

**§ 701.20**

**21 CFR Ch. I (4-1-10 Edition)**

to exaggerate the amount of the cosmetic contained in the package; for example, “giant pint” and “full quart.” Dual or combination declarations of net quantity of contents as provided for in paragraphs (a), (c), and (j) of this section (for example, a combination of net weight plus numerical count) are not regarded as supplemental net quantity statements and shall be located on the principal display panel.

(r) A separate statement of the net quantity of contents in terms of the metric system is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels.

(s) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

**Subpart C—Labeling of Specific Ingredients**

**§ 701.20 Detergent substances, other than soap, intended for use in cleansing the body.**

(a) In its definition of the term *cosmetic*, the Federal Food, Drug, and Cos-

metic Act specifically excludes soap. The term *soap* is nowhere defined in the act. In administering the act, the Food and Drug Administration interprets the term “soap” to apply only to articles that meet the following conditions:

(1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and

(2) The product is labeled, sold, and represented only as soap.

(b) Products intended for cleansing the human body and which are not “soap” as set out in paragraph (a) of this section are “cosmetics,” and accordingly they are subject to the requirements of the act and the regulations thereunder. For example, such a product in bar form is subject to the requirement, among others, that it shall bear a label containing an accurate statement of the weight of the bar in avoirdupois pounds and ounces, this statement to be prominently and conspicuously displayed so as to be likely to be read under the customary conditions of purchase and use.

**§ 701.30 Ingredient names established for cosmetic ingredient labeling.**

The Commissioner establishes the following names for the purpose of cosmetic ingredient labeling pursuant to paragraph (e) of § 701.3:

Chemical name or description	Chemical formula	Established label name
Trichlorofluoromethane .....	CCl <sub>3</sub> F .....	Chlorofluorocarbon 11.
Trichlorofluoromethane and 0.3 pct nitromethane .....	CCl <sub>3</sub> F+CH <sub>3</sub> NO <sub>2</sub> ..	Chlorofluorocarbon 11 S.
Dichlorodifluoromethane .....	CCl <sub>2</sub> F <sub>2</sub> .....	Chlorofluorocarbon 12.
Chlorodifluoromethane .....	CHClF <sub>2</sub> .....	Hydrochlorofluorocarbon 22.
1, 2-dichloro-1, 1, 2, 2-tetrafluoroethane .....	CClF <sub>2</sub> CClF <sub>2</sub> .....	Chlorofluorocarbon 114.
1-Chloro-1, 1-difluoroethane .....	CH <sub>3</sub> CClF <sub>2</sub> .....	Hydrochlorofluorocarbon 142 B.
1, 1-difluoroethane .....	CH <sub>3</sub> CHF <sub>2</sub> .....	Hydrofluorocarbon 152 A.
Ethyl ester of hydrolyzed animal protein is the ester of ethyl alcohol and the hydrolysate of collagen or other animal protein, derived by acid, enzyme, or other form of hydrolysis.	.....	Ethyl ester of hydrolyzed animal protein.

[42 FR 24255, May 13, 1977, as amended at 45 FR 3577, Jan. 18, 1980]

**PART 710—VOLUNTARY REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENTS**

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

SOURCE: 39 FR 10059, Mar. 15, 1974, unless otherwise noted.

**§ 710.1 Who should register.**

The owner or operator of a cosmetic product establishment which is not exempt under § 710.9 and engages in the manufacture or packaging of a cosmetic product is requested to register for each such establishment, whether or not the product enters interstate commerce. This request extends to any foreign cosmetic product establishment whose products are exported for sale in any State as defined in section 201(a)(1) of the act. No registration fee is required.

**§ 710.2 Time for registration.**

The owner or operator of an establishment entering into the manufacture or packaging of a cosmetic product should register his establishment within 30 days after the operation begins.

**§ 710.3 How and where to register.**

Form FD-2511 ("Registration of Cosmetic Product Establishment") is 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 to Cosmetic Product Establishment Registration, Food and Drug Administration, 5100

Paint Branch Pkwy., College Park, MD 20740.

[39 FR 10059, Mar. 15, 1974, as amended at 68 FR 15355, Mar. 31, 2003]

**§ 710.4 Information requested.**

Form FD-2511 requests information on the name and address of the cosmetic product establishment, including post office ZIP code; all business trading names used by the establishment; and the type of business (manufacturer and/or packer). The information requested should be given separately for each establishment as defined in § 700.3(j) of this chapter.

[39 FR 10059, Mar. 15, 1974, as amended at 46 FR 38073, July 24, 1981; 54 FR 39640, Sept. 27, 1989]

**§ 710.5 Amendments to registration.**

Within 30 days after a change in any of the information contained on a submitted Form FD-2511, a new Form FD-2511 should be submitted to amend the registration. This amendment is also necessary when a registration is to be canceled because an establishment has changed its name and no longer conducts business under the original name.

**§ 710.6 Notification of registrant; cosmetic product establishment registration number.**

The Commissioner of Food and Drugs will provide the registrant with a validated copy of Form FD-2511 as evidence of registration. This validated copy will be sent only to the location shown for the registering establishment. A permanent registration number will be assigned to each cosmetic product establishment registered in accordance with the regulations in this part.

**§ 710.7 Inspection of registrations.**

A copy of the Form FD-2511 filed by the registrant will be available for inspection at the Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

[39 FR 10059, Mar. 15, 1974, as amended at 68 FR 15355, Mar. 31, 2003]