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 the authority of the Secretary [of Health and Human Services] to amend, in accordance with section 516 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360f), as amended by this section, and chapter 5 of title 5, United States Code, regulations promulgated pursuant to such section 516, as amended by this section.''

§ 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 regulation made effective under subsection (b) of such section upon the regulation's publication) making a device a banned device,

(6) the issuance of an order under section 360j(f)(2) of this title,

(7) an order under section 360j(g)(4) of this title disapproving an application for an exemption of a device for investigational use or an order under section 360j(g)(5) of this title withdrawing such an exemption for a device,

(8) an order pursuant to section 360c(i) of this title, or

(9) a regulation under section 360e(i)(2) or 360j(*l*)(5)(B) of this title,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28. For purposes of this section, the term ''record'' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) Additional data, views, and arguments

If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify his findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and his recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

(c) Standard for review

Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5 and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation described in paragraph (2) or (5) of subsection (a) and an order issued after the review provided by section 360e(g) of this title shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

(d) Finality of judgments

The judgment of the court affirming or setting aside, in whole or in part, any regulation or