

## § 860.136

§ 860.95, relating to exemptions from certain requirements of the act.

(7) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

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

### **§ 860.136 Procedures for transitional products under section 520(l) of the act.**

(a) Section 520(l)(2) of the act applies to reclassification proceedings initiated by a manufacturer or importer for reclassification of a device currently in class III by operation of section 520(l)(1) of the act. This section applies only to devices that the Food and Drug Administration regarded as "new drugs" before May 28, 1976.

(b) The procedures for effecting reclassification under section 520(l) are as follows:

(1) The manufacturer or importer of the device files a petition for reclassification of the device in accordance with § 860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it, allowing the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) The Commissioner provides the petitioner an opportunity for a regulatory hearing conducted in accordance with part 16 of this chapter.

(4) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.

(5) Within 180 days after the petition is filed (where the Commissioner has determined it to be adequate for review), the Commissioner, by order in the form of a letter to the petitioner, either denies the petition or classifies the device into class I or class II in accordance with the criteria set forth in § 860.3(c).

(6) Within a reasonable time after issuance of an order under this section,

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the Commissioner announces the order by notice published in the FEDERAL REGISTER.

### **PART 861—PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT**

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AUTHORITY: 21 U.S.C. 351, 352, 360c, 360d, 360gg-360ss, 371, 374; 42 U.S.C. 262, 264.

SOURCE: 45 FR 7484, Feb. 1, 1980, unless otherwise noted.

#### **Subpart A—General**

##### **§ 861.1 Purpose and scope.**

(a) This part implements section 514 of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the establishment, amendment, and revocation of performance standards applicable to devices intended for human use.

(b) The Food and Drug Administration may determine that a performance standard, as described under special controls for class II devices in § 860.7(b) of this chapter, is necessary to provide reasonable assurance of the safety and effectiveness of the device. Performance standards may be established for:

(1) A class II device;

(2) A class III device which, upon the effective date of the standard, is reclassified into class II; and

(3) A class III device, as a condition to premarket approval under section 515 of the act, to reduce or eliminate a risk or risks associated with such device.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[45 FR 7484, Feb. 1, 1980, as amended at 45 FR 23686, Apr. 8, 1980; 57 FR 58404, Dec. 10, 1992]

#### § 861.5 Statement of policy.

In carrying out its duties under this section, the Food and Drug Administration will, to the maximum extent practical:

(a) Use personnel, facilities, and other technical support available in other Federal agencies;

(b) Consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(c) Invite participation, through conferences, workshops, or other means, by representatives of scientific, professional, industry, or consumer organizations who can make a significant contribution.

#### § 861.7 Contents of standards.

Any performance standard established under this part will include such provisions as the Food and Drug Administration determines are necessary to provide reasonable assurance of the safety and effectiveness of the device or devices for which it is established. Where necessary to provide such assurance, a standard will address (but need not be limited to):

(a) Performance characteristics of the device;

(b) The design, construction, components, ingredients, and properties of the device, and its compatibility with power systems and connections to such systems;

(c) The manufacturing processes and quality control procedures applicable to the device;

(d) Testing of the device on either a sample or a 100-percent basis by the manufacturer, or, if it is determined that no other more practical means are available to the Food and Drug Administration to assure the conformity of the device to the standard, providing for testing by the Food and Drug Administration or a third person to ensure that the device conforms to the standard;

(e) The publication of the results of each test or of certain tests of the device to show that the device conforms to the portions of the standard for which the test or tests were required;

(f) Manufacturers' certification to purchasers or to the Food and Drug Administration that the device conforms to the applicable performance standard;

(g) Restrictions on the sale and distribution of the device, but only to the extent authorized under section 520(e) of the act;

(h) The use, and the form and content, of labeling for the proper installation, maintenance, operation, and use of the device. Among the provisions that may be required in the labeling are warnings; storage and transportation information; expiration dates; the date and place of manufacture; the results that may be expected if the device is used properly; the ranges of accuracy of diagnostic information; instructions regarding the proper care of, and the proper components, accessories, or other equipment to be used with the device; and statements concerning the appropriate patient population, for example, a statement that the device is considered safe and effective only when used by, or in the treatment of, a patient who has been tested by particular designated procedures and found to have an illness or condition for which use of the device is indicated by a person skilled in the use of the device.

### Subpart B—Procedures for Performance Standards Development and Publication

#### § 861.20 Summary of standards development process.

The procedure by which a performance standard for a device may be established, amended, or revoked is as follows:

(a) The Food and Drug Administration (FDA) will publish in the FEDERAL REGISTER a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(1) A notice of proposed rulemaking for the establishment or amendment of