

Food and Drug Administration, HHS

§ 897.1

modify, or revoke the proposed regulation making the device a banned device. If the Commissioner decides to affirm or modify the proposed regulation to make a device a banned device, the Commissioner will amend subpart B by adding the name or description of the device, or both, to the list of banned devices. If the Commissioner decides to revoke a proposed regulation making a device a banned device, a notice of termination of rulemaking proceedings and reasons therefor will be published in the FEDERAL REGISTER.

(e) The Commissioner may declare the special effective date provided by this section to be in effect after the publication of a proposed regulation under § 895.21(d), if, based on new information, or upon reconsideration of previously available information, the Commissioner makes the determination and provides the appropriate notices and an opportunity for a hearing in accordance with paragraphs (a) and (c) of this section.

(f) Those devices that have been named banned devices under § 895.30 and that have already been sold to the public may be subject to relabeling by the manufacturer, distributor, importer, or any other person(s) responsible for the labeling of the device or may be subject to the provisions of section 518(a) or (b) of the act.

[44 FR 29221, May 18, 1979, as amended at 57 FR 58405, Dec. 10, 1992]

Subpart B—Listing of Banned Devices

§ 895.101 Prosthetic hair fibers.

Prosthetic hair fibers are devices intended for implantation into the human scalp to simulate natural hair or conceal baldness. Prosthetic hair fibers may consist of various materials; for example, synthetic fibers, such as modacrylic, polyacrylic, and polyester; and natural fibers, such as processed human hair. Excluded from the banned device are natural hair transplants, in which a person's hair and its surrounding tissue are surgically removed from one location on the person's scalp and then grafted onto another area of the person's scalp.

[48 FR 25136, June 3, 1983]

PART 897—CIGARETTES AND SMOKELESS TOBACCO

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AUTHORITY: 21 U.S.C. 352, 360, 360h, 360i, 360j, 371, 374, 393.

SOURCE: 61 FR 44615, Aug. 28, 1996, unless otherwise noted.

Subpart A—General Provisions

§ 897.1 Scope.

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 897.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

§ 897.3 Definitions.

(a) *Cigarette* means any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a)(1) of this section.

(b) *Cigarette tobacco* means any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements pertaining to cigarettes shall also apply to cigarette tobacco.

(c) *Distributor* means any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

(d) *Manufacturer* means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.

(e) *Nicotine* means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or C₁₀H₁₄N₂, including any salt or complex of nicotine.

(f) *Package* means a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers.

(g) *Point of sale* means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption.

(h) *Retailer* means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

(i) *Smokeless tobacco* means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity.

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

§ 897.10 General responsibilities of manufacturers, distributors, and retailers.

Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.

§ 897.12 Additional responsibilities of manufacturers.

In addition to the other responsibilities under this part, each manufacturer shall remove from each point of sale all self-service displays, advertising, labeling, and other items that the manufacturer owns that do not comply with the requirements under this part.

§ 897.14 Additional responsibilities of retailers.

In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(a) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(b)(1) Except as otherwise provided in § 897.16(c)(2)(i) and in paragraph (b)(2) of this section, each retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(2) No such verification is required for any person over the age of 26;

(c) Except as otherwise provided in § 897.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);

(d) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(e) Each retailer shall ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

§ 897.16 Conditions of manufacture, sale, and distribution.

(a) *Restriction on product names.* A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) *Minimum cigarette package size.* Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) *Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale.* (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include

vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d) *Free samples.* No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco.

(e) *Restrictions on labels, labeling, and advertising.* No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subparts C and D of this part, and other applicable requirements.

Subpart C—Labels

§ 897.24 Established names for cigarettes and smokeless tobacco.

Each cigarette or smokeless tobacco package shall bear, as provided in section 502 of the act, the following established name: "Cigarettes", "Cigarette Tobacco", "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff", or "Dry Snuff", whichever name is appropriate.

§ 897.25 Statement of intended use and age restriction.

Each cigarette or smokeless tobacco package, that is offered for sale, sold, or otherwise distributed shall bear the following statement: "Nicotine-Delivery Device for Persons 18 or Older".

Subpart D—Labeling and Advertising

§ 897.30 Scope of permissible forms of labeling and advertising.

(a)(1) A manufacturer, distributor, or retailer may, in accordance with this

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subpart D, disseminate or cause to be disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional material; and in audio or video formats delivered at a point-of-sale.

(2) A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The manufacturer, distributor, or retailer shall send this notice to the Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane (HFD-40), rm. 17B-20, Rockville, MD 20857.

(b) No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school.

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

§ 897.32 Format and content requirements for labeling and advertising.

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self-service displays are

permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

(c) Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, advertising permitted under this subpart D, shall include, as provided in section 502 of the act, the product's established name and a statement of its intended use as follows: "Cigarettes—A Nicotine-Delivery Device for Persons 18 or Older", "Cigarette Tobacco—A Nicotine-Delivery Device for Persons 18 or Older", or "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff" or "Dry Snuff", whichever is appropriate for the product, followed by the words "A Nicotine-Delivery Device for Persons 18 or Older".

§ 897.34 Sale and distribution of non-tobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless

tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

EFFECTIVE DATE NOTE: At 61 FR 44617, Aug. 28, 1996, in § 897.34, paragraph (c) was added, effective Feb. 28, 1998. At 61 FR 47550, Sept. 9, 1996, the effective date was corrected to Aug. 28, 1998.

PART 898—PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

Sec.

898.11 Applicability.

898.12 Performance standard.

898.13 Compliance dates.

898.14 Exemptions and variances.

AUTHORITY: 21 U.S.C. 351, 352, 360c, 360d, 360gg-360ss, 371, 374; 42 U.S.C. 262, 264.

SOURCE: 62 FR 25497, May 9, 1997, unless otherwise noted.

§ 898.11 Applicability.

Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in § 898.12.

§ 898.12 Performance standard.

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)

601-1: Medical Electrical Equipment

601-1 (1988) Part 1: General requirements for safety

Amendment No. 1 (1991)

Amendment No. 2 (1995).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.

§ 898.13 Compliance dates.

The dates for compliance with the standard set forth in § 898.12(a) shall be as follows:

(a) For electrode lead wires and patient cables used with, or intended for use with, the following devices, the date for which compliance is required is May 11, 1998: