

**§ 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, Department of Health and Human Services, Washington, DC 20204, 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, Department of Health and Human Services, Washington, DC 20204, according to the instructions provided with the forms.

[57 FR 3129, Jan. 28, 1992]

**§ 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.

(2) The name and address, including post office ZIP code, of the manufacturer or packer of the product if different from the person designated on the label of the product, when the manufacturer or packer submits the information requested under this paragraph.

(3) The brand name or names of the cosmetic product.

(4) The cosmetic product category or categories.

(5) The ingredients in the product.

(b) The person filing Form FDA-2512 should:

(1) Provide the information requested in paragraph (a) of this section.

(2) Have the form signed by an authorized individual.

(3) Provide poison control centers with ingredient information and/or

adequate diagnostic and therapeutic procedures to permit rapid evaluation and treatment of accidental ingestion or other accidental use of the cosmetic product.

(4) Provide ingredient information (and, when requested, ingredient samples) to a licensed physician who, in connection with the treatment of a patient, requests assistance in determining whether an ingredient in the cosmetic product is the cause of the problem for which the patient is being treated.

(c) One or more of the following cosmetic product categories should be cited to indicate the product's intended use.

(1) *Baby products.* (i) Baby shampoos.  
(ii) Lotions, oils, powders, and creams.

(iii) Other baby products.  
(2) *Bath preparations.* (i) Bath oils, tablets, and salts.

(ii) Bubble baths.  
(iii) Bath capsules.  
(iv) Other bath preparations.  
(3) *Eye makeup preparations.* (i) Eyebrow pencil.

(ii) Eyeliner.  
(iii) Eye shadow.  
(iv) Eye lotion.  
(v) Eye makeup remover.  
(vi) Mascara.

(vii) Other eye makeup preparations.  
(4) *Fragrance preparations.* (i) Colognes and toilet waters.

(ii) Perfumes.  
(iii) Powders (dusting and talcum) (excluding aftershave talc).  
(iv) Sachets.

(v) Other fragrance preparations.

(5) *Hair preparations (noncoloring).*

(i) Hair conditioners.

(ii) Hair sprays (aerosol fixatives).

(iii) Hair straighteners.

(iv) Permanent waves.

(v) Rinses (noncoloring).

(vi) Shampoos (noncoloring).

(vii) Tonics, dressings, and other hair

grooming aids.

(viii) Wave sets.

(ix) Other hair preparations.

(6) *Hair coloring preparations.* (i) Hair

dyes and colors (all types requiring caution statement and patch test).

(ii) Hair tints.

(iii) Hair rinses (coloring).

(iv) Hair shampoos (coloring).