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

PART 861—PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT

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.

§ 861.7 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.

§ 861.17 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;
§ 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 a performance standard for a device will:

(i) Set forth a finding, with supporting justification, that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device;

(ii) Set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate;

(iii) Invite interested persons to submit to the Food and Drug Administration, requests for changes in the classification of the device pursuant to §860.132 of this chapter, based on new information relevant to the classification; and

(iv) Invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Commissioner of Food and Drugs.

(2) A notice of proposed rulemaking for the revocation of a performance standard will set forth a finding, with supporting justification, that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(b) A notice under this section will provide for a comment period of not less than 60 days.

(c) If, after publication of a notice under paragraph (a) of this section, FDA receives a request to change the classification of the device, FDA will,