stitutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 360j(g) of this title.

**(2) Additional actions**

In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (d), the Secretary, in collaboration with the device sponsor, may, as appropriate—

(A) coordinate with the sponsor regarding early agreement on a data development plan;

(B) take steps to ensure that the design of clinical trials is as efficient and flexible as practicable, when scientifically appropriate;

(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection with regard to application for approval under section 360e(c) of this title; and

(D) agree in writing to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

**(f) Priority review guidance**

**(1) Content**

Not later than 1 year after December 13, 2016, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

(A) set forth the process by which a person may seek a designation under subsection (d);

(B) provide a template for requests under subsection (c);

(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 draft version of that 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 360*l* of this title.

(June 25, 1938, ch. 675, §515B, formerly §515C, as added Pub. L. 114–255, div. A, title III, §3051(a), Dec. 13, 2016, 130 Stat. 1121; renumbered §515B and amended Pub. L. 115–52, title IX, §901(f), (g), Aug. 18, 2017, 131 Stat. 1076, 1077.)

**Editorial Notes**

AMENDMENTS

2017—Pub. L. 115–52, §901(f)(1), made technical amendment to directory language of Pub. L. 114–255, §3051(a), which added this section.

Subsec. (f)(2). Pub. L. 115–52, §901(g), substituted ''a draft version of that guidance'' for ''a proposed guidance''.

**Statutory Notes and Related Subsidiaries**

EFFECTIVE DATE OF 2017 AMENDMENT

Pub. L. 115–52, title IX, §901(f), Aug. 18, 2017, 131 Stat. 1076, provided that the renumbering and amendment made by section 901(f) is effective as of the enactment of Pub. L. 114–255.

## §360e–4. Predetermined change control plans for devices

**(a) Approved devices**

**(1) In general**

Notwithstanding section 360e(d)(5)(A) of this title, a supplemental application shall not be required for a change to a device approved under section 360e of this title, if such change is consistent with a predetermined change control plan that is approved pursuant to paragraph (2).

**(2) Predetermined change control plan**

The Secretary may approve a predetermined change control plan submitted in an application, including a supplemental application, under section 360e of this title that describes planned changes that may be made to the device (and that would otherwise require a supplemental application under section 360e of this title), if the device remains safe and effective without any change.

**(3) Scope**

The Secretary may require that a change control plan include labeling required for safe

and effective use of the device as such device changes pursuant to such plan, notification requirements if the device does not function as intended pursuant to such plan, and performance requirements for changes made under the plan.

**(b) Cleared devices**

**(1) In general**

Notwithstanding section 360(k) of this title, a premarket notification shall not be required for a change to a device cleared under section 360(k) of this title, if such change is consistent with an established predetermined change control plan granted pursuant to paragraph (2).

**(2) Predetermined change control plan**

The Secretary may clear a predetermined change control plan submitted in a notification submitted under section 360(k) of this title that describes planned changes that may be made to the device (and that would otherwise require a new notification), if—

(A) the device remains safe and effective without any such change; and

(B) the device would remain substantially equivalent to the predicate.

**(3) Scope**

The Secretary may require that a change control plan include labeling required for safe and effective use of the device as such device changes pursuant to such plan, notification requirements if the device does not function as intended pursuant to such plan, and performance requirements for changes made under the plan.

**(c) Predicate devices**

In making a determination of substantial equivalence pursuant to section 360c(i) of this title, the Secretary shall not compare a device to changed versions of a device implemented in accordance with an established predetermined change control plan as a predicate device. Only the version of the device cleared or approved, prior to changes made under the predetermined change control plan, may be used by a sponsor as a predicate device.

(June 25, 1938, ch. 675, § 515C, as added Pub. L. 117–328, div. FF, title III, § 3308(a), Dec. 29, 2022, 136 Stat. 5835.)

**Editorial Notes**

PRIOR PROVISIONS

A prior section 515C of act June 25, 1938, was renumbered section 515B and is classified to section 360e–3 of this title.

## § 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 for one or more intended uses; 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 or to make such intended use or uses a banned intended use or uses. A device that is banned for one or more intended uses is not a legally marketed device under section 396 of this title when intended for such use or uses.

**(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; Pub. L. 117–328, div. FF, title III, § 3306(a), Dec. 29, 2022, 136 Stat. 5834.)

**Editorial Notes**

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, § 3306(a)(2), inserted ''or to make such intended use or uses a banned intended use or uses. A device that is banned for one or more intended uses is not a legally marketed device under section 396 of this title when intended for such use or uses'' after ''banned device'' in concluding provisions.

Subsec. (a)(1). Pub. L. 117–328, § 3306(a)(1), inserted ''for one or more intended uses'' before semicolon at end.

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.''

**Statutory Notes and Related Subsidiaries**

CONSTRUCTION OF 2022 AMENDMENT

Pub. L. 117–328, div. FF, title III, § 3306(b), Dec. 29, 2022, 136 Stat. 5834, provided that: ''Nothing in this section [amending this section] shall be construed to limit