

(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

**(2) Process**

Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a proposed guidance.

**(g) Rule of construction**

Nothing in this section shall be construed to affect—

(1) the criteria and standards for evaluating an application pursuant to section 360e(c) of this title, a report and request for classification under section 360c(f)(2) of this title, or a report under section 360(k) of this title, including the recognition of valid scientific evidence as described in section 360c(a)(3)(B) of this title and consideration and application of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

(2) the authority of the Secretary with respect to clinical holds under section 360j(g)(8)(A) of this title;

(3) the authority of the Secretary to act on an application pursuant to section 360e(d) of this title before completion of an establishment inspection, as the Secretary determines appropriate; or

(4) the authority of the Secretary with respect to postmarket surveillance under sections 360i(h) and 360l of this title.

(June 25, 1938, ch. 675, § 515C, as added Pub. L. 114-255, div. A, title III, § 3051(a), Dec. 13, 2016, 130 Stat. 1121.)

CODIFICATION

Section 3051(a) of Pub. L. 114-255, which directed amendment of chapter V of the Federal Food, Drug, and Cosmetic Act by adding section 515C “after section 515B, as added by section 3034(b)”, was executed by adding section 515C after section 515A of such Act to reflect the probable intent of Congress. Neither section 3034(b) nor any other provision of Pub. L. 114-255 added a section 515B.

**§ 360f. Banned devices**

**(a) General rule**

Whenever the Secretary finds, on the basis of all available data and information, that—

(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in

labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

**(b) Special effective date**

The Secretary may declare a proposed regulation under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation.

(June 25, 1938, ch. 675, § 516, as added Pub. L. 94-295, § 2, May 28, 1976, 90 Stat. 560; amended Pub. L. 101-629, § 18(d), Nov. 28, 1990, 104 Stat. 4529.)

AMENDMENTS

1990—Subsec. (a). Pub. L. 101-629 struck out “and after consultation with the appropriate panel or panels under section 360c of this title” after “data and information” in introductory provisions and struck out at end “The Secretary shall afford all interested persons opportunity for an informal hearing on a regulation proposed under this subsection.”

**§ 360g. Judicial review**

**(a) Petition; record**

Not later than thirty days after—

(1) the promulgation of a regulation under section 360c of this title classifying a device in class I, an administrative order changing the classification of a device to class I, or an order under subsection (f)(2) of such section reclassifying a device or denying a petition for reclassification of a device,

(2) the promulgation of a regulation under section 360d of this title establishing, amending, or revoking a performance standard for a device,

(3) the issuance of an order under section 360d(b)(2) or 360e(b)(2)(B) of this title denying a request for reclassification of a device,

(4) the promulgation of a regulation under paragraph (3) of section 360e(b) of this title requiring a device to have an approval of a premarket application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 360e(g)(1) or 360e(g)(2)(C) of this title,

(5) the promulgation of a regulation under section 360f of this title (other than a proposed