

§ 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.