

SUBCHAPTER G—COSMETICS

PART 700—GENERAL

Subpart A—General Provisions

Sec.

700.3 Definitions.

Subpart B—Requirements for Specific Cosmetic Products

700.11 Cosmetics containing bithionol.

700.13 Use of mercury compounds in cosmetics including use as skinbleaching agents in cosmetic preparations also regarded as drugs.

700.14 Use of vinyl chloride as an ingredient, including propellant of cosmetic aerosol products.

700.15 Use of certain halogenated salicylanilides as ingredients in cosmetic products.

700.16 Use of aerosol cosmetic products containing zirconium.

700.18 Use of chloroform as an ingredient in cosmetic products.

700.19 Use of methylene chloride as an ingredient of cosmetic products.

700.23 Chlorofluorocarbon propellants.

700.25 Tamper-resistant packaging requirements for cosmetic products.

700.27 Use of prohibited cattle materials in cosmetic products.

700.35 Cosmetics containing sunscreen ingredients.

AUTHORITY: 21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374.

SOURCE: 39 FR 10054, Mar. 15, 1974, unless otherwise noted.

Subpart A—General Provisions

§700.3 Definitions.

As used in this subchapter:

(a) The term *act* means the Federal Food, Drug, and Cosmetic Act.

(b) The term *cosmetic product* means a finished cosmetic the manufacture of which has been completed. Any cosmetic product which is also a drug or device or component thereof is also subject to the requirements of Chapter V of the act.

(c) The term *flavor* means any natural or synthetic substance or substances used solely to impart a taste to a cosmetic product.

(d) The term *fragrance* means any natural or synthetic substance or sub-

stances used solely to impart an odor to a cosmetic product.

(e) The term *ingredient* means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product.

(f) The term *proprietary ingredient* means any cosmetic product ingredient whose name, composition, or manufacturing process is protected from competition by secrecy, patent, or copyright.

(g) The term *chemical description* means a concise definition of the chemical composition using standard chemical nomenclature so that the chemical structure or structures of the components of the ingredient would be clear to a practicing chemist. When the composition cannot be described chemically, the substance shall be described in terms of its source and processing.

(h) The term *cosmetic raw material* means any ingredient, including an ingredient that is a mixture, which is used in the manufacture of a cosmetic product for commercial distribution and is supplied to a cosmetic product manufacturer, packer, or distributor by a cosmetic raw material manufacturer or supplier.

(i) The term *commercial distribution* of a cosmetic product means annual gross sales in excess of \$1,000 for that product.

(j) *Establishment* means a place of business where cosmetic products are manufactured or packaged.

(k) The term *manufacture* of a cosmetic product means the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.

(l) The term *packaging* of a cosmetic product means filling or labeling the product container, including changing the immediate container or label (but excluding changing other labeling) at any point in the distribution of the cosmetic product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(m) The term *all business trading names used by the establishment* means any name which is used on a cosmetic product label and owned by the cosmetic product manufacturer or packer, but is different from the principal name under which the cosmetic product manufacturer or packer is registered.

(n) The definitions and interpretations contained in sections 201, 601, and 602 of the act shall be applicable to such terms when used in the regulations in this subchapter.

(o) *System of commercial distribution* of a cosmetic product means any distribution outside the establishment manufacturing the product, whether for sale, to promote future sales (including free samples of the product), or to gage consumer acceptance through market testing, in excess of \$1,000 in cost of goods.

(p) *Filed screening procedure* means a procedure that is:

(1) On file with the Food and Drug Administration and subject to public inspection;

(2) Designed to determine that there is a reasonable basis for concluding that an alleged injury did not occur in conjunction with the use of the cosmetic product; and

(3) Which is subject, upon request by the Food and Drug Administration, to an audit conducted by the Food and Drug Administration at reasonable times and, where an audit is conducted, such audit shows that the procedure is consistently being applied and that the procedure is not disregarding reportable information.

(q) *Reportable experience* means an experience involving any allergic reaction, or other bodily injury, alleged to be the result of the use of a cosmetic product under the conditions of use prescribed in the labeling of the product, under such conditions of use as are customary or reasonably foreseeable for the product or under conditions of misuse, that has been reported to the manufacturer, packer, or distributor of the product by the affected person or any other person having factual knowledge of the incident, other than an alleged experience which has been determined to be unfounded or spurious

when evaluated by a filed screening procedure.

[39 FR 10054, Mar.15, 1974, as amended at 46 FR 38073, July 24, 1981]

Subpart B—Requirements for Specific Cosmetic Products

§ 700.11 Cosmetics containing bithionol.

(a) Bithionol has been used to some extent as an antibacterial agent in cosmetic preparations such as detergent bars, shampoos, creams, lotions, and bases used to hide blemishes. New evidence of clinical experience and photopatch tests indicate that bithionol is capable of causing photosensitivity in man when used topically and that in some instances the photosensitization may persist for prolonged periods as severe reactions without further contact with sensitizing articles. Also, there is evidence to indicate that bithionol may produce cross-sensitization with other commonly used chemicals such as certain halogenated salicylanilides and hexachlorophene. It is, therefore, the view of the Food and Drug Administration that bithionol is a deleterious substance which may render any cosmetic product that contains it injurious to users. Accordingly, any cosmetic containing bithionol is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(b) Regulatory proceedings may be initiated with respect to any cosmetic preparation containing bithionol shipped within the jurisdiction of the act after March 15, 1968.

§ 700.13 Use of mercury compounds in cosmetics including use as skinbleaching agents in cosmetic preparations also regarded as drugs.

(a) Mercury-containing cosmetic preparations have been represented for many years as skin-bleaching agents or as preparations to remove or prevent freckles and/or brown spots (so-called age spots). Preparations intended for such use are regarded as drugs as well as cosmetics. In addition to such use as skin-bleaching agents, mercury compounds have also been widely used as preservatives in cosmetics such as

hand and body creams and lotions; hair shampoos, hair sets and rinses, hair straighteners, hair coloring, and other preparations; bath oils, bubble bath, and other bath preparations; makeup; antiperspirants and deodorants; and eye-area cosmetics.

(b) The toxicity of mercury compounds is extensively documented in scientific literature. It is well known that mercury compounds are readily absorbed through the unbroken skin as well as through the lungs by inhalation and by intestinal absorption after ingestion. Mercury is absorbed from topical application and is accumulated in the body, giving rise to numerous adverse effects. Mercury is a potent allergen and sensitizer, and skin irritation is common after topical application. Cosmetic preparations containing mercury compounds are often applied with regularity and frequency for prolonged periods. Such chronic use of mercury-containing skin-bleaching preparations has resulted in the accumulation of mercury in the body and the occurrence of severe reactions. Recently it has also been determined that microorganisms in the environment can convert various forms of mercury into highly toxic methyl mercury which has been found in the food supply and is now considered to be a serious environmental problem.

(c) The effectiveness of mercury-containing preparations as skin-bleaching agents is questionable. The Food and Drug Administration has not been provided with well controlled studies to document the effectiveness of these preparations. Although mercurial preservatives are recognized as highly effective, less toxic and satisfactory substitutes are available except in the case of certain eye-area cosmetics.

(d) Because of the known hazards of mercury, its questionable efficacy as a skin-bleaching agent, and the availability of effective and less toxic nonmercurial preservatives, there is no justification for the use of mercury in skin-bleaching preparations or its use as a preservative in cosmetics, with the exception of eye-area cosmetics for which no other effective and safe nonmercurial preservative is available. The continued use of mercurial preservatives in such eye-area cosmetics

is warranted because mercury compounds are exceptionally effective in preventing *Pseudomonas* contamination of cosmetics and *Pseudomonas* infection of the eye can cause serious injury, including blindness. Therefore:

(1) The Food and Drug Administration withdraws the opinion expressed in trade correspondence TC-9 (issued May 13, 1939) and concludes that any product containing mercury as a skin-bleaching agent and offered for sale as skin-bleaching, beauty, or facial preparation is misbranded within the meaning of sections 502(a), 502(f)(1) and (2), and 502(j), and may be a new drug without approval in violation of section 505 of the Federal Food, Drug, and Cosmetic Act. Any such preparation shipped within the jurisdiction of the Act after January 5, 1973 will be the subject of regulatory action.

(2) The Food and Drug Administration withdraws the opinion expressed in trade correspondence TC-412 (issued Feb. 11, 1944) and will regard as adulterated within the meaning of section 601(a) of the Act any cosmetic containing mercury unless the cosmetic meets the conditions of paragraph (d)(2) (i) or (ii) of this section.

(i) It is a cosmetic containing no more than a trace amount of mercury and such trace amount is unavoidable under conditions of good manufacturing practice and is less than 1 part per million (0.0001 percent), calculated as the metal; or

(ii) It is a cosmetic intended for use only in the area of the eye, it contains no more than 65 parts per million (0.0065 percent) of mercury, calculated as the metal, as a preservative, and there is no effective and safe nonmercurial substitute preservative available for use in such cosmetic.

§ 700.14 Use of vinyl chloride as an ingredient, including propellant of cosmetic aerosol products.

(a) Vinyl chloride has been used as an ingredient in cosmetic aerosol products including hair sprays. Where such aerosol products are used in the confines of a small room, as is often the case, the level of vinyl chloride to which the

individual may be exposed could be significantly in excess of the safe level established in connection with occupational exposure. Evidence indicates that vinyl chloride inhalation can result in acute toxicity, manifested by dizziness, headache, disorientation, and unconsciousness where inhaled at high concentrations. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Furthermore, vinyl chloride has recently been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride. It is the view of the Commissioner that vinyl chloride is a deleterious substance which may render any cosmetic aerosol product that contains it as an ingredient injurious to users. Accordingly, any cosmetic aerosol product containing vinyl chloride as an ingredient is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(b) Any cosmetic aerosol product containing vinyl chloride as an ingredient shipped within the jurisdiction of the Act is subject to regulatory action.

[39 FR 30830, Aug. 26, 1974]

§ 700.15 Use of certain halogenated salicylanilides as ingredients in cosmetic products.

(a) Halogenated salicylanilides (tribromsalan (TBS, 3,4',5'-tribromosalicylanilide), dibromsalan (DBS, 4'5'-dibromosalicylanilide), metabromsalan (MBS, 3,5 - dibromosalicylanilide) and 3,3',4,5'-tetrachlorosalicylanilide (TCSA)) have been used as antimicrobial agents for a variety of purposes in cosmetic products. These halogenated salicylanilides are potent photosensitizers and cross-sensitizers and can cause disabling skin disorders. In some instances, the photosensitization may persist for prolonged periods as a severe reaction without further exposure to these chemicals. Safer alternative antimicrobial agents are available.

(b) These halogenated salicylanilides are deleterious substances which render any cosmetic that contains them injurious to users. Therefore, any cosmetic product that contains such a halogenated salicylanilide as an ingre-

redient at any level for any purpose is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(c) Any cosmetic product containing these halogenated salicylanilides as an ingredient that is initially introduced into interstate commerce after December 1, 1975, that is not in compliance with this section is subject to regulatory action.

[40 FR 50531, Oct. 30, 1975]

§ 700.16 Use of aerosol cosmetic products containing zirconium.

(a) Zirconium-containing complexes have been used as an ingredient in cosmetics and/or cosmetics that are also drugs, as, for example, aerosol antiperspirants. Evidence indicates that certain zirconium compounds have caused human skin granulomas and toxic effects in the lungs and other organs of experimental animals. When used in aerosol form, some zirconium will reach the deep portions of the lungs of users. The lung is an organ, like skin, subject to the development of granulomas. Unlike the skin, the lung will not reveal the presence of granulomatous changes until they have become advanced and, in some cases, permanent. It is the view of the Commissioner that zirconium is a deleterious substance that may render any cosmetic aerosol product that contains it injurious to users.

(b) Any aerosol cosmetic product containing zirconium is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(c) Any such cosmetic product introduced in interstate commerce after September 15, 1977 is subject to regulatory action.

[42 FR 41376, Aug. 16, 1977]

§ 700.18 Use of chloroform as an ingredient in cosmetic products.

(a) Chloroform has been used as an ingredient in cosmetic products. Recent information has become available associating chloroform with carcinogenic effects in animals. Studies conducted by the National Cancer Institute have demonstrated that the oral administration of chloroform to mice

§ 700.19

and rats induced hepatocellular carcinomas (liver cancer) in mice and renal tumors in male rats. Scientific literature indicates that chloroform is absorbed from the gastrointestinal tract, through the respiratory system, and through the skin. The Commissioner concludes that, on the basis of these findings, chloroform is a deleterious substance which may render injurious to users any cosmetic product that contains chloroform as an ingredient.

(b) Any cosmetic product containing chloroform as an ingredient is adulterated and is subject to regulatory action under sections 301 and 601(a) of the Federal Food, Drug, and Cosmetic Act. Any cosmetic product containing chloroform in residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient, is not, for the purpose of this section, considered to contain chloroform as an ingredient.

[41 FR 26845, June 29, 1976]

§ 700.19 Use of methylene chloride as an ingredient of cosmetic products.

(a) Methylene chloride has been used as an ingredient of aerosol cosmetic products, principally hair sprays, at concentrations generally ranging from 10 to 25 percent. In a 2-year animal inhalation study sponsored by the National Toxicology Program, methylene chloride produced a significant increase in benign and malignant tumors of the lung and liver of male and female mice. Based on these findings and on estimates of human exposure from the customary use of hair sprays, the Food and Drug Administration concludes that the use of methylene chloride in cosmetic products poses a significant cancer risk to consumers, and that the use of this ingredient in cosmetic products may render these products injurious to health.

(b) Any cosmetic product that contains methylene chloride as an ingredient is deemed adulterated and is subject to regulatory action under sections 301 and 601(a) of the Federal Food, Drug, and Cosmetic Act.

[54 FR 27342, June 29, 1989]

21 CFR Ch. I (4–1–10 Edition)

§ 700.23 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in cosmetics as propellants in self-preserved containers is prohibited as provided in § 2.125 of this chapter.

[43 FR 11317, Mar. 17, 1978]

§ 700.25 Tamper-resistant packaging requirements for cosmetic products.

(a) *General.* Because most cosmetic liquid oral hygiene products and vaginal products are not now packaged in tamper-resistant retail packages, there is the opportunity for the malicious adulteration of those cosmetic products with health risks to individuals who unknowingly purchase adulterated products and with loss of consumer confidence in the security of cosmetic product packages. The Food and Drug Administration has the authority and responsibility under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national requirement for tamper-resistant packaging of cosmetic liquid oral hygiene products or products used vaginally that will improve the packaging security and help assure the safety of those products. Such a cosmetic product for retail sale that is not packaged in a tamper-resistant package or that is not properly labeled under this section is adulterated under section 601 of the act or misbranded under section 602 of the act, or both.

(b) *Requirement for tamper-resistant package.* Each manufacturer and packer who packages a cosmetic liquid oral hygiene product or vaginal product for retail sale shall package the product in a tamper-resistant package, if this product is accessible to the public while held for sale. A tamper-resistant package is one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design (e.g., an aerosol product container) or by the use of an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of

this section, the term “distinctive by design” means the packaging cannot be duplicated with commonly available materials or through commonly available processes. For purposes of this section, the term “aerosol product” means a product which depends upon the power of a liquified or compressed gas to expel the contents from the container. A tamper-resistant package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(c) *Labeling.* Each retail package of a cosmetic product covered by this section, except aerosol products as defined in paragraph (b) of this section, is required to bear a statement that is prominently placed so that consumers are alerted to the specific tamper-resistant feature of the package. The labeling statement is also required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-resistant feature chosen to meet the requirement in paragraph (b) of this section is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say “For your protection, this bottle has an imprinted seal around the neck.”

(d) *Requests for exemptions from packaging and labeling requirements.* A manufacturer or packer may request an exemption from the packaging and labeling requirements of this section. A request for an exemption is required to be submitted in the form of a citizen petition under §10.30 of this chapter and should be clearly identified on the envelope as a “Request for Exemption from Tamper-resistant Rule.” The petition is required to contain the following:

- (1) The name of the product.
- (2) The reasons that the product’s compliance with the tamper-resistant packaging or labeling requirements of

this section is unnecessary or cannot be achieved.

(3) A description of alternative steps that are available, or that the petitioner has already taken, to reduce the likelihood that the product will be the subject of malicious adulteration.

(4) Other information justifying an exemption.

This information collection requirement has been approved by the Office of Management and Budget under number 0910-0149.

(e) *Effective date.* Cosmetic products covered by this section are required to comply with the requirements of this section on the dates listed below except to the extent that a product’s manufacturer or packer has obtained an exemption from a packaging or labeling requirement.

(1) *Initial effective date for packaging requirements.* (i) The packaging requirement in paragraph (b) of this section is effective on February 7, 1983 for each affected cosmetic product (except vaginal tablets) packaged for retail sale on or after that date, except for the requirement in paragraph (b) of this section for a distinctive indicator or barrier to entry.

(ii) The packaging requirement in paragraph (b) of this section is effective on May 5, 1983 for each cosmetic product that is a vaginal tablet packaged for retail sale on or after that date.

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each affected cosmetic product packaged for retail sale on or after that date, except that the requirement for a specific label reference to any identifying characteristic is effective on February 6, 1984 for each affected cosmetic product packaged for retail sale on or after that date.

(3) *Retail level effective date.* The tamper-resistant packaging requirement of paragraph (b) of this section is effective February 6, 1984 for each affected cosmetic product held for sale on or after that date that was packaged for retail sale before May 5, 1983. This does

§ 700.27

21 CFR Ch. I (4–1–10 Edition)

not include the requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design. Products packaged for retail sale after May 5, 1983, as required to be in compliance with all aspects of the regulations without regard to the retail level effective date.

[47 FR 50451, Nov. 5, 1982; 48 FR 1707, Jan. 14, 1983; 48 FR 11427, Mar. 18, 1983, as amended at 48 FR 16664, Apr. 19, 1983; 48 FR 37624, Aug. 19, 1983]

EFFECTIVE DATE NOTE: See 48 FR 41579, Sept. 16, 1983, for a document announcing an interim stay of the effective date of certain provisions in paragraph (e)(3) of § 700.25.

§ 700.27 Use of prohibited cattle materials in cosmetic products.

(a) *Definitions.* The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) apply to such terms when used in this part. The following definitions also apply:

(1) Prohibited cattle materials means specified risk materials, small intestine of all cattle except as provided in paragraph (b)(2) of this section, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated (MS) (Beef). Prohibited cattle materials do not include the following:

(i) Tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, hides and hide-derived products, and milk and milk products, and

(ii) Cattle materials inspected and passed from a country designated under paragraph (e) of this section.

(2) *Inspected and passed* means that the product has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time it was inspected and passed, it was found to be not adulterated.

(3) *Mechanically Separated (MS)(Beef)* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses that meet the specifications contained in 9 CFR 319.5, the regulation that prescribes the standard of identity for MS (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(5) *Specified risk material* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain not more than 0.15 percent insoluble impurities as determined by the method entitled “Insoluble Impurities” (AOCS Official Method Ca 3a-46), American Oil Chemists’ Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a-46. You may obtain copies of the method from the AOCS (<http://www.aocs.org>) 2211 W. Bradley Ave. Champaign, IL 61821. Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or transesterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or transesterification may be applied to obtain the desired product.

(b) *Requirements.* (1) No cosmetic shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials.

(2) The small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine, as measured from the caeco-colic junction and progressing proximally towards the jejunum, or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

(c) *Records.* (1) Manufacturers and processors of a cosmetic that is manufactured from, processed with, or otherwise contains, material from cattle must establish and maintain records sufficient to demonstrate that the cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials.

(2) Records must be retained for 2 years after the date they were created.

(3) Records must be retained at the manufacturing or processing establishment or at a reasonably accessible location.

(4) The maintenance of electronic records is acceptable. Electronic records are considered to be reasonably accessible if they are accessible from an onsite location.

(5) Records required by this section and existing records relevant to compliance with this section must be available to FDA for inspection and copying.

(6) When filing entry with U.S. Customs and Border Protection, the importer of record of a cosmetic manufactured from, processed with, or otherwise containing, cattle material must affirm that the cosmetic was manufactured from, processed with, or otherwise contains, cattle material and must affirm that the cosmetic was manufactured in accordance with this section. If a cosmetic is manufactured from, processed with, or otherwise contains, cattle material, then the importer of record must, if requested, provide within 5 days records sufficient to demonstrate that the cosmetic is not manufactured from, processed with, or

does not otherwise contain, prohibited cattle material.

(7) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in §11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

(d) *Adulteration.* Failure of a manufacturer or processor to operate in compliance with the requirements of paragraph (b) or (c) of this section renders a cosmetic adulterated under section 601(c) of the act.

(e) *Process for designating countries.* A country seeking designation must send a written request to the Director, Office of the Center Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, at the address designated in 21 CFR 5.1100. The request shall include information about a country's bovine spongiform encephalopathy (BSE) case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether specified risk materials, the small intestine of cattle except as provided in paragraph (b)(2) of this section, material from non-ambulatory disabled cattle, or MS (Beef) from cattle from the country should be considered prohibited cattle materials. FDA shall respond in writing to any such request and may impose conditions in granting any such request. A country designation granted by FDA under this paragraph will be subject to future review by FDA, and may be revoked if FDA determines that it is no longer appropriate.

[70 FR 53068, Sept. 7, 2005, as amended at 71 FR 59668, Oct. 11, 2006; 73 FR 20794, Apr. 17, 2008]

§ 700.35 Cosmetics containing sunscreen ingredients.

(a) A product that includes the term "sunscreen" in its labeling or in any other way represents or suggests that it is intended to prevent, cure, treat, or mitigate disease or to affect a structure or function of the body comes

within the definition of a drug in section 201(g)(1) of the act. Sunscreen active ingredients affect the structure or function of the body by absorbing, reflecting, or scattering the harmful, burning rays of the sun, thereby altering the normal physiological response to solar radiation. These ingredients also help to prevent diseases such as sunburn and may reduce the chance of premature skin aging, skin cancer, and other harmful effects due to the sun when used in conjunction with limiting sun exposure and wearing protective clothing. When consumers see the term “sunscreen” or similar sun protection terminology in the labeling of a product, they expect the product to protect them in some way from the harmful effects of the sun, irrespective of other labeling statements. Consequently, the use of the term “sunscreen” or similar sun protection terminology in a product’s labeling generally causes the product to be subject to regulation as a drug. However, sunscreen ingredients may also be used in some products for nontherapeutic, nonphysiologic uses (e.g., as a color additive or to protect the color of the product). To avoid consumer misunderstanding, if a cosmetic product contains a sunscreen ingredient and uses the term “sunscreen” or similar sun protection terminology anywhere in its labeling, the term must be qualified by describing the cosmetic benefit provided by the sunscreen ingredient.

(b) The qualifying information required under paragraph (a) of this section shall appear prominently and conspicuously at least once in the labeling in conjunction with the term “sunscreen” or other similar sun protection terminology used in the labeling. For example: “Contains a sunscreen—to protect product color.”

[64 FR 27693, May 21, 1999]

PART 701—COSMETIC LABELING

Subpart A—General Provisions

Sec.

- 701.1 Misbranding.
- 701.2 Form of stating labeling requirements.
- 701.3 Designation of ingredients.
- 701.9 Exemptions from labeling requirements.

Subpart B—Package Form

- 701.10 Principal display panel.
- 701.11 Identity labeling.
- 701.12 Name and place of business of manufacturer, packer, or distributor.
- 701.13 Declaration of net quantity of contents.

Subpart C—Labeling of Specific Ingredients

- 701.20 Detergent substances, other than soap, intended for use in cleansing the body.
- 701.30 Ingredient names established for cosmetic ingredient labeling.

AUTHORITY: 21 U.S.C. 321, 352, 361, 362, 363, 371, 374; 15 U.S.C. 1454, 1455.

SOURCE: 39 FR 10056, Mar. 15, 1974, unless otherwise noted.

Subpart A—General Provisions

§ 701.1 Misbranding.

(a) Among representations in labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug, or device.

(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

§ 701.2 Form of stating labeling requirements.

(a) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by section 602(c) of the Act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space

therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device;

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b)(1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

§ 701.3 Designation of ingredients.

(a) The label on each package of a cosmetic shall bear a declaration of the

name of each ingredient in descending order of predominance, except that fragrance or flavor may be listed as fragrance or flavor. An ingredient which is both fragrance and flavor shall be designated by each of the functions it performs unless such ingredient is identified by name. No ingredient may be designated as fragrance or flavor unless it is within the meaning of such term as commonly understood by consumers. Where one or more ingredients is accepted by the Food and Drug Administration as exempt from public disclosure pursuant to the procedure established in § 720.8(a) of this chapter, in lieu of label declaration of identity the phrase "and other ingredients" may be used at the end of the ingredient declaration.

(b) The declaration of ingredients shall appear with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The declaration shall appear on any appropriate information panel in letters not less than $\frac{1}{16}$ of an inch in height and without obscuring design, vignettes, or crowding. In the absence of sufficient space for such declaration on the package, or where the manufacturer or distributor wishes to use a decorative container, the declaration may appear on a firmly affixed tag, tape, or card. In those cases where there is insufficient space for such declaration on the package, and it is not practical to firmly affix a tag, tape, or card, the Commissioner may establish by regulation an acceptable alternate, e.g., a smaller type size. A petition requesting such a regulation as an amendment to this paragraph shall be submitted pursuant to part 10 of this chapter.

(c) A cosmetic ingredient shall be identified in the declaration of ingredients by:

(1) The name specified in § 701.30 as established by the Commissioner for that ingredient for the purpose of cosmetic ingredient labeling pursuant to paragraph (e) of this section;

(2) In the absence of the name specified in § 701.30, the name adopted for that ingredient in the following editions and supplements of the following

§701.3

21 CFR Ch. I (4–1–10 Edition)

compendia, listed in order as the source to be utilized:

(i) CTFA (Cosmetic, Toiletry and Fragrance Association, Inc.) Cosmetic Ingredient Dictionary, Second Ed., 1977 (available from the Cosmetic, Toiletry and Fragrance Association, Inc. 1110 Vermont Ave. NW., Suite 800, Washington, DC 20005, or at the National Archives and Records Administration (NARA), which is incorporated by reference, except for the following deletions and revisions. (For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.)

(a) The following names are not adopted for the purpose of cosmetic ingredient labeling:

Acid Black 58
Acid Black 107
Acid Black 139
Acid Blue 168
Acid Blue 170
Acid Blue 188
Acid Blue 209
Acid Brown 19
Acid Brown 30
Acid Brown 44
Acid Brown 45
Acid Brown 46
Acid Brown 48
Acid Brown 224
Acid Orange 80
Acid Orange 85
Acid Orange 86
Acid Orange 88
Acid Orange 89
Acid Orange 116
Acid Red 131
Acid Red 213
Acid Red 252
Acid Red 259
Acid Violet 73
Acid Violet 76
Acid Violet 99
Acid Yellow 114
Acid Yellow 127
Direct Yellow 81
Solvent Black 5
Solvent Brown 43
Solvent Yellow 63
Solvent Yellow 90

(b) The following names are adopted for the purpose of cosmetic ingredient labeling, provided the respective monographs are revised to describe their otherwise disclosed chemical compositions, or describe their chemical compositions more precisely, and such re-

vised monographs are published in supplements to this dictionary edition by July 18, 1980.

Acid Black 2
Benzophenone-11
Carbomer 934
Carbomer 934P
Carbomer 940
Carbomer 941
Carbomer 960
Carbomer 961
Chlorofluorocarbon 11S
Dimethicone Copolyol
Disperse Red 17
Pigment Green 7
Polyamino Sugar Condensate
SD Alcohol (all 27 alphanumeric designations)
Sodium Chondroitin Sulfate
Synthetic Beeswax

(c) The following names are adopted for the purpose of cosmetic ingredient labeling until January 19, 1981.

Amphoteric (all 20 numeric designations)
Quaternium (all 49 numeric designations)

(ii) United States Pharmacopeia, 19th Ed., 1975, and Second Supplement to the USP XIX and NF XIV, 1976. (Copies are available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.)

(iii) National Formulary, 14th Ed., 1975, and Second Supplement to the USP XIX and NF XIV, 1976. (Copies are available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.)

(iv) Food Chemicals Codex, 2d Ed., 1972; First Supplement, 1974, and Second Supplement, 1975, which are incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at

the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(v) USAN and the USP dictionary of drug names, USAN 1975, 1961-1975 cumulative list. (Copies are available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.)

(3) In the absence of such a listing, the name generally recognized by consumers.

(4) In the absence of any of the above, the chemical or other technical name or description.

(d) Where a cosmetic product is also an over-the-counter drug product, the declaration shall declare the active drug ingredients as set forth in § 201.66(c)(2) and (d) of this chapter, and the declaration shall declare the cosmetic ingredients as set forth in § 201.66(c)(8) and (d) of this chapter.

(e) Interested persons may submit a petition requesting the establishment of a specific name for a cosmetic ingredient pursuant to part 10 of this chapter. The Commissioner may also propose such a name on his own initiative.

(f) As an alternative to listing all ingredients in descending order of predominance, ingredients may be grouped and the groups listed in the following manner and order:

(1) Ingredients, other than color additives, present at a concentration greater than 1 percent, in descending order of predominance; followed by

(2) Ingredients, other than color additives, present at a concentration of not more than 1 percent, without respect to order of predominance; followed by

(3) Color additives, without respect to order of predominance. Ingredients specified in paragraph (f)(2) of this section may be included with those specified in paragraph (f)(1) of this section

and listed in descending order of predominance.

(g) A declaration of ingredients may include an ingredient not in the product if the ingredient is identified by the phrase "may contain" and:

(1) It is a color additive added to some batches of the product for purposes of color matching; or

(2)(i) The same declaration of ingredients is also used for other products similar in composition and intended for the same use, including products which may be assortments of products similar in composition and intended for the same use; and

(ii) Such products are "shaded" products, i.e., those falling within the product categories identified in § 720.4 (c)(3), (7) and (8)(v) of this chapter; and

(iii) All products sharing the common declaration of ingredients are sold by the labeler under a common trade name or brand designation, and no trade name or brand designation not common to all such products appears in the labeling of any of them; and

(iv) The ingredient is a color additive.

(h) As an alternative to a declaration of color additive ingredients for each product, the color additives of an assortment of cosmetic products that are sold together in the same package may be declared in a single composite list in a manner that is not misleading and that indicates that the list pertains to all the products.

(i) As an alternative to the declaration of ingredients specified in paragraph (b) of this section, the declaration of ingredients may appear in letters not less than $\frac{1}{16}$ of an inch in height in labeling accompanying the product, as for example, on padded sheets or in leaflets, if the total surface area of the package is less than 12 square inches. This paragraph is inapplicable to any packaged cosmetic product enclosed in an outer container, e.g., a folding carton. In addition, this paragraph is applicable only to cosmetic products meeting one of the following requirements:

(1) The cosmetic products are held and displayed for sale in tightly compartmented trays or racks of a display unit. The holder of the labeling bearing

§701.3

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

the declaration of ingredients shall be attached to the display unit; or

(2) The cosmetic products are “shaded” products, i.e., those falling within the product categories identified in §720.4 (c)(3), (7) and (8)(v) of this chapter, and are held for sale in tightly compartmented trays or racks. The holder of the labeling bearing the declaration of ingredients shall be attached to a display chart bearing samples of the product shades, which is displayed to purchasers. Such a display chart shall be of such construction and design as to permit its continuous use as a display, such as on a counter, and shall be designed for the primary purpose of displaying samples of the shades of the products.

(j) The holder of labeling bearing a declaration of ingredients and used in accordance with paragraph (i) of this section shall be attached to the display unit or chart and shall meet one of the following conditions:

(1) The labeling is on the front of the display unit or chart and can be read in full by a purchaser facing the display unit or chart under customary conditions of retail sale; or

(2) The labeling is on the front of the display unit or chart, is partially visible, and is accompanied by a conspicuous notice on the front of the display unit or chart describing the location of such labeling in letters not less than $\frac{3}{16}$ of an inch in height, e.g., “Ingredient lists above”, that can be read by a purchaser facing the display unit or chart under customary conditions of retail sale, or by the notice required by provisions in paragraph (k)(3) of this section, if conspicuous at all times; or

(3) The labeling is on a side of the display unit or chart, but not on the top, back, or bottom, and is accompanied by a conspicuous notice on the front of the display unit or chart describing the location of such labeling in letters not less than $\frac{3}{16}$ of an inch in height, e.g., “Ingredient lists located on right side of display”, that can be read by a purchaser facing the display unit or chart under customary conditions of retail sale.

(k) Any use of a display unit or chart bearing labeling under the provisions of paragraph (i) of this section shall meet the following requirements:

(1) All articles of labeling bearing ingredient declarations and used in conjunction with any one display unit or chart shall be identical and shall declare the ingredients of all products sold in conjunction with the display unit or chart for which the ingredient declaration is made pursuant to paragraph (i) of this section.

(2) Any display unit or chart intended for such use shall be shipped together with the labeling intended to be attached to it.

(3) Every display unit or chart and/or labeling system shall be designed so that the words “Federal law requires ingredient lists to be displayed here” in letters not less than $\frac{3}{16}$ of an inch in height (i) become conspicuous when no ingredient declarations are displayed and when the last list has been taken, or (ii) are conspicuous at all times adjacent to the place where ingredient declarations are to be attached.

(4) Any labeling containing a declaration of ingredients which reflects a formulation change and not shipped accompanying a display unit or chart shall be dated. Whenever any formulation change is made, and the labeling containing the declaration of ingredients is thereby required to be used in conjunction with products of both the old and new formulations, the labeling shall declare the ingredients of both the old and new formulations separately in a way that is not misleading and in a way that permits the purchaser to identify the ingredient declaration applicable to each package, or which clearly advises the purchaser that the formulation has been changed and that either declaration may be applicable.

(5) Sufficient copies of the declaration of ingredients shall be provided with each shipment of a cosmetic so that a purchaser may obtain a copy of the declaration with each purchase. Display units and replacement labeling for display units shall be accompanied by instructions to the retailer, which when followed will result in compliance with the requirements of this section. Copies of the declaration accompanying refills shall be attached to the specific refill items to which they pertain, or shall be packed with the specific refill items to which they pertain,

in a container that does not contain other cosmetic products.

(6) The firm whose name appears on a product pursuant to § 701.12 shall promptly mail a copy of the declaration of ingredients to any person requesting it.

(7) The display unit or chart shall be designed and located such that the labeling is easily accessible to a purchaser facing the display unit or chart under customary conditions of retail sale.

(1) The provisions of this section do not require the declaration of incidental ingredients that are present in a cosmetic at insignificant levels and that have no technical or functional effect in the cosmetic. For the purpose of this paragraph, incidental ingredients are:

(1) Substances that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient.

(2) Processing aids, which are as follows:

(i) Substances that are added to a cosmetic during the processing of such cosmetic but are removed from the cosmetic in accordance with good manufacturing practices before it is packaged in its finished form.

(ii) Substances that are added to a cosmetic during processing for their technical or functional effect in the processing, are converted to substances the same as constituents of declared ingredients, and do not significantly increase the concentration of those constituents.

(iii) Substances that are added to a cosmetic during the processing of such cosmetic for their technical and functional effect in the processing but are present in the finished cosmetic at insignificant levels and do not have any technical or functional effect in that cosmetic.

(m) In the event that there is a current or anticipated shortage of a cosmetic ingredient, the declaration required by this section may specify alternatives to any ingredients that may be affected. An alternative ingredient shall be declared either (1) immediately following the normally used in-

redient for which it substitutes, in which case it shall be identified as an alternative ingredient by the word "or" following the name of the normally used ingredient and any other alternative ingredient, or (2) following the declaration of all normally used ingredients, in which case the alternative ingredients in the group so listed shall be listed in expected descending order of predominance or in accordance with the provisions of paragraph (f) of this section and shall be identified as alternative ingredients by the phrase "may also contain". This paragraph is inapplicable to any ingredient mentioned in advertising, or in labeling other than in the declaration of ingredients required by this section.

(n) In the event that the shortage of a cosmetic ingredient necessitates a formulation change, packages bearing labels declaring the ingredients of the old formulation may be used if the revised ingredient declaration appears (1) on a firmly affixed tag, tape, card, or sticker or similar overlabeling attached to the package and bearing the conspicuous words "new ingredient list" in letters not less than $\frac{1}{16}$ of an inch in height, or (2) on labeling inside an unsealed package and the package bears the conspicuous words, on a sticker or similar overlabeling, "new ingredient list inside" in letters not less than $\frac{1}{16}$ of an inch in height.

(o) The ingredients of products that are similar in composition and intended for the same use may be declared as follows:

(1) The declaration of ingredients for an assortment of such products that are sold together in the same package, e.g., eyeshadows of different colors, may declare the ingredients that are common to all the products, in a single list in their cumulative order of predominance or in accordance with the provisions of paragraph (f) of this section, together with a statement, in terms that are as informative as practicable and that are not misleading, declaring the other ingredients and identifying the products in which they are present. The color additive ingredients of all the products in such an assortment, whether or not common to all

§ 701.3

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

the products, may be declared in a single composite list following the declaration of the other ingredients without identifying the products in which they are present.

(2) The ingredients of an assortment of such products that are sold together in the same package, e.g., eyeshadows of different colors, may be declared in a single list in their cumulative order of predominance or in accordance with the provisions of paragraph (f) of this section, if the package is designed such that it has a total surface area available to bear labeling of less than 12 square inches. For the purpose of this paragraph, surface area is not available for labeling if physical characteristics of the package surface, e.g., decorative relief, make application of a label impractical.

(3) The declaration of ingredients for such a product that is individually packaged and bears a label that is shared with other products pursuant to the provisions of paragraph (g)(2) of this section, e.g., one lipstick in a line of lipsticks, may declare the ingredients that are common to all such products, in a single list in their cumulative order of predominance or in accordance with the provisions of paragraph (f) of this section, together with a statement, in terms that are as informative as practicable and that are not misleading, declaring the other ingredients in such products, and identifying the products in which they are present. The color additive ingredients shall be declared in accordance with the provisions of paragraph (g) of this section.

(4) The declaration of ingredients for an assortment of such cosmetic products that bears a label that is shared with other products pursuant to the provisions of paragraph (g)(2) of this section, e.g., one of several compacts in a line of compacts, may declare the ingredients that are common to all such products, in a single list in their cumulative order of predominance or in accordance with the provisions of paragraph (f) of this section, together with a statement, in terms that are as informative as practicable and that are not misleading, declaring the other ingredients in such products and identifying the products in which they are

present. The color additive ingredients shall be declared in accordance with the provisions of paragraph (g) of this section.

(p) As an alternative to the declaration of ingredients in letters not less than $\frac{1}{16}$ of an inch in height, letters may be not less than $\frac{1}{32}$ of an inch in height if the package is designed such that it has a total surface area available to bear labeling of less than 12 square inches. For the purpose of this paragraph, surface area is not available for labeling if physical characteristics of the package surface, e.g., decorative relief, make application of a label impractical.

(q) The inside containers in a multiunit or multicomponent retail cosmetic package are not required to bear a declaration of ingredients when the labeling of the multiunit or multicomponent retail cosmetic package meets all the requirements of this section and the inside containers are not intended to be, and are not customarily, separated from the retail package for retail sale.

(r) In the case of cosmetics distributed to the consumers by direct mail, as an alternative to the declaration of ingredients on an information panel, the declaration of ingredients may appear in letters not less than $\frac{1}{16}$ of an inch in height in labeling that accompanies and specifically relates to the cosmetic(s) mailed, or in labeling furnished to each consumer for his personal use and from which he orders cosmetics through the mail, e.g., a direct mail sales catalog or brochure, provided all of the following additional requirements are met:

(1) The declarations of ingredients are conspicuous and presented in a way that permits the consumer to identify the declaration of ingredients applicable to each cosmetic.

(2) The package mailed to the consumer is accompanied by a notice located on, or affixed to, the top of the package or on top of the contents inside the package, or on the face of the package platform surrounding and holding the product(s), readily visible to the consumer on opening of the package, and provides the following information in letters not less than $\frac{3}{16}$ of an inch in height:

(i) The location of the declarations of ingredients, e.g., in an accompanying brochure, or in a sales catalog used for ordering;

(ii) A statement that a copy of the declaration of ingredients will be mailed promptly to any person requesting it; and

(iii) The name and place of business of the mail order distributor.

(3) The mail order distributor promptly mails a copy of the declaration of ingredients to any person requesting it.

[39 FR 10056, Mar. 15, 1974, as amended at 40 FR 8922, Mar. 3, 1975; 40 FR 18426, Apr. 28, 1975; 42 FR 4718, Jan. 25, 1977; 42 FR 15676, Mar. 22, 1977; 42 FR 24255, May 31, 1977; 42 FR 46516, Sept. 16, 1977; 42 FR 61257, Dec. 2, 1977; 45 FR 3577, Jan. 18, 1980; 47 FR 9397, Mar. 5, 1982; 54 FR 24900, June 12, 1989; 64 FR 13297, Mar. 17, 1999; 69 FR 18803, Apr. 9, 2004]

§ 701.9 Exemptions from labeling requirements.

(a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a cosmetic which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of sections 601(a) and 602(b) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such cosmetic is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such cosmetic in such establishment as will insure, if such specifications are followed, that such cosmetic will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each

keep a copy of such agreement until 2 years after the final shipment or delivery of such cosmetic from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(b) An exemption of a shipment or other delivery of a cosmetic under paragraph (a)(1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(c) An exemption of a shipment or other delivery of a cosmetic under paragraph (a)(2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(d) An exemption of a shipment or other delivery of a cosmetic under paragraph (a)(2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(2) Upon refusal by the operator of the establishment where such cosmetic is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

Subpart B—Package Form

§ 701.10 Principal display panel.

The term *principal display panel* as it applies to cosmetics in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon

§701.11

by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents of all packages of substantially the same size, the term "area of the principal display panel" means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference; and

(c) In the case of any other shape of container, 40 percent of the total surface of the container: *Provided, however*, That where such container presents an obvious "principal display panel" such as the top of a triangular or circular package, the area shall consist of the entire top surface.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

§701.11 Identity labeling.

(a) The principal display panel of a cosmetic in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The common or usual name of the cosmetic; or

(2) An appropriately descriptive name or, when the nature of the cosmetic is obvious, a fanciful name understood by the public to identify such cosmetic; or

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

(3) An appropriate illustration or vignette representing the intended cosmetic use.

(c) The statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

§701.12 Name and place of business of manufacturer, packer, or distributor.

(a) The label of a cosmetic in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied in the case of a corporation only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for "Company," "Incorporated," etc., may be used and "The" may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) Where the cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such cosmetic; such as, "Manufactured for _____", "Distributed by _____", or any other wording that expresses the facts.

(d) The statement of the place of business shall include the street address, city, State, and ZIP Code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear either on the label or the labeling (including the invoice).

(e) If a person manufactures, packs, or distributes a cosmetic at a place other than his principal place of business, the label may state the principal

place of business in lieu of the actual place where such cosmetic was manufactured or packed or is to be distributed, unless such statement would be misleading.

§ 701.13 Declaration of net quantity of contents.

(a) The label of a cosmetic in package form shall bear a declaration of the net quantity of contents. This shall be expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement shall be in terms of fluid measure if the cosmetic is liquid or in terms of weight if the cosmetic is solid, semisolid, or viscous, or a mixture of solid and liquid. If there is a firmly established, general consumer usage and trade custom of declaring the net quantity of a cosmetic by numerical count, linear measure, or measure of area, such respective term may be used. If there is a firmly established, general consumer usage and trade custom of declaring the contents of a liquid cosmetic by weight, or a solid, semisolid, or viscous cosmetic by fluid measure, it may be used. Whenever the Commissioner determines for a specific packaged cosmetic that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination of these does not facilitate value comparisons by consumers, he shall by regulation designate the appropriate term or terms to be used for such cosmetic.

(b) Statements of weight shall be in terms of avoirdupois pound and ounce. Statements of fluid measure shall be in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid-ounce subdivisions thereof and shall express the volume at 68 °F. (20 °C.).

(c) When the declaration of quantity of contents by numerical count, linear measure, or measure of area does not give accurate information as to the quantity of cosmetic in the package, it shall be augmented by such statement of weight, measure, or size of the individual units or the total weight or measure of the cosmetic as will give such information.

(d) The declaration may contain common or decimal fractions. A common fraction shall be in terms of

halves, quarters, eighths, sixteenths, or thirty-seconds; except that if there exists a firmly established, general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places. A statement that includes small fractions of an ounce shall be deemed to permit smaller variations than one which does not include such fractions.

(e) The declaration shall be located on the principal display panel of the label; with respect to packages bearing alternate principal display panels, it shall be duplicated on each principal display panel: *Provided, That:*

(1) The principal display panel of a cosmetic marketed in a "boudoir-type" container including decorative cosmetic containers of the "cartridge," "pill box," "compact," or "pencil" variety, and those with a capacity of one-fourth ounce or less, may be considered to be a tear-away tag or tape affixed to the decorative container and bearing the mandatory label information as required by this part, but the type size of the net quantity of contents statement shall be governed by the dimensions of the decorative container; and

(2) The principal display panel of a cosmetic marketed on a display card to which the immediate container is affixed may be considered to be the display panel of the card, and the type size of the net quantity of content statement is governed by the dimensions of the display card.

(f) The declaration shall appear as a distinct item on the principal display panel, shall be separated (by at least a space equal to the height of the lettering used in the declaration) from other printed label information appearing above or below the declaration and (by at least a space equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement) from other printed label information appearing to the left or right of the declaration. It shall not include any term qualifying a unit of weight, measure, or count (such as "giant pint" and "full quart") that tends to

exaggerate the amount of the cosmetic in the container. It shall be placed on the principal display panel within the bottom 30 percent of the area of the label panel in line generally parallel to the base on which the package rests as it is designed to be displayed: *Provided*, That:

(1) On packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of this part; and

(2) In the case of a cosmetic that is marketed with both outer and inner retail containers bearing the mandatory label information required by this part, and the inner container is not intended to be sold separately, the net quantity of contents placement requirement of this section applicable to such inner containers is waived.

(g) The declaration shall accurately reveal the quantity of cosmetic in the package exclusive of wrappers and other material packed therewith: *Provided*, That:

(1) In the case of cosmetics packed in containers designed to deliver the cosmetic under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on the container are followed. The propellant is included in the net quantity declaration; and

(2) In the case of a package which contains the integral components making up a complete kit, and which is designed to deliver the components in the manner of an application (for example, a home permanent wave kit), the declaration may state the net quantity of the contents in nondeceptive terms of the number of applications available in the kit when the instructions for use as shown on the container are followed.

(h) The declaration shall appear in conspicuous and easily legible boldface print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is

so formed on the surface. Requirements of conspicuousness and legibility shall include the specifications that:

(1) The ratio of height to width (of the letter) shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide).

(2) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter “o” or its equivalent that shall meet the minimum standards.

(3) When fractions are used, each component numeral shall meet one-half the minimum height standards.

(i) The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(1) Not less than one-sixteenth inch in height on packages the principal display panel of which has an area of 5 square inches or less.

(2) Not less than one-eighth inch in height on packages the principal display panel of which has an area of more than 5 but not more than 25 square inches.

(3) Not less than three-sixteenths inch in height on packages the principal display panel of which has an area of more than 25 but not more than 100 square inches.

(4) Not less than one-fourth inch in height on packages the principal display panel of which has an area of more than 100 square inches, except not less than one-half inch in height if the area is more than 400 square inches.

Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in paragraphs (i)(1) through (4) of this section shall be increased by one-sixteenth of an inch.

(j) On packages containing less than 4 pounds or 1 gallon and labeled in terms of weight or fluid measure:

(1) The declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (1 pound or 1 pint or more), followed in parentheses by a declaration

in pounds for weight units, with any remainder in terms of ounces or common or decimal fractions of the pound (as set forth in paragraphs (m)(1) and (2) of this section), or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (as set forth in paragraphs (m)(3) and (4) of this section). Net weight or fluid measure of less than 1 ounce shall be expressed in common or decimal fractions of the respective ounce and not in drams.

(2) The declaration may appear in more than one line. The term "net weight" shall be used when stating the net quantity of contents in terms of weight. Use of the terms "net" or "net contents" in terms of fluid measure or numerical count is optional. It is sufficient to distinguish avoirdupois ounce from fluid ounce through association of terms; for example, "Net wt. 6 oz." or "6 oz. net wt." and "Net contents 6 fl. oz." or "6 fl. oz."

(k) On packages containing 4 pounds or 1 gallon or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for weight units with any remainder in terms of ounces or common or decimal fractions of the pound; in the case of fluid measure, it shall be expressed in the largest whole unit (gallons, followed by common or decimal fractions of a gallon or by the next smaller whole unit or units (quarts or quarts and pints)) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart (as set forth in paragraph (m)(5) of this section).

(1) [Reserved]

(m) Examples: (1) A declaration of 1½ pounds weight shall be expressed as "Net wt. 24 oz. (1 lb. 8 oz.)", "Net wt. 24 oz. (1½ lb.)", or "Net wt. 24 oz. (1.5 lb.)".

(2) A declaration of three-fourths pound avoirdupois weight shall be expressed as "Net wt. 12 oz."

(3) A declaration of 1 quart liquid measure shall be expressed as "Net contents 32 fl. oz. (1 qt.)".

(4) A declaration of 1¾ quarts liquid measure shall be expressed as "Net

contents 56 fl. oz. (1 qt. 1½ pt.)" or "Net contents 56 fl. oz. (1 qt. 1 pt. 8 oz.)" but not in terms of quart and ounce such as "Net content 56 fl. oz. (1 qt. 24 oz.)".

(5) A declaration of 2½ gallons liquid measure shall be expressed in the alternative as "Net contents 2 gal. 2 qt." and not as "2 gal. 4 pt."

(n) For quantities, the following abbreviations and none other may be employed (periods and plural forms are optional):

weight wt.	inch in.
square sq.	gallon gal.
fluid fl.	quart qt.
yard yd.	pint pt.
feet or foot ft.	ounce oz.
	pound lb.

(o) On packages labeled in terms of linear measure, the declaration shall be expressed both in terms of inches and, if applicable (1 foot or more), the largest whole units (yards, yards and feet, feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of inches and any remainder shall be in terms of inches or common or decimal fractions of the foot or yard. Examples are "86 inches (2 yd. 1 ft. 2 inches)", "90 inches (2½ yd.)", "30 inches (2.5 ft.)", etc.

(p) On packages labeled in terms of area measure, the declaration shall be expressed in terms of square inches and, if applicable (1 square foot or more), the largest whole square unit (square yards, square yards and square feet, square feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of square inches and any remainder shall be in terms of square inches or common or decimal fractions of the square foot or square yard; for example, "158 sq. inches (1 sq. ft. 14 sq. inches)", etc.

(q) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents, provided that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends

§ 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 ₃ F	Chlorofluorocarbon 11.
Trichlorofluoromethane and 0.3 pct nitromethane	CCl ₃ F+CH ₃ NO ₂ ..	Chlorofluorocarbon 11 S.
Dichlorodifluoromethane	CCl ₂ F ₂	Chlorofluorocarbon 12.
Chlorodifluoromethane	CHClF ₂	Hydrochlorofluorocarbon 22.
1, 2-dichloro-1, 1, 2, 2-tetrafluoroethane	CClF ₂ CClF ₂	Chlorofluorocarbon 114.
1-Chloro-1, 1-difluoroethane	CH ₃ CClF ₂	Hydrochlorofluorocarbon 142 B.
1, 1-difluoroethane	CH ₃ CHF ₂	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

Sec.

- 710.1 Who should register.
- 710.2 Time for registration.
- 710.3 How and where to register.
- 710.4 Information requested.
- 710.5 Amendments to registration.
- 710.6 Notification of registrant; cosmetic product establishment registration number.
- 710.7 Inspection of registrations.
- 710.8 Misbranding by reference to registration or to registration number.
- 710.9 Exemptions.

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]

§ 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 (4–1–10 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.

(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).

(v) Hair color sprays (aerosol).

(vi) Hair lighteners with color.

(vii) Hair bleaches.

(viii) Other hair coloring preparations.

(7) *Makeup preparations (not eye)*. (i) Blushers (all types).

(ii) Face powders.

(iii) Foundations.

(iv) Leg and body paints.

(v) Lipstick.

(vi) Makeup bases.

(vii) Rouges.

(viii) Makeup fixatives.

(ix) Other makeup preparations.

(8) *Manicuring preparations*. (i) Basecoats and undercoats.

(ii) Cuticle softeners.

(iii) Nail creams and lotions.

(iv) Nail extenders.

(v) Nail polish and enamel.

(vi) Nail polish and enamel removers.

(vii) Other manicuring preparations.

(9) *Oral hygiene products*. (i) Dentifrices (aerosol, liquid, pastes, and powders).

(ii) Mouthwashes and breath fresheners (liquids and sprays).

(iii) Other oral hygiene products.

(10) *Personal cleanliness*. (i) Bath soaps and detergents.

(ii) Deodorants (underarm).

(iii) Douches.

(iv) Feminine hygiene deodorants.

(v) Other personal cleanliness products.

(11) *Shaving preparations*. (i) Aftershave lotions.

§ 720.5

- (ii) Beard softeners.
- (iii) Men's talcum.
- (iv) Preshave lotions (all types).
- (v) Shaving cream (aerosol, brushless, and lather).
- (vi) Shaving soap (cakes, sticks, etc.).
- (vii) Other shaving preparation products.

(12) *Skin care preparations, (creams, lotions, powder, and sprays).* (i) Cleansing (cold creams, cleansing lotions, liquids, and pads).

- (ii) Depilatories.
- (iii) Face and neck (excluding shaving preparations).
- (iv) Body and hand (excluding shaving preparations).
- (v) Foot powders and sprays.
- (vi) Moisturizing.
- (vii) Night.
- (viii) Paste masks (mud packs).
- (ix) Skin fresheners.
- (x) Other skin care preparations.

(13) *Suntan preparations.* (i) Suntan gels, creams, and liquids.

- (ii) Indoor tanning preparations.
- (iii) Other suntan preparations.
- (d) Ingredients in the product should be listed as follows:

(1) A list of each ingredient of the cosmetic product in descending order of predominance by weight (except that the fragrance and/or flavor may be designated as such without naming each individual ingredient when the manufacturer or supplier of the fragrance and/or flavor refuses to disclose ingredient data).

(2) An ingredient should be listed by the name adopted by the Food and Drug Administration (FDA) for the ingredient pursuant to § 701.3(c) of this chapter.

(3) In the absence of a name adopted by FDA pursuant to § 701.3(c) of this chapter, its common or usual name, if it has one, or its chemical or technical name should be listed.

(4) If an ingredient is a mixture, each ingredient of the mixture should be listed in accordance with paragraphs (d)(2) and (d)(3) of this section, unless such mixture is a formulation voluntarily registered on Form FDA 2512, in which case such mixture should be identified as "fragrance," "flavor," "fragrance and flavor" or "base formulation," as appropriate, and by stating

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

its FDA-assigned cosmetic product ingredient statement number.

(5) When the manufacturer or supplier of a fragrance and/or flavor refuses to disclose ingredient data, the fragrance and/or flavor should be listed as such. The nonconfidential listing of the product name and/or trade name or name of the manufacturer or supplier of each proprietary fragrance and/or flavor mixture is optional.

(e) A separate Form FDA-2512 should be filed for each different formulation of a cosmetic product. However, except for the hair coloring preparations listed in paragraph (c)(6) of this section for which a statement for each shade of such product is required, a single Form FDA-2512 may be filed for two or more shades of a cosmetic product where only the amounts of the color additive ingredient used are varied or in the case of flavors and fragrances where only the amounts of the flavors and fragrances used are varied.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0030)

[39 FR 10060, Mar. 15, 1974, as amended at 46 FR 38073, July 24, 1981; 57 FR 3129, Jan. 28, 1992]

§ 720.5 [Reserved]

§ 720.6 Amendments to statement.

Changes in the information requested under §§ 720.4 (a)(3) and (a)(5) on the ingredients or brand name of a cosmetic product should be submitted by filing an amended Form FDA 2512 within 60 days after the product is entered into commercial distribution. Other changes do not justify immediate amendment, but should be shown by filing an amended Form FDA 2512 within a year after such changes. Notice of discontinuance of commercial distribution of a cosmetic product formulation should be submitted by Form FDA 2514 within 180 days after discontinuance of commercial distribution becomes known to the person filing.

[57 FR 3130, Jan. 28, 1992, as amended at 67 FR 9587, Mar. 4, 2002]

§ 720.7 Notification of person submitting cosmetic product ingredient statement.

When Form FDA 2512 is received, FDA will either assign a permanent cosmetic product ingredient statement number or a Food and Drug Administration (FDA) reference number in those cases where a permanent number cannot be assigned. Receipt of the form will be acknowledged by sending the individual signing the statement an appropriate notice bearing either the FDA reference number or the permanent cosmetic product ingredient statement number. If the person submitting Form FDA 2512 has not complied with §§ 720.4 (b)(1) and (b)(2), the person will be notified as to the manner in which the statement is incomplete.

[57 FR 3130, Jan. 28, 1992]

§ 720.8 Confidentiality of statements.

(a) Data and information contained in, attached to, or included with Forms FDA 2512 and FDA 2514, and amendments thereto are submitted voluntarily to the Food and Drug Administration (FDA). Any request for confidentiality of a cosmetic ingredient submitted with such forms or separately will be handled in accordance with the procedure set forth in this section. The request for confidentiality will also be subject to the provisions of § 20.111 of this chapter, as well as to the exemptions in subpart D of part 20 of this chapter and to the limitations on exemption in subpart E of part 20 of this chapter.

(b) Any request for confidentiality of the identity of a cosmetic ingredient should contain a full statement, in a well-organized format, of the factual and legal grounds for that request, including all data and other information on which the petitioner relies, as well as representative information known to the petitioner that is unfavorable to the petitioner's position. The statement of the factual grounds should include, but should not be limited to, scientific or technical data, reports, tests, and other relevant information addressing the following factors that FDA will consider in determining

whether the identity of an ingredient qualifies as a trade secret:

(1) The extent to which the identity of the ingredient is known outside petitioner's business;

(2) The extent to which the identity of the ingredient is known by employees and others involved in petitioner's business;

(3) The extent of measures taken by the petitioner to guard the secrecy of the information;

(4) The value of the information about the identity of the claimed trade secret ingredient to the petitioner and to its competitors;

(5) The amount of effort or money expended by petitioner in developing the ingredient; and

(6) The ease or difficulty with which the identity of the ingredient could be properly acquired or duplicated by others.

(c) The request for confidentiality should also be accompanied by a statement that the identity of the ingredient for which confidentiality is requested has not previously been published or disclosed to anyone other than as provided in § 20.81(a) of this chapter.

(d) FDA will return to the petitioner any request for confidentiality that contains insufficient data to permit a review of the merits of the request. FDA will also advise the petitioner about the additional information that is necessary to enable the agency to proceed with its review of the request.

(e) If, after receiving all of the data that are necessary to make a determination about whether the identity of an ingredient is a trade secret, FDA tentatively decides to deny the request, the agency will inform the person requesting trade secrecy of its tentative determination in writing. FDA will set forth the grounds upon which it relied in making this tentative determination. The petitioner may withdraw the records for which FDA has tentatively denied a request for confidentiality or may submit, within 60 days from the date of receipt of the written notice of the tentative denial, additional relevant information and arguments and request that the agency reconsider its decision in light of both

§ 720.9

the additional material and the information that it originally submitted.

(f) If the petitioner submits new data in response to FDA's tentative denial of trade secret status, the agency will consider that material together with the information that was submitted initially before making its final determination.

(g) A final determination that an ingredient is not a trade secret within the meaning of § 20.61 of this chapter constitutes final agency action that is subject to judicial review under 5 U.S.C. Chapter 7. If suit is brought within 30 calendar days after such a determination, FDA will not disclose the records involved or require that the disputed ingredient or ingredients be disclosed in labeling until the matter is finally determined in the courts. If suit is not brought within 30 calendar days after a final determination that an ingredient is not a trade secret within the meaning of 21 CFR 20.61, and the petitioner does not withdraw the records for which a request for confidentiality has been denied, the records involved will be made a part of FDA files and will be available for public disclosure upon request.

[51 FR 11444, Apr. 3, 1986, as amended at 57 FR 3130, Jan. 28, 1992; 68 FR 25288, May 12, 2003]

§ 720.9 Misbranding by reference to filing or to statement number.

The filing of Form FDA 2512 or assignment of a number to the statement does not in any way denote approval by the Food and Drug Administration of the firm or the product. Any representation in labeling or advertising that creates an impression of official approval because of such filing or such number will be considered misleading.

[57 FR 3130, Jan. 28, 1992]

PART 740—COSMETIC PRODUCT WARNING STATEMENTS

Subpart A—General

Sec.

740.1 Establishment of warning statements.
740.2 Conspicuousness of warning statements.

21 CFR Ch. I (4–1–10 Edition)

Subpart B—Warning Statements

740.10 Labeling of cosmetic products for which adequate substantiation of safety has not been obtained.

740.11 Cosmetics in self-pressurized containers.

740.12 Feminine deodorant sprays.

740.17 Foaming detergent bath products.

740.18 Coal tar hair dyes posing a risk of cancer.

740.19 Suntanning preparations.

AUTHORITY: 21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374.

Subpart A—General

§ 740.1 Establishment of warning statements.

(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

(b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in part 10 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

[40 FR 8917, Mar. 3, 1975, as amended at 42 FR 15676, Mar. 22, 1977]

§ 740.2 Conspicuousness of warning statements.

(a) A warning statement shall appear on the label prominently and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, but in no case may the letters and/or numbers be less than $\frac{1}{16}$ inch in height, unless an exemption pursuant to paragraph (b) of this section is established.

(b) If the label of any cosmetic package is too small to accommodate the information as required by this section, the Commissioner may establish by regulation an acceptable alternative

method, e.g., type size smaller than $\frac{1}{16}$ inch in height. A petition requesting such a regulation, as an amendment to this section, shall be submitted to the Division of Dockets Management in the form established in part 10 of this chapter.

[40 FR 8917, Mar. 3, 1975, as amended at 42 FR 15676, Mar. 22, 1977; 69 FR 13717, Mar. 24, 2004]

Subpart B—Warning Statements

§ 740.10 Labeling of cosmetic products for which adequate substantiation of safety has not been obtained.

(a) Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

Warning—The safety of this product has not been determined.

(b) An ingredient or product having a history of use in or as a cosmetic may at any time have its safety brought into question by new information that in itself is not conclusive. The warning required by paragraph (a) of this section is not required for such an ingredient or product if:

(1) The safety of the ingredient or product had been adequately substantiated prior to development of the new information;

(2) The new information does not demonstrate a hazard to human health; and

(3) Adequate studies are being conducted to determine expeditiously the safety of the ingredient or product.

(c) Paragraph (b) of this section does not constitute an exemption to the adulteration provisions of the Act or to any other requirement in the Act or this chapter.

[40 FR 8917, Mar. 3, 1975]

§ 740.11 Cosmetics in self-pressurized containers.

(a)(1) The label of a cosmetic packaged in a self-pressurized container and intended to be expelled from the pack-

age under pressure shall bear the following warning:

Warning—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120° F. Keep out of reach of children.

(2) In the case of products intended for use by children, the phrase “except under adult supervision” may be added at the end of the last sentence in the warning required by paragraph (a)(1) of this section.

(3) In the case of products packaged in glass containers, the word “break” may be substituted for the word “puncture” in the warning required by paragraph (a)(1) of this section.

(4) The words “Avoid spraying in eyes” may be deleted from the warning required by paragraph (a)(1) of this section in the case of a product not expelled as a spray.

(b)(1) In addition to the warning required by paragraph (a)(1) of this section, the label of a cosmetic packaged in a self-pressurized container in which the propellant consists in whole or in part of a halocarbon or a hydrocarbon shall bear the following warning:

Warning—Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

(2) The warning required by paragraph (b)(1) of this section is not required for the following products:

(i) Products expelled in the form of a foam or cream, which contain less than 10 percent propellant in the container.

(ii) Products in a container with a physical barrier that prevents escape of the propellant at the time of use.

(iii) Products of a net quantity of contents of less than 2 ozs. that are designed to release a measured amount of product with each valve actuation.

(iv) Products of a net quantity of contents of less than $\frac{1}{2}$ oz.

(c) Labeling requirements for cosmetics packaged in a self-pressurized container containing or manufactured with a chlorofluorocarbon propellant or other ozone-depleting substance designated by the Environmental Protection Agency (EPA) are set forth in 40 CFR part 82.

[40 FR 8917, Mar. 3, 1975, as amended at 42 FR 22033, Apr. 29, 1977; 54 FR 39640, Sept. 27, 1989; 61 FR 20101, May 3, 1996]

§ 740.12

21 CFR Ch. I (4–1–10 Edition)

§ 740.12 Feminine deodorant sprays.

(a) For the purpose of this section, the term “feminine deodorant spray” means any spray deodorant product whose labeling represents or suggests that the product is for use in the female genital area or for use all over the body.

(b) The label of a feminine deodorant spray shall bear the following statement:

Caution—For external use only. Spray at least 8 inches from skin. Do not apply to broken, irritated, or itching skin. Persistent, unusual odor or discharge may indicate conditions for which a physician should be consulted. Discontinue use immediately if rash, irritation, or discomfort develops.

The sentence “Spray at least 8 inches from skin” need not be included in the cautionary statement for products whose expelled contents do not contain a liquified gas propellant such as a halocarbon or hydrocarbon propellant.

(c) Use of the word “hygiene” or “hygienic” or a similar word or words renders any such product misbranded under section 602(a) of the Federal Food, Drug, and Cosmetic Act. The use of any word or words which represent or suggest that such products have a medical usefulness renders such products misbranded under section 502(a) of the Act and illegal new drugs marketed in violation of section 505 of the Act.

[40 FR 8929, Mar. 3, 1975]

§ 740.17 Foaming detergent bath products.

(a) For the purpose of this section, a foaming detergent bath product is any product intended to be added to a bath for the purpose of producing foam that contains a surface-active agent serving as a detergent or foaming ingredient.

(b) The label of foaming detergent bath products within the meaning of paragraph (a) of this section, except for those products that are labeled as intended for use exclusively by adults, shall bear adequate directions for safe use and the following caution:

Caution—Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occurs. Consult your physician if irritation persists. Keep out of reach of children.

(c) In the case of products intended for use by children, the phrase “except under adult supervision” may be added at the end of the last sentence in the caution required by paragraph (b) of this section.

[51 FR 20475, June 5, 1986]

§ 740.18 Coal tar hair dyes posing a risk of cancer.

(a) The principal display panel of the label and any labeling accompanying a coal tar hair dye containing any ingredient listed in paragraph (b) of this section shall bear, in accordance with the requirements of § 740.2, the following:

Warning—Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals.

(b) Hair dyes containing any of the following ingredients shall comply with the requirements of this section: (1) 4-methoxy-*m*-phenylenediamine (2,4-diaminoanisole) and (2) 4-methoxy-*m*-phenylenediamine sulfate (2,4-diaminoanisole sulfate).

[44 FR 59522, Oct. 16, 1979]

EFFECTIVE DATE NOTE: At 47 FR 7829, Feb. 23, 1982, § 740.18 was stayed until further notice, effective Sept. 18, 1980.

§ 740.19 Suntanning preparations.

The labeling of suntanning preparations that do not contain a sunscreen ingredient must display the following warning: “Warning—This product does not contain a sunscreen and does not protect against sunburn. Repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer, and other harmful effects to the skin even if you do not burn.” For purposes of this section, the term “suntanning preparations” includes gels, creams, liquids, and other topical products that are intended to provide cosmetic effects on the skin while tanning through exposure to UV radiation (e.g., moisturizing or conditioning products), or to give the appearance of a tan by imparting color to the skin through the application of approved color additives (e.g., dihydroxyacetone) without the need for exposure to UV radiation. The term “suntanning preparations” does not include products intended to provide sun

Food and Drug Administration, HHS

§ 740.19

protection or otherwise intended to affect the structure or any function of the body.

[64 FR 27693, May 21, 1999]

PARTS 741–799 [RESERVED]