

(5) The determination as to whether the deception or risk of illness or injury or the danger to the health of individuals could be corrected by labeling or change in labeling, or change in advertising if the device is a restricted device;

(6) The determination of whether the required labeling or change of labeling, or change in advertising if the device is a restricted device, if any, has been made in accordance with paragraph (c) of this section;

(7) The determination as to whether, and the reasons why, the banning should apply to devices already in commercial distribution or those already sold to the ultimate user, or both; and

(8) Any other data and information that the Commissioner believes are pertinent to the proceeding. The notice will afford all interested persons an opportunity to submit written comments within 30 days after the date of publication of the proposed regulation. All nonconfidential information upon which the proposed finding is based, including the recommendations of the panel, will be available for public review in the Dockets Management Branch, Food and Drug Administration.

The notice will afford all interested persons an opportunity to submit written comments and request an informal hearing, as defined in section 201(y) of the act, before the Food and Drug Administration within 30 days after the date of publication of the proposed regulation. If a request for an informal hearing is granted, the hearing will be conducted as a regulatory hearing under the applicable provisions of part 16 of this chapter. All nonconfidential information upon which the proposed finding is based, including the recommendations of the panel, will be available for public review in the office of the Dockets Management Branch, Food and Drug Administration.

(e)(1) If, after reviewing the administrative record of the regulatory hearing before the Food and Drug Administration, if any, the written comments received on the proposed regulation, and any additional available data and information, the Commissioner determines to ban a device, a final regulation to this effect will be published in

the FEDERAL REGISTER. The final regulation will amend subpart B by adding the name or description of the device, or both, to the list of banned devices.

(2) If the Commissioner determines not to ban the device, a notice of withdrawal and termination of rulemaking proceedings and reasons therefor will be published in the FEDERAL REGISTER.

(f) The effective date of a final regulation to make a device a banned device, promulgated under paragraph (e) of this section, will be the date of publication of the final regulation in the FEDERAL REGISTER unless the Commissioner, for reasons stated, determines that the effective date should be later than the date of the publication and specifies that date in the notice. Each such regulation will specify whether devices already in commercial distribution or sold to the ultimate user or both are banned.

(g) A regulation promulgated under paragraph (e) of this section is final agency action, subject to judicial review under section 517 of the act.

(h) Upon petition of any interested person submitted in accordance with § 10.30 of this chapter, or as a matter of discretion, the Commissioner may institute proceedings to amend or revoke a regulation that made a device a banned device if the Commissioner finds that the conditions that constituted the basis for the regulation banning the device are no longer applicable. When appropriate, the procedures in this section will be employed in such proceedings.

[44 FR 29221, May 18, 1979, as amended at 53 FR 11254, Apr. 6, 1988; 57 FR 58405, Dec. 10, 1992]

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

(a) A manufacturer, distributor, or importer of a device may be required to submit to the Food and Drug Administration all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and

substantial danger to the health of individuals. The data and information required by the Commissioner may include scientific or test data, reports, records, or other information, including data and information on whether the device is safe and effective for its intended use or when used as directed, whether the device performs according to the claims made for the device, and information on adulteration or misbranding. Any relevant information that is voluntarily submitted will also be reviewed.

(b) A manufacturer, distributor, or importer of a device required to submit data and information as provided in paragraph (a) of this section will be notified in writing by the Food and Drug Administration that such data and information shall be submitted. The written notification will advise the manufacturer, distributor, or importer of the device that the purpose for the request is to enable the Commissioner to determine whether any of the conditions listed in paragraph (a) of this section or §895.30(a)(1) exists with respect to the device such that a proceeding should be initiated to make the device a banned device. When the required data and information can be identified by the Food and Drug Administration at the time of the notification, the agency will provide such identification to the manufacturer, distributor, or importer of the device.

(c) The required data and information shall be submitted to the Food and Drug Administration no more than 30 days after the date of receipt of the request, unless the Commissioner determines that the data and information shall be submitted by some other date and so informs the manufacturer, distributor, or importer, in which case the data and information shall be submitted on the date specified by the Commissioner.

(d) If the data or information submitted to the Food and Drug Administration is sufficient to persuade the Commissioner that the deception or risk of illness or injury or the danger to the health of individuals presented by a device could be corrected or eliminated by labeling or change in labeling, or change in advertising if the device is a

restricted device, the Commissioner will proceed in accordance with §895.25.

(e) If the data or information submitted to the Food and Drug Administration is insufficient to show that the device does not present a substantial deception or an unreasonable and substantial risk of illness or injury, or an unreasonable, direct, and substantial danger to the health of individuals, or if the manufacturer, distributor, or importer fails to submit the required information, the Commissioner may rely upon this insufficiency or failure to submit the required information in considering whether to initiate a proceeding to make the device a banned device under §895.21(d) and, when appropriate, to establish a special effective date in accordance with §895.30. The Commissioner may also initiate other regulatory action as provided in the act or this chapter.

#### **§895.25 Labeling.**

(a) If the Commissioner determines that the substantial deception or unreasonable and substantial risk of illness or injury or the unreasonable, direct, and substantial danger to the health of individuals presented by a device can be corrected or eliminated by labeling or a change in labeling, or change in advertising if the device is a restricted device, the Commissioner will provide written notice to the manufacturer, distributor, importer, or any other person(s) responsible for the labeling or advertising of the device specifying:

(1) The deception or risk of illness or injury or the danger to the health of individuals,

(2) The labeling or change in labeling, or change in advertising if the device is a restricted device, necessary to correct the deception or eliminate or reduce such risk or danger, and

(3) The period of time within which the labeling, change in labeling, or change in advertising must be accomplished.

(b) In specifying the labeling or change in labeling or change in advertising to correct the deception or to eliminate or reduce the risk of illness or injury or the danger to the health of individuals, the Commissioner may require the manufacturer, distributor,