

Food and Drug Administration, HHS

§ 861.34

(c) If, after publication of a notice under paragraph (a) of this section, FDA receives a request to change the classification of the device, FDA will, within 60 days of the publication of the notice and after consultation with the appropriate panel under § 860.125 of this chapter, either deny the request or give notice of its intent to initiate a change in the classification under § 860.130.

(d) If FDA initiates a rulemaking proceeding under paragraph (a) of this section, FDA will:

(1) Complete the proceeding and establish the performance standard for the device in accordance with this part and § 10.40 of this chapter; or

(2) Terminate the proceeding by publishing in the FEDERAL REGISTER a notice announcing such termination and the reasons therefor and, unless the proceeding is terminated because the device is a banned device, initiate a proceeding in accordance with section 513(e) of the act to reclassify the device; or

(3) Take other appropriate action.

[57 FR 58404, Dec. 10, 1992]

§ 861.24 Existing standard as a proposed standard.

(a) The Food and Drug Administration may accept an existing standard or a proposed or draft standard if it includes:

(1) A description of the procedures used to develop the standard and a list of the persons and organizations that participated in its development, to the extent that such information is available or reasonably obtainable;

(2) An identification of the specific portions of the existing standard that the person submitting the standard believes are appropriate for adoption as, or inclusion in, the proposed standard; and

(3) A summary of the test data, or, if requested by the Food and Drug Administration, all such data or other information supporting the specific portions of the standard identified by the person submitting the standard.

(b) The Food and Drug Administration will publish a notice in the FEDERAL REGISTER stating either that it has accepted, or accepted with modification, as a proposed standard, an existing standard or one that has been

developed, or that an existing standard is not acceptable, together with the reasons therefor.

[45 FR 7484, Feb. 1, 1980, as amended at 57 FR 58405, Dec. 10, 1992]

§ 861.30 Development of standards.

The Food and Drug Administration (FDA), while engaged in the development of a proposed standard under this section will:

(a) Support its proposed performance standard by such test data or other documents or materials as may reasonably be required;

(b) Provide interested persons an opportunity to participate in the development of the standard by accepting comments and, where appropriate, holding public meetings on issues relating to development of the standard. Notice of the opportunity to participate in the development of the standard will be furnished in a manner reasonably calculated to reach the majority of persons interested in the development of the standard. This requirement shall be satisfied by publishing such a notice in the FEDERAL REGISTER. Whenever it is appropriate, FDA will use the FEDERAL REGISTER to make announcements about the standard development process of standard developers other than Federal agencies.

(c) Maintain records disclosing the course of development of the proposed standard, the comments and other information submitted by a person in connection with such development (including comments and information regarding the need for a standard), and such other information as may be required to evaluate the standard.

[45 FR 7484, Feb. 1, 1980, as amended at 57 FR 58405, Dec. 10, 1992]

§ 861.34 Amendment or revocation of a standard.

(a) The Food and Drug Administration will provide for periodic evaluation of performance standards to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

(b) The Food and Drug Administration may, on its own initiative or upon petition of an interested party, amend