

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

Subpart A—General Provisions

Sec.

897.1 Scope.

897.2 Purpose.

897.3 Definitions.

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

897.10 General responsibilities of manufacturers, distributors, and retailers.

897.12 Additional responsibilities of manufacturers.

897.14 Additional responsibilities of retailers.

897.16 Conditions of manufacture, sale, and distribution.

Subpart C—Labels

897.24 Established names for cigarettes and smokeless tobacco.

897.25 Statement of intended use and age restriction.

Subpart D—Labeling and Advertising

897.30 Scope of permissible forms of labeling and advertising.

897.32 Format and content requirements for labeling and advertising.

897.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

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.