to the expiry of the registration validity date . In extenuating circumstances, the application will be accepted at a later date but not later than two months prior to the expiry of the registration

2. The application shall include the following:

   - Application form for the renewal of registration of cosmetic product in three copies signed by the responsible technical person(see Appendix (5).
   - Original receipt confirming payment of fees for the renewal of registration.
   - The analytical methods that will quantitatively measure the characteristic structural and chemical properties of every functional ingredients of the dosage form (when applicable)
   - The finished product specifications.
   - The latest master formula for the product.
   - The latest artwork illustration of the packaging material /sample of the printed packaging material and labeling

3. Sufficient samples for analysis accompanied by a reference standard material from the functional ingredient. (when applicable). For required sample quantities (see appendix (7))

4. The Department of Drug Control and Registration reserves the right to ask for any additional documents with regard to the registered cosmetic product file.

7 Section 3: Amendment to the registration of cosmetic products

Amendments to the registration of a cosmetic product shall be applied to the Drug Control and Registration Department (MOH).

Changes or variations requirements are illustrated in ***Appendix (4)***. Any other changes not included in the appendix of changes shall be applied-for and the department shall notify the applicant with the requirements and decision.

1. The application form should be submitted to the Drug Control and Registration Department. (See appendix (6)).
2. An application for a change in the site of manufacture shall be accompanied by:
   - Declaration by the manufacturer that there has been no change in the manufacturing procedure or in the cosmetic product specification.
   - The Certificate of Good Manufacturing Practice.
   - An authenticated free sale certificate issued from the relevant health authorities of the new site (except E.U countries).
   - Certificate of analysis from the manufacturer.
   - Authenticated copy of the manufacturing license for the new site from the relevant health authority of the country of origin.

3. The Department of Drug Control & Registration reserve the right to require additional data or waive any of the above requirements.

8 Section 4: Appendices

1. **Appendix (1):** Label Claims of different cosmetic products
2. **Appendix (2):** Application form "Registration of Cosmetic Products"
3. **Appendix (3):** The required testing parameters for cosmetics
4. **Appendix (4):** Changes and variations in registered cosmetic product.
5. **Appendix (5):** Renewal of the registration of cosmetic product.
6. **Appendix (6):** Amendments to the registration of cosmetic product.
7. **Appendix (4):** Number of samples required for registration and renewal purposes.

Appendix (1)

Label Claims of different cosmetic products

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

2. **Bath preparations**:- 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.

3. **Eye makeup preparations:-** include eyebrow pencil, eyeliner, eye shadow, eye makeup remover, and mascara. Examples of cosmetic claims include adding luster, beautifying, coating, colouring, conditioning, curling eyelashes, rlimiting creases, improving appearance, 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 in eye makeup preparations, typically should not be marketed as having ophthalmic benefits.

4. **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 "aromatherapy" would be considered a drug claim.

5. **Hair Care Preparations (Non colouring):-** include conditioners, sprays, straighteners, permanent waves, rinses, shampoos, tonics, dressings, grooming aids, and wave sets. Cosmetic claims 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 DDCR considers to be drug claims include those relating to prevention or treatment of scaling, itching, psoriasis, and similar conditions and claims of treating of hair loss. The presence of pharmacologically active ingredient could make the 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 drug-functional cosmetics.

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

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

8. **Manicuring preparations:-** manicuring preparations include polish and enamel, basecoats and undercoats, cuticle softeners, nail crèmes and lotions, and nail extenders. The general cosmetic claim include beautifying, coating, colouring, conditioning, containing a sunscreen, long-lasting, moisturizing, preventing chipping and cracking, protecting, reinforcing, removing cuticles, softening, and strengthening. The deterrence of nail biting and thumb sucking

are not allowed claims and there are no products that are generally recognized as safe and effective for this purpose.

9. **Oral Hygiene products**:- include dentifrices, mouthwashes, and breath-fresheners (claims include cleaning teeth and gums, deodorizing, freshening breath, preventing or reducing bad breath, and refreshing. Preventing cavities or tooth decay, and whitening or bleaching teeth. Claims like healing wounds, killing bacteria and fungi, relieving sore throat, sore mouth, and other oral discomfort are not allowed).

10. **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, or disinfectant, removing lice, relieving itches removing earwax and treating acne, hemorrhoids, or swimmers ear are drug claims and prohibited.

11. **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.

12. **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. Cosmetic claims 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, removes warts and has a transdermal carrier system.

13. **Anti-Aging–** claims like tightening and moisturizing tired skin and dramatic astringent activity are allowed as cosmetic. Claims such as an amazing protein lotion to imply nourishment of the skin, face lift without surgery, super active are drug claims**.**

14. **Suntan and Sunscreen preparations-** suntan and sunscreen preparations include suntan gels, creams and liquids, indoor tanning preparations, sunscreens, and sun blocks. Most sunscreens are skin care and makeup preparations, therefore, their cosmetic claims will be similar. Because they prevent skin damage by blocking or absorbing ultraviolet light.

15. **Toothpaste-** the claim of tooth paste is similar to oral hygiene claim if its main claims were for the beautification of the teeth, the prevention of caries. A cosmetic toothpaste would likely have to contain no known therapeutic or drug-like ingredients.

Appendix(2)

Application form

Registration of Cosmetic Products

To the Director of Drug Control and Registration Department:

I hereby request your approval to register the following cosmetic product.

1. Details of the applicant:
   - Name of the applicant:……
2. Details of the manufacturer:
   - Name of the manufacturer: ……
   - Plant address: ……..
   - Tel No.:……Fax No.:……..…….
   - E-mail address/website: ……
3. Details of the local agent:
   - Name of the agent: ……..……
   - Address: ……..……..
   - Tel No.:……Fax No.:…….
   - E-mail address: ……
4. Details of the cosmetic product:
   - Name of the product: ……..……
   - Pharmaceutical dosage form: ……..
   - Colour of the product:……..
   - Presentation:
     - Package size: ……
     - Content: ……..……
     - Type of package: ……
   - Uses of the product:……..……
     ……
     ……
     ……

- **Composition**:

No.	Name(s) of Ingredients	Monograph Reference	Quantity	Function

5. Attachments:
   - Samples from the finished product.
   - Samples from the secondary packaging materials containing all the printed matter/or the packaging materials artwork.
   - Finished product specifications.
   - The original composition of the product signed by the manufacturer.
   - BSE certificate (where one of the ingredients is from biological origin).
   - Bank receipt to assure that registration fees were paid.

Name of Applicant	Signature	Date
……..	……	……

****

For office use only

- Application number: ……..….
- Name of a application receiver: ……
- Date of receipt: ……...
- Decision:

( ) Approved ( ) To be completed ( ) Rejected

Registration Number: …… Registration Date: .....

Appendix (3)

The required testing parameters for cosmetics

1.**Creams & Pastes:**

- Microbial load
- pH
- Stability (14 days in $40^{O}C$)
- Viscosity.
- Moisture (% H_2O)

2. Solutions:

- Microbial load.
- pH
- Stability (14 days in $40^{O}C$)
- Density.

3. Emulsions:

- Microbial load.
- pH
- Stability
- Density.

4. Pressed Powders:

- Microbial load.

5. Lipsticks:

- Microbial load.
- Break point.

6. Nail Polishes:

- Stability.
- Viscosity.

7. Aerosols:

- Microbial load.
- Hermetic sealing
- Content of propulsion gas

8. Shampoos:

- Microbial load.
- pH
- Stability.
- Viscosity.
- Detergent content.
- Nacl

9. Pencils:

- Microbial load.

10. Gels:

- Microbial load.
- pH
- Stability.
- Density.
- Viscosity.

11. Tooth Pastes:

- % of fluoride
- Total amount of lead
- Microbial load.

Appendix (4)

Changes and variations in registered cosmetic product.

1	**Change of product name**	
	Conditions	
	-	There is no change to the product (formulation, specifications, manufacturing source and process) except the product name change
	-	No confusion with another cosmetic product either when spoken or written;
	Documentation to be submitted	
	1)	Official letter from the manufacturer explaining the requested change .
	2)	A declaration from the applicant that there is no change to the product except name
	3)	The master formula and the finished product specification of the new proposed name.
	4)	Revised draft package insert and labeling incorporating the proposed variation;
2	**Addition of new pack size**	
	Conditions There is no change to the product (formulation, specifications, manufacturing source and process)	
	Documentations to be submitted	
	1)	Official letter from the manufacturer explaining the requested change
	2)	Packaging materials specifications for the new pack size
3	**Change in the master formula and finished product specifications**	
	Documentations to be submitted	
	1)	The new master formula of the product
	2)	The new finished product specifications
	3)	The new proposed labeling containing the ingredients of the new formula .
	4)	Samples from the product for analysis .
4	**Addition of new colour or fragrance.**	
	Condition	
	-	No change in other ingredients and product specifications .
	Documentations to be submitted	
	1)	The new formula
	2)	Packaging material and labeling of the product.
	3)	Samples from the changed product

Appendix (5)

Application Form: Renewal of the registration of cosmetic product

To: The Director of Drug Control and Registration Department
We hereby request that the registration of the following cosmetic product to be renewed.

- **Applicant information**:

- Applicant's Name (Responsible Technical Person):……....
- Manufacturer name and address:…….……
  ……
- Name and address of the importer (for imported cosmetic products only):
  ……..……
  ……

-Product information:

- Name of the cosmetic product: ……..……..
- Registration No:……
- License validity date:……..
- Dosage form : ……..
- Quantity (weight/volume) per pack: ……
- Primary packaging materials type:…….
- Purpose of re-registration:
- ( ) Manufacturing and marketing.
- ( ) Import and marketing.

Signature of the responsible technical person **Date**

……... **……..**

****

Attachments:

□ Original receipt confirming payment of re-registration fees.
□ Latest master formula of the product
□ Latest method(s) of analysis (when applicable)
□ The latest coloured artwork illustration of the packaging materials
□ The latest finished product specifications
□ Sufficient samples from finished products for analysis purposes.

****

For Office use only:

- Name of receiver:……
- Date of receiving ……..
- Remarks:……
  …

Signature: …… Date:……

Appendix (6)

Application Form: Amendments to the Registration of Cosmetic Products.

1. **Product information**:
   - Name of the product:……
   - Registration No.:……
   - Registration validity date:……..
   - Name of the local agent: ……..

2. **Type of change**:

□ Change in the name of product.
□ Addition of new pack size.
□ Change in the master formula or finished product specification
□ Addition of new colour or fragrance
□ Change in packaging materials(type, colour ,etc.)
□ Other change specify
……
……

3. **Attachments (please specify)**
   1- ……
   2- ……
   3- …….
   4- ……

.....

For office use only
- Date of receiving the application:
- Name of the receiver:
- Decision

( ) Approved ( ) rejected ( ) Others

****

Name: …….
Date: …….
Signature: ……

Appendix (7)

Number of Samples required for Registration and Renewal Purposes

No.	Product	Weight / Volume	No. of Samples
1	Liquids, Gels, Creams, Pastes	More than 30ml	Two samples
2	Liquids, Gels, Creams, Pastes	Less than 30ml	Five Samples
3	Aerosols	-	Two samples
4	Loose Powder, Compact Powder	-	Five Samples
5	Lipstick, Lip Liner, Eye Liner, Pencils, Mascara	-	Five Samples