

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