

subpart E of part 807 of this chapter subject to § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996; 65 FR 2323, Jan. 14, 2000]

PART 895—BANNED DEVICES

Subpart A—General Provisions

Sec.

895.1 Scope.

895.20 General.

895.21 Procedures for banning a device.

895.22 Submission of data and information by the manufacturer, distributor, or importer.

895.25 Labeling.

895.30 Special effective date.

Subpart B—Listing of Banned Devices

895.101 Prosthetic hair fibers.

AUTHORITY: 21 U.S.C. 352, 360f, 360h, 360i, 371.

SOURCE: 44 FR 29221, May 18, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 895.1 Scope.

(a) This part describes the procedures by which the Commissioner may institute proceedings to make a device intended for human use that presents substantial deception or an unreasonable and substantial risk of illness or injury a banned device.

(b) This part applies to any “device”, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (act) that is intended for human use.

(c) A device that is made a banned device in accordance with this part is adulterated under section 501(g) of the act. A restricted device that is banned may also be misbranded under section 502(q) of the act.

(d) Although this part does not cover devices intended for animal use, the manufacturer, distributor, importer, or any other person(s) responsible for the labeling of the device that is banned cannot avoid the ban by relabeling the device for veterinary use. A device that has been banned from human use but that also has a valid veterinary use may be marketed for use as a veterinary device only under the following conditions: The device shall comply

with all requirements applicable to veterinary devices under the Federal Food, Drug, and Cosmetic Act and this chapter, and the label for the device shall bear the following statement: “For Veterinary Use Only. Caution: Federal law prohibits the distribution of this device for human use.” A device so labeled, however, that is determined by the Food and Drug Administration to be intended for human use, will be considered to be a banned device. In determining whether such a device is intended for human use, the Food and Drug Administration will consider, among other things, the ultimate destination of the device.

§ 895.20 General.

The Commissioner may initiate a proceeding to make a device a banned device whenever the Commissioner finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury that the Commissioner determines cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, or by a change in advertising if the device is a restricted device.

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

§ 895.21 Procedures for banning a device.

(a) Before initiating a proceeding to make a device a banned device, the Commissioner shall find that the continued marketing of the device presents a substantial deception or an unreasonable and substantial risk of illness or injury.

(1) In determining whether the deception or risk of illness or injury is substantial, the Commissioner will consider whether the deception or risk posed by continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing.

(2) In determining whether a device is deceptive, the Commissioner will consider whether users of the device may be deceived or otherwise harmed by the