

§ 860.125

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(9) Copies of source documents from which new information used to support the petition has been obtained (attached as appendices to the petition).

(10) A financial certification or disclosure statement or both as required by part 54 of this chapter.

(b) Each petition submitted pursuant to this section shall be:

(1) Addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Regulations Staff (HFZ-215), 1350 Piccard Dr., Rockville, MD 20857;

(2) Marked clearly with the section of the act under which the petition is being submitted, i.e., “513(e),” “513(f),” “514(b),” “515(b),” or “520(l) Petition”;

(3) Bound in a volume or volumes, where necessary; and

(4) Submitted in an original and two copies.

[43 FR 32993, July 28, 1978, as amended at 49 FR 14505, Apr. 12, 1984; 53 FR 11253, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990; 63 FR 5254, Feb. 2, 1998; 65 FR 17137, Mar. 31, 2000]

§ 860.125 Consultation with panels.

(a) When the Commissioner is required to refer a reclassification petition to a classification panel for its recommendation under § 860.134, or is 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