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.

§ 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.

§ 700.23 Chlorofluorocarbon propellants.

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

§ 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 avail-
able processes. For purposes of this sec-
tion, the term “aerosol product”
means a product which depends upon
the power of a liquified or compressed
gas to expel the contents from the con-
tainer. A tamper-resistant package
may involve an immediate-container
and closure system or secondary-con-
tainer or carton system or any combi-
nation of systems intended to provide
a visual indication of package integ-
ity. The tamper-resistant feature
shall be designed to and shall remain
intact when handled in a reasonable
manner during manufacture, distribu-
tion, and retail display.

(c) Labeling. Each retail package of a
cosmetic product covered by this sec-
tion, except aerosol products as defined
in paragraph (b) of this section, is re-
quired to bear a statement that is
prominently placed so that consumers
are alerted to the specific tamper-re-
sistant feature of the package. The la-
beling 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 iden-
tifying characteristic, that character-
istic is required to be referred to
in the labeling statement. For exam-
ple, the labeling statement on a bottle
with a shrink band could say “For your
protection, this bottle has an im-
printed seal around the neck.”

(d) Requests for exemptions from pack-
aging and labeling requirements. A man-
ufacturer or packer may request an ex-
emption from the packaging and label-
ing requirements of this section. A re-
quest 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 peti-
tion is required to contain the fol-
lowing:

(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 peti-
tioner 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 require-
ment has been approved by the Office
of Management and Budget under num-
ber 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 manufac-
turer or packer has obtained an exemp-
tion from a packaging or labeling re-
quirement.

(1) Initial effective date for packing-
aging requirements. (i) The packaging require-
ment in paragraph (b) of this section is
effective on February 7, 1983 for each
affected cosmetic product (except vag-
inal tablets) packaged for retail sale on
or after that date, except for the re-
quirement in paragraph (b) of this sec-
tion for a distinctive indicator or bar-
rier to entry.
(ii) The packaging requirement in
paragraph (b) of this section is effec-
tive on May 5, 1983 for each cosmetic
product that is a vaginal tablet pack-
aged for retail sale on or after that
date, except for the re-
quirement in paragraph (b) of this sec-
tion for a distinctive indicator or bar-
rier to entry.

(2) Initial effective date for labeling re-
quirements. The requirement in para-
graph (b) of this section that the indi-
cator or barrier to entry be distinctive
by design and the requirement in para-
graph (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 tam-
per-resistant packaging requirement of
paragraph (b) of this section is effec-
tive 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
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.


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” (AACS 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_regulations/code_of_federal_regulations/ibr_locations.html.

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