

significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

(j) *Petition* means a submission seeking reclassification of a device in accordance with § 860.123.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58403, Dec. 10, 1992; 65 FR 56480, Sept. 19, 2000]

**§ 860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.**

(a) This section governs the availability for public disclosure and the use by the Commissioner of data and information submitted to classification panels or to the Commissioner in connection with the classification or reclassification of devices under this part.

(b) In general, data and information submitted to classification panels in connection with the classification of devices under § 860.84 will be available immediately for public disclosure upon request. However, except as provided by the special rules in paragraph (c) of this section, this provision does not apply to data and information exempt from public disclosure in accordance with part 20 of this chapter: Such data and information will be available only in accordance with part 20.

(c)(1) Safety and effectiveness data submitted to classification panels or to the Commissioner in connection with the classification of a device under § 860.84, which have not been disclosed previously to the public, as described in § 20.81 of this chapter, shall be regarded as confidential if the device is classified in to class III. Because the classification of a device under § 860.84 may be ascertained only upon publication of a final regulation, all safety and effectiveness data that have not been disclosed previously are not available for public disclosure unless and until the device is classified into class I or II, in which case the procedure in paragraph (c)(2) of this section applies.

(2) Thirty days after publication of a final regulation under § 860.84

classifying a device into class I or class II, safety and effectiveness data submitted for that device that had been regarded as confidential under paragraph (c)(1) of this section will be available for public disclosure and placed on public display in the office of the Dockets Management Branch, Food and Drug Administration unless, within that 30-day period, the person who submitted the data demonstrates that the data still fall within the exemption for trade secrets and confidential commercial information described in § 20.61 of this chapter. Safety and effectiveness data submitted for a device that is classified into class III by regulation in accordance with § 860.84 will remain confidential and unavailable for public disclosure so long as such data have not been disclosed to the public as described in § 20.81 of this chapter.

(3) Because device classification affects generic types of devices, in making determinations under § 860.84 concerning the initial classification of a device, the classification panels and the Commissioner may consider safety and effectiveness data developed for another device in the same generic type, regardless of whether such data are regarded currently as confidential under paragraph (c)(1) of this section.

(d)(1) The fact of its existence and the contents of a petition for reclassification filed in accordance with § 860.130 or § 860.132 are available for public disclosure at the time the petition is received by the Food and Drug Administration.

(2) The fact of the existence of a petition for reclassification filed in accordance with § 860.134 or § 860.136 is available for public disclosure at the time the petition is received by the Food and Drug Administration. The contents of such a petition are not available for public disclosure for the period of time following its receipt (not longer than 30 days) during which the petition is reviewed for any deficiencies preventing the Commissioner from making a decision on it. Once it is determined that the petition contains no deficiencies preventing the Commissioner from making a decision on it, the petition will be filed with the Dockets Management Branch and its entire contents will be available for public disclosure

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and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. If, during this 30-day period of time, the petition is found to contain deficiencies that prevent the Commissioner from making a decision on it, the petitioner will be so notified and afforded an opportunity to correct the deficiencies.

Thirty days after notice to the petitioner of deficiencies in the petition, the contents of the petition will be available for public disclosure unless, within that 30 days, the petitioner submits supplemental material intended to correct the deficiencies in the petition. The Commissioner, in the Commissioner's discretion, may allow withdrawal of a deficient petition during the 30-day period provided for correcting deficiencies. Any supplemental material submitted by the petitioner, together with the material in the original petition, is considered as a new petition. The new petition is reviewed for deficiencies in the same manner as the original petition, and the same procedures for notification and correction of deficiencies are followed. Once the petitioner has corrected the deficiencies, the entire contents of the petition will be available for public disclosure and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. Deficient petitions which have not been corrected within 180 days after notification of deficiency will be returned to the petitioner and will not be considered further unless resubmitted.

(e) The Commissioner may not disclose, or use as the basis for reclassification of a device from class III to class II, any information reported to or otherwise obtained by the Commissioner under section 513, 514, 515, 516, 518, 519, 520(f), 520(g), or 704 of the act that falls within the exemption described in § 20.61 of this chapter for trade secrets and confidential commercial information. The exemption described in § 20.61 does not apply to data or information contained in a petition for reclassification submitted in accordance with § 860.130 or § 860.132, or in a petition submitted in accordance with § 860.134 or § 860.136 that has been determined to contain no deficiencies

that prevent the Commissioner from making a decision on it. Accordingly, all data and information contained in such petitions may be disclosed by the Commissioner and used as the basis for reclassification of a device from class III to class II.

(f) For purposes of this section, safety and effectiveness data include data and results derived from all studies and tests of a device on animals and humans and from all studies and tests of the device itself intended to establish or determine its safety and effectiveness.

### § 860.7 Determination of safety and effectiveness.

(a) The classification panels, in reviewing evidence concerning the safety and effectiveness of a device and in preparing advice to the Commissioner, and the Commissioner, in making determinations concerning the safety and effectiveness of a device, will apply the rules in this section.

(b) In determining the safety and effectiveness of a device for purposes of classification, establishment of performance standards for class II devices, and premarket approval of class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors:

(1) The persons for whose use the device is represented or intended;

(2) The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

(3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

(4) The reliability of the device.

(c)(1) Although the manufacturer may submit any form of evidence to the Food and Drug Administration in an attempt to substantiate the safety and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will