section (a) [amending this section] shall apply to human drug applications submitted after September 30, 2017.''

§ 360n–1. Priority review for qualified infectious disease products

(a) In general

If the Secretary designates a drug under section 355f(d) of this title as a qualified infectious disease product, then the Secretary shall give priority review to the first application submitted for approval for such drug under section 355(b) of this title, or section 262(a) of title 42, that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness.

(b) Construction

Nothing in this section shall prohibit the Secretary from giving priority review to a human drug application or efficacy supplement submitted for approval under section 355(b) of this title that otherwise meets the criteria for the Secretary to grant priority review.

(June 25, 1938, ch. 675, § 524A, as added Pub. L. 112–144, title VIII, § 802(a), July 9, 2012, 126 Stat. 1079; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(N), Dec. 13, 2016, 130 Stat. 1154; Pub. L. 117–328, div. FF, title III, § 3212(b), Dec. 29, 2022, 136 Stat. 5826.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328 inserted '', or section 262(a) of title 42, that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness'' before period at end.

2016—Pub. L. 114–255 designated existing provisions as subsec. (a), inserted heading, substituted ''the first application'' for ''any application'', and added subsec. (b).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Pub. L. 112–144, title VIII, § 802(b), July 9, 2012, 126 Stat. 1079, provided that: ''Section 524A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360n–1], as added by subsection (a), applies only with respect to an application that is submitted under section 505(b) of such Act (21 U.S.C. 355(b)) on or after the date of the enactment of this Act [July 9, 2012].''

§ 360n–2. Ensuring cybersecurity of devices

(a) In general

A person who submits an application or submission under section 360(k), 360c, 360e(c), 360e(f), or 360j(m) of this title for a device that meets the definition of a cyber device under this section shall include such information as the Secretary may require to ensure that such cyber device meets the cybersecurity requirements under subsection (b).

(b) Cybersecurity requirements

The sponsor of an application or submission described in subsection (a) shall—

(1) submit to the Secretary a plan to monitor, identify, and address, as appropriate, in a reasonable time, postmarket cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and related procedures;

(2) design, develop, and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure, and make available postmarket updates and patches to the device and related systems to address—

(A) on a reasonably justified regular cycle, known unacceptable vulnerabilities; and

(B) as soon as possible out of cycle, critical vulnerabilities that could cause uncontrolled risks;

(3) provide to the Secretary a software bill of materials, including commercial, open-source, and off-the-shelf software components; and

(4) comply with such other requirements as the Secretary may require through regulation to demonstrate reasonable assurance that the device and related systems are cybersecure.

(c) Definition

In this section, the term ''cyber device'' means a device that—

(1) includes software validated, installed, or authorized by the sponsor as a device or in a device;

(2) has the ability to connect to the internet; and

(3) contains any such technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats.

(d) Exemption

The Secretary may identify devices, or categories or types of devices, that are exempt from meeting the cybersecurity requirements established by this section and regulations promulgated pursuant to this section. The Secretary shall publish in the Federal Register, and update, as appropriate, a list of the devices, or categories or types of devices, so identified by the Secretary.

(June 25, 1938, ch. 675, § 524B, as added Pub. L. 117–328, div. FF, title III, § 3305(a), Dec. 29, 2022, 136 Stat. 5832.)

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 90 days after Dec. 29, 2022, see section 3305(d) of Pub. L. 117–328, set out as an Effective Date of 2022 Amendment note under section 331 of this title.

CONSTRUCTION

Nothing in section 3305(a) of Pub. L. 117–328, which enacted this section, to be construed to affect the Secretary's of Health and Human Services authority related to ensuring that there is a reasonable assurance of the safety and effectiveness of devices, which may include ensuring that there is a reasonable assurance of the cybersecurity of certain cyber devices, including for devices approved or cleared prior to Dec. 29, 2022, see section 3305(c) of Pub. L. 117–328, set out as a Construction of 2022 Amendment note under section 331 of this title.

GUIDANCE FOR INDUSTRY AND FDA STAFF ON DEVICE CYBERSECURITY

Pub. L. 117–328, div. FF, title III, § 3305(e), Dec. 29, 2022, 136 Stat. 5833, provided that: ''Not later than 2 years after the date of enactment of this Act [Dec. 29, 2022], and periodically thereafter as appropriate, the

Secretary [of Health and Human Services], in consultation with the Director of the Cybersecurity and Infrastructure Security Agency, shall review and, as appropriate and after soliciting and receiving feedback from device manufacturers, health care providers, third-party-device servicers, patient advocates, and other appropriate stakeholders, update the guidance entitled 'Content of Premarket Submissions for Management of Cybersecurity in Medical Devices' (or a successor document).''

[For definition of ''device'' as used in section 3305(e) of Pub. L. 117–328, set out above, see section 321(h) of this title, as made applicable by section 3305(h) of Pub. L. 117–328, which is set out below.]

RESOURCES REGARDING CYBERSECURITY OF DEVICES

Pub. L. 117–328, div. FF, title III, §3305(f), Dec. 29, 2022, 136 Stat. 5834, provided that: ''Not later than 180 days after the date of enactment of this Act [Dec. 29, 2022], and not less than annually thereafter, the Secretary [of Health and Human Services] shall update public information provided by the Food and Drug Administration, including on the website of the Food and Drug Administration, with information regarding improving cybersecurity of devices. Such information shall include information on identifying and addressing cyber vulnerabilities for health care providers, health systems, and device manufacturers, and how such entities may access support through the Cybersecurity and Infrastructure Security Agency and other Federal entities, including the Department of Health and Human Services, to improve the cybersecurity of devices.''

[For definition of ''device'' as used in section 3305(f) of Pub. L. 117–328, set out above, see section 321(h) of this title, as made applicable by section 3305(h) of Pub. L. 117–328, which is set out below.]

DEFINITION

Pub. L. 117–328, div. FF, title III, §3305(h), Dec. 29, 2022, 136 Stat. 5834, provided that: ''In this section [enacting this section, amending section 331 of this title, and enacting provisions set out as notes under this section and section 331 of this title], the term 'device' has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).''

PART B—DRUGS FOR RARE DISEASES OR CONDITIONS

§ 360aa. Recommendations for investigations of drugs for rare diseases or conditions

(a) Request by sponsor; response by Secretary

The sponsor of a drug for a disease or condition which is rare in the States may request the Secretary to provide written recommendations for the non-clinical and clinical investigations which must be conducted with the drug before—

(1) it may be approved for such disease or condition under section 355 of this title, or

(2) if the drug is a biological product, it may be licensed for such disease or condition under section 262 of title 42.

If the Secretary has reason to believe that a drug for which a request is made under this section is a drug for a disease or condition which is rare in the States, the Secretary shall provide the person making the request written recommendations for the non-clinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request under this section, would be necessary for approval of such drug for such disease or condition under section 355 of this title or licensing of such drug for such disease or condition under section 262 of title 42.

(b) Regulations

The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

(June 25, 1938, ch. 675, §525, as added Pub. L. 97–414, §2(a), Jan. 4, 1983, 96 Stat. 2049; amended Pub. L. 99–91, §3(a)(1), Aug. 15, 1985, 99 Stat. 387; Pub. L. 105–115, title I, §125(b)(2)(F), (G), Nov. 21, 1997, 111 Stat. 2325, 2326.)

Editorial Notes

AMENDMENTS

1997—Subsec. (a). Pub. L. 105–115, §125(b)(2)(G), struck out '', certification of such drug for such disease or condition under section 357 of this title,'' before ''or licensing of such drug'' in closing provisions.

Subsec. (a)(1) to (3). Pub. L. 105–115, §125(b)(2)(F), inserted ''or'' at end of par. (1), redesignated par. (3) as (2), and struck out former par. (2), which read as follows: ''if the drug is an antibiotic, it may be certified for such disease or condition under section 357 of this title, or''.

1985—Subsec. (a). Pub. L. 99–91 struck out ''or'' at end of par. (1), inserted par. (2), redesignated former par. (2) as (3) and struck out ''before'' after ''product,'', and in last sentence inserted provisions relating to certification of such drug for disease or condition under section 357 of this title and substituted ''licensing of such drug for such disease or condition under section 262 of title 42'' for ''licensing under section 262 of title 42 for such disease or condition''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1985 AMENDMENT

Pub. L. 99–91, §8, Aug. 15, 1985, 99 Stat. 392, provided that:

''(a) GENERAL RULE.—Except as provided in subsection (b), this Act and the amendments made by this Act [amending this section, sections 360bb, 360cc, and 360ee of this title, and sections 295g–1 and 6022 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under section 301 of this title and section 236 of Title 42] shall take effect October 1, 1985.

''(b) EXCEPTION.—The amendments made by sections 2, 3, and 6(a) [amending this section and sections 360bb and 360cc of this title] shall take effect on the date of the enactment of this Act [Aug. 15, 1985]. The amendment made by section 6(b) [amending section 6022 of Title 42] shall take effect October 19, 1984. The amendments made by section 7 [amending section 295g–1 of Title 42] shall take effect October 1, 1984 and shall cease to be in effect after September 30, 1985.''

RARE DISEASE ENDPOINT ADVANCEMENT PILOT PROGRAM

Pub. L. 117–328, div. FF, title III, §3208, Dec. 29, 2022, 136 Stat. 5821, provided that:

''(a) IN GENERAL.—The Secretary [of Health and Human Services] shall establish a pilot program under which the Secretary establishes procedures to provide increased interaction with sponsors of rare disease drug development programs for purposes of advancing the development of efficacy endpoints, including surrogate and intermediate endpoints, for drugs intended to treat rare diseases, including through—

''(1) determining eligibility of participants for such program; and

''(2) developing and implementing a process for applying to, and participating in, such a program.

''(b) PUBLIC WORKSHOPS.—The Secretary shall conduct up to 3 public workshops, which shall be completed not later than September 30, 2026, to discuss topics relevant to the development of endpoints for rare diseases, which may include discussions about—

''(1) novel endpoints developed through the pilot program established under this section; and