### § 861.36 Effective dates.

(a) A regulation establishing, amending, or revoking a performance standard will set forth the date upon which it will take effect. To the extent practical, consistent with the public health and safety, such effective date will be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade.

(b) Except as provided in paragraph (c) of this section, no regulation establishing, amending, or revoking a standard may take effect before 1 year after the date of its publication unless:

(1) The Food and Drug Administration determines that an earlier effective date is necessary to protect the public health and safety; or

(2) The standard has been established for a device that, by the effective date of the standard, has been reclassified from class III to class II.

(c) The Food and Drug Administration may declare a proposed regulation amending a standard effective on publication in the FEDERAL REGISTER if it determines that making the regulation so effective is in the public interest. A proposed amendment of a performance standard made effective upon publication may not prohibit the introduction or delivery for introduction into interstate commerce of a device that conforms to the standard without the change or changes provided in the proposed amendment until the effective date of any final action on the proposal.

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

### § 861.38 Standards advisory committees.

(a) The Food and Drug Administration will establish advisory committees to which proposed regulations may be referred, and these committees shall consider such referrals in accordance with this section and part 14 of this chapter. Such advisory committees, which may not be classification panels, shall be considered ad hoc advisory committees. Their members shall be selected in accordance with §§ 14.82 and 14.84, except that no member may be a regular full-time FDA employee. Each advisory committee established under this section shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry.

(b) A proposed regulation to establish, amend, or revoke a performance standard shall be referred to an advisory committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment if:

(1) The Food and Drug Administration determines that such referral is necessary or appropriate under the circumstances; or

(2) Requested by an interested person, in the form of a citizen petition in accordance with § 10.30 of this chapter, which is made within the period provided for comment on the proposed regulation and which demonstrates good cause for referral.

(c) When a proposed regulation is referred to an advisory committee, the Food and Drug Administration will furnish the committee with the data and information upon which the proposed regulation is based. After independently reviewing the materials furnished by the Food and Drug Administration and any other available data and information, the advisory committee shall, within 60 days of the referral, submit a report and recommendation on the proposed regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of the report and recommendation will be publicly displayed in the office of the Division of Dockets Management, Food and Drug Administration.

(d) Where appropriate, each proposed regulation establishing a standard published in the FEDERAL REGISTER will include a call for nominations to the advisory committee for that particular standard.

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