

§ 895.101

serious one that the Commissioner believes will endanger the health of individuals who have been, or will be, exposed to the device. In assessing the degree of danger, the Commissioner need not find that the danger is immediate, and it shall be sufficient for the Commissioner to determine that the danger may involve a serious long-term risk.

(c) If the Commissioner makes a proposed regulation effective in accordance with this section, the Commissioner will, as expeditiously as possible, give interested persons prompt notice of this action in the FEDERAL REGISTER.

(d) After the hearing, if any, and after considering any written comments submitted on the proposal and any additional available information and data, the Commissioner will as expeditiously as possible either affirm, 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]

21 CFR Ch. I (4-1-11 Edition)

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 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