

## § 860.130

## 21 CFR Ch. I (4-1-03 Edition)

required, or chooses, to consult with a panel concerning a reclassification petition, such as under § 860.130, § 860.132, or § 860.136, the Commissioner will distribute a copy of the petition, or its relevant portions, to each panel member and will consult with the panel in one of the following ways:

(1) Consultation by telephone with at least a majority of current voting panel members and, when possible, nonvoting panel members;

(2) Consultation by mail with at least a majority of current voting panel members and, when possible, nonvoting panel members; and

(3) Discussion at a panel meeting.

(b) The method of consultation chosen by the Commissioner will depend upon the importance and complexity of the subject matter involved and the time available for action. When time and circumstances permit, the Commissioner will consult with a panel through discussion at a panel meeting.

(c) When a petition is submitted under § 860.134 for a post-enactment, not substantially equivalent device ("new device"), in consulting with the panel the Commissioner will obtain a recommendation that includes the information described in § 860.84(d). In consulting with a panel about a petition submitted under § 860.130, § 860.132, or § 860.136, the Commissioner may or may not obtain a formal recommendation.

### **§ 860.130 General procedures under section 513(e) of the act.**

(a) Section 513(e) of the act applies to reclassification proceedings under the act based upon new information.

(b) A proceeding to reclassify a device under section 513(e) may be initiated:

(1) On the initiative of the Commissioner alone;

(2) On the initiative of the Commissioner in response to a request for change in classification based upon new information, under section 514(b) or 515(b) of the act (see § 860.132); or

(3) In response to the petition of an interested person, based upon new information, filed in accordance with § 860.123.

(c) By regulation promulgated under this section, the Commissioner may

change the classification from class III into:

(1) Class II if the Commissioner determines that special controls in addition to general controls would provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls to provide assurance; or

(2) Class I if the Commissioner determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

(d) The rulemaking procedures in § 10.40 of this chapter apply to proceedings to reclassify a device under section 513(e), except that the Commissioner may secure a recommendation with respect to a proposed reclassification from the classification panel to which the device was last referred. The panel will consider a proposed reclassification submitted to it by the Commissioner in accordance with the consultation procedures of § 860.125. Any recommendation submitted to the Commissioner by the panel will be published in the FEDERAL REGISTER when the Commissioner promulgates a regulation under this section.

(e) Within 180 days after the filing of a petition for reclassification under this section, the Commissioner, by order published in the FEDERAL REGISTER, will either deny the petition or give notice of his intent to initiate a change in the classification of the device.

(f) If a device is reclassified under this section, the regulation effecting the reclassification may revoke any special control or premarket approval requirement that previously applied to the device but that is no longer applicable because of the change in classification.

(g) A regulation under this section changing the classification of a device from class III to class II may provide that such classification will not take effect until the effective date of a special control for the device established under section 514 of the act.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992]