

REGULATION PART D-5 COSMETIC: LISTING OF COSMETICS SPECIALTIES

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D-5.1.0 Republic Act 3720, otherwise known as the Food, Drug and Cosmetic Act, states, as amended by RA 7394, among other things, that the policy of the State is to ensure safe and good quality supply of cosmetic and to regulate the production, sale and traffic of same to protect the health of the people. For the proper Implementation of the above policy, and under authority of Section 26(a) of R.A. 3720, the following rules and regulations governing the listing and sale of cosmetic specialties Is promulgated In order to ensure the quality and safety of cosmetic supply in the country.

D-5.1.1 A cosmetic product without pre-market approval shall be distributed and sold only after having been officially listed with BFAD.

D-5.1.2A cosmetic is an article within the meaning of Section 10(h) of RA 3720 as amended by Article 4(u) of R.A 7394.

D-5.1.3 No cosmetic specialty shall be accepted for a listing from any applicant unless such applicant is a holder of a current permit issued by the BFAD to engage In the manufacture, importation, sale or distribution of such cosmetic specialty.

D-5.1.4 The application for listing of cosmetic specialty (without pre-market approval) manufactured locally shall be accompanied by the following requirements:

- a. Application letter from the manufacturer, importer or distributor
- b. Complete formulation of the finished product.
- c. Technical specifications of the finished product.
- d. One unattached label or specimen of the proposed label reflecting the ingredients used and other labelling materials.
- e. One commercial presentation of the finished product.
- f. Brand Name Clearance.
- g. Certificate of Agreement between manufacturer and distributor.

The application for listing of a foreign manufactured cosmetic specialty shall be accompanied by the requirements set forth on Section D-5.1.4, plus the following requirements:

- a. Approved Certificate of Registration or Free Sale Certificate from the country of origin or Its duly authenticated copy.
- b. Certificate of Agreement with the foreign firm.

D-5.1.5 The BFAD, upon receipt of application for listing the cosmetic specialty shall be evaluated In terms of:

- a. Completeness of documentary requirements.
- b. Absence of non permissible substances
- c. Compliance with the specific standards and labelling requirements for cosmetic products under M.C. 19-A, s. 1992

D-5.1.6 if the submitted application shows compliance with all the requirements, the cosmetic shall be deemed listed with the BFAD.

D.5.1.7 BFAD will Issue a Certificate of Product Listing (CPU within thirty (30) working days from the date of filing. This will be valid for one (1) year, and will entitle the product to be freely sold in the market thereafter. Listed cosmetics shall be given Cosmetic Listing Number (CL #) which will be reflected on the packaging label, within three (3) months from the issuance of CPL.

Any changes In the formulation of listed cosmetic product must be pre-cleared with the BFAD. Pre-clearance will be accompanied by the following documents:

- a. Letter from the manufacturer stating any changes In the formulation, packaging design, label text, etc.
- b. List of the new formulation of the product or copy of the packaging design or label text.
- c. Commercial presentation of the sample bearing the change.

D-5,1.8 The requirements for renewal of listing of special cosmetics:

- a. Application letter from the manufacturer, importer or distributor.
- b. Xerox copy of the current Certificate of Product Listing (CPL).
- c. One unattached label or specimen of the final label.
- d. One commercial presentation of the sample.

D-5.1.9 Initial List- The initial list of cosmetic specialty subject to listing Is hereto attached as Annex "A". Inclusion of other products and modification of this list may be done by BFAD through an appropriate Memorandum Circular upon recommendation by the BFAD Cosmetic Industry Group based on- the latest pertinent scientific data.

D-5.1.10 Applicants for Listing of Cosmetic Specialty are required to fully and truthfully disclose all pertinent Information and documentation regarding the product. Failure to fully disclose material Information about the product or misrepresentation thereof shall be ground for cancellation of BFAD Certificate of Product Listing and/or the impositions of other sanctions stated by existing law and regulations. Cosmetic products found to be misbranded or adulterated during monitoring shall be a ground for recall of the product from the market and cancellation of Certificate of Product Listing.

D-5.1.11 Separability Clause - If in case any provision of this Administrative Order is declared invalid, the remainder of the Circular shall continue to be enforced and In effect.

D-5.1.12 Repealing Clause - All administrative orders, rules and regulations and other administrative issuance or parts thereof inconsistent with the provisions of this regulations are hereby repealed or modified accordingly.

D-5.1.13 Effectivity - This regulation shall take effect fifteen (15) days after its publication in a newspaper of

general circulation.

Adopted: 18 May 1994

(Sgd) JUAN M. FLAVIER, M.D.,
M.P.H.

Secretary of Health

Annex "A"

Cosmetic Specialty Qualified for Listing (Without Pre Market Approval)

After Shave Lotions

Baby Lotions, Oils, Powders and Creams

Baby Shampoos

Bath Oils, Tablets and Salts

Beard Softeners

Blushers

Bubble Baths

Colognes and Toilet Waters

Cuticle Softeners

Dusting and Talcum Powders

Face Powders

Face Body and Hand Creams and Lotions

Foundations

Fragrance Products (Perfume)

Hair Conditioners

Leg and Body Paints

Lipsticks

Makeup Bases

Men's Talcum

Moisturizing Creams and Lotions

Nail Creams and Lotions

Nail Extenders

Nail Polish and Enamel Removers

Nail Polish and Enamels

Perfumes

Preshave Lotions

Rinses, Non-coloring

Rouges

Shampoos, Non-coloring

Shaving Creams

Skin Fresheners

Tonic, Dressings and Other Hair Grooming Aids

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