

§ 710.8

§ 710.8 Misbranding by reference to registration or to registration number.

Registration of a cosmetic product establishment or assignment of a registration number does not in any way denote approval of the firm or its products by the Food and Drug Administration. Any representation in labeling or advertising that creates an impression of official approval because of registration or possession of a registration number will be considered misleading.

§ 710.9 Exemptions.

The following classes of persons are not requested to register in accordance with this part 710 because the Commissioner has found that such registration is not justified:

(a) Beauty shops, cosmetologists, retailers, pharmacies, and other persons and organizations that compound cosmetic products at a single location and administer, dispense, or distribute them at retail from that location and who do not otherwise manufacture or package cosmetic products at that location.

(b) Physicians, hospitals, clinics, and public health agencies.

(c) Persons who manufacture, prepare, compound, or process cosmetic products solely for use in research, pilot plant production, teaching, or chemical analysis, and who do not sell these products.

PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT COMPOSITION STATEMENTS

Sec.

720.1 Who should file.

720.2 Times for filing.

720.3 How and where to file.

720.4 Information requested about cosmetic products.

720.5 [Reserved]

720.6 Amendments to statement.

720.7 Notification of person submitting cosmetic product ingredient statement.

720.8 Confidentiality of statements.

720.9 Misbranding by reference to filing or to statement number.

AUTHORITY: 21 U.S.C. 321, 331, 361, 362, 371, 374.

21 CFR Ch. I (4–1–12 Edition)

SOURCE: 39 FR 10060, Mar. 15, 1974, unless otherwise noted.

§ 720.1 Who should file.

Either the manufacturer, packer, or distributor of a cosmetic product is requested to file Form FDA 2512 (“Cosmetic Product Ingredient Statement”), whether or not the cosmetic product enters interstate commerce. This request extends to any foreign manufacturer, packer, or distributor of a cosmetic product exported for sale in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act. No filing fee is required.

[57 FR 3129, Jan. 28, 1992]

§ 720.2 Times for filing.

Within 180 days after forms are made available to the industry, Form FDA 2512 should be filed for each cosmetic product being commercially distributed as of the effective date of this part. Form FDA 2512 should be filed within 60 days after the beginning of commercial distribution of any product not covered within the 180-day period.

[57 FR 3129, Jan. 28, 1992]

§ 720.3 How and where to file.

Forms FDA 2512 and FDA 2514 (“Discontinuance of Commercial Distribution of Cosmetic Product Formulation”) are obtainable on request from the Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form should be mailed or delivered to: Cosmetic Product Statement, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, according to the instructions provided with the forms.

[57 FR 3129, Jan. 28, 1992, as amended at 68 FR 15355, Mar. 31, 2003]

§ 720.4 Information requested about cosmetic products.

(a) Form FDA–2512 requests information on:

(1) The name and address, including post office ZIP code of the person (manufacturer, packer, or distributor) designated on the label of the product.