Subsec. (c). Pub. L. 117–328, § 3201(b), amended subsec. (c) generally. Prior to amendment, subsec. (c) related to an additional one-time report to be done within 180 days of Aug. 18, 2017.

Subsec. (d). Pub. L. 117–328, § 3201(c)(1), added subsec. (d) and struck out former subsec. (d). Prior to amendment, text read as follows: ''If a holder of an approved application fails to submit the information required under subsection (a), (b), or (c), the Secretary may move the application holder's drugs from the active section of the list published under subsection 355(j)(7)(A) of this title to the discontinued section of the list, except that the Secretary shall remove from the list in accordance with subsection 355(j)(7)(C) of this title drugs the Secretary determines have been withdrawn from sale for reasons of safety of effectiveness.''

Subsec. (e). Pub. L. 117–328, § 3201(d), substituted ''section 355(j)(7)(A) of this title'' for ''subsection 355(j)(7)(A) of this title'' and ''section 355(j)(7)(C) of this title'' for ''subsection 355(j)(7)(C) of this title''.

Pub. L. 117–328, § 3201(c)(2), inserted ''The Secretary shall update the list published under section 262(k)(9)(A) of title 42 based on information provided under subsections (a), (b), and (c) by identifying as discontinued biological products that are not available for sale, except that biological products for which the license has been revoked or suspended for safety, purity, or potency reasons shall be removed from the list in accordance with section 262(k)(9)(B) of title 42.'' before ''The Secretary shall make monthly updates'' and substituted ''monthly updates to the lists referred to in the preceding sentences'' for ''monthly updates to the list'' and ''and shall update such lists based on'' for ''and shall update the list based on''.

§ 356j. Discontinuance or interruption in the production of medical devices

(a) In general

A manufacturer of a device that—

(1) is critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery; or

(2) for which the Secretary determines that information on potential meaningful supply disruptions of such device is needed during, or in advance of, a public health emergency;

shall, during, or in advance of, a public health emergency declared by the Secretary under section 247d of title 42, notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the device (except for discontinuances as a result of an approved modification of the device) or an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States, and the reasons for such discontinuance or interruption.

(b) Timing

A notice required under subsection (a) shall be submitted to the Secretary—

(1) at least 6 months prior to the date of the discontinuance or interruption; or

(2) if compliance with paragraph (1) is not possible, as soon as practicable.

(c) Distribution

(1) Public availability

To the maximum extent practicable, subject to paragraph (2), the Secretary shall distribute, through such means as the Secretary determines appropriate, information on the discontinuance or interruption of the manufacture of devices reported under subsection (a) to appropriate organizations, including physician, health provider, patient organizations, and supply chain partners, as appropriate and applicable, as described in subsection (g).

(2) Public health exception

The Secretary may choose not to make information collected under this section publicly available pursuant to this section if the Secretary determines that disclosure of such information would adversely affect the public health, such as by increasing the possibility of unnecessary over purchase of product, component parts, or other disruption of the availability of medical products to patients.

(d) Confidentiality

Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(e) Failure to meet requirements

If a person fails to submit information required under subsection (a) in accordance with subsection (b)—

(1) the Secretary shall issue a letter to such person informing such person of such failure;

(2) not later than 30 calendar days after the issuance of a letter under paragraph (1), the person who receives such letter shall submit to the Secretary a written response to such letter setting forth the basis for noncompliance and providing information required under subsection (a); and

(3) not later than 45 calendar days after the issuance of a letter under paragraph (1), the Secretary shall make such letter and any response to such letter under paragraph (2) available to the public on the internet website of the Food and Drug Administration, with appropriate redactions made to protect information described in subsection (d), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of such response, the person had a reasonable basis for not notifying as required under subsection (a), the requirements of this paragraph shall not apply.

(f) Expedited inspections and reviews

If, based on notifications described in subsection (a) or (h) or any other relevant information, the Secretary concludes that there is, or is likely to be, a shortage of an[1] device, the Secretary shall, as appropriate—

(1) prioritize and expedite the review of a submission under section 360c(f)(2) of this title, 360e of this title, review of a notification under section 360(k) of this title, or 360j(m) of this title for a device that could help mitigate or prevent such shortage; or

(2) prioritize and expedite an inspection or reinspection of an establishment that could help mitigate or prevent such shortage.

[1] So in original. Probably should be ''a''.

(g) Device shortage list

(1) Establishment

The Secretary shall establish and maintain an up-to-date list of devices that are determined by the Secretary to be in shortage in the United States.

(2) Contents

For each device included on the list under paragraph (1), the Secretary shall include the following information:

(A) The category or name of the device in shortage.

(B) The name of each manufacturer of such device.

(C) The reason for the shortage, as determined by the Secretary, selecting from the following categories:

(i) Requirements related to complying with good manufacturing practices.

(ii) Regulatory delay.

(iii) Shortage or discontinuance of a component or part.

(iv) Discontinuance of the manufacture of the device.

(v) Delay in shipping of the device.

(vi) Delay in sterilization of the device.

(vii) Demand increase for the device.

(viii) Facility closure.

(D) The estimated duration of the shortage as determined by the Secretary.

(3) Public availability

(A) In general

Subject to subparagraphs (B) and (C), the Secretary shall make the information in the list under paragraph (1) publicly available.

(B) Trade secrets and confidential information

Nothing in this subsection shall be construed to alter or amend section 1905 of title 18 or section 552(b)(4) of title 5.

(C) Public health exception

The Secretary may elect not to make information collected under this subsection publicly available if the Secretary determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of the device to patients).

(h) Additional notifications

The Secretary may receive voluntary notifications from a manufacturer of a device that is life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery, or any other device the Secretary determines to be critical to the public health, pertaining to a permanent discontinuance in the manufacture of the device (except for any discontinuance as a result of an approved modification of the device) or an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States, and the reasons for such discontinuance or interruption.

(i) Rule of construction

Nothing in this section shall be construed to affect the authority of the Secretary on March 27, 2020, to expedite the review of devices under section 360e of this title, section 360e–3 of this title relating to the priority review program for devices, and section 360bbb–3 of this title relating to the emergency use authorization authorities.

(j) Definitions

In this section:

(1) Meaningful disruption

The term ''meaningful disruption''—

(A) means a change in production that is reasonably likely to lead to a reduction in the supply of a device by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product;

(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time, not to exceed 6 months;

(C) does not include interruptions in manufacturing of components or raw materials so long as such interruptions do not result in a shortage of the device and the manufacturer expects to resume operations in a reasonable period of time; and

(D) does not include interruptions in manufacturing that do not lead to a reduction in procedures or diagnostic tests associated with a medical device designed to perform more than one procedure or diagnostic test.

(2) Shortage

The term ''shortage'', with respect to a device, means a period of time when the demand or projected demand for the device within the United States exceeds the supply of the device.

(June 25, 1938, ch. 675, § 506J, as added Pub. L. 116–136, div. A, title III, § 3121, Mar. 27, 2020, 134 Stat. 363; amended Pub. L. 117–328, div. FF, title II, § 2514(a), Dec. 29, 2022, 136 Stat. 5805.)

Editorial Notes

AMENDMENTS

2022—Subsec. (f). Pub. L. 117–328, § 2514(a)(1), inserted ''or (h)'' after ''subsection (a)'' in introductory provisions.

Subsecs. (h) to (j). Pub. L. 117–328, § 2514(a)(2), (3), added subsec. (h) and redesignated former subsecs. (h) and (i) as (i) and (j), respectively.

Statutory Notes and Related Subsidiaries

GUIDANCE ON VOLUNTARY NOTIFICATIONS OF DISCONTINUANCE OR INTERRUPTION OF DEVICE MANUFACTURE

Pub. L. 117–328, div. FF, title II, § 2514(b), Dec. 29, 2022, 136 Stat. 5806, provided that: ''Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Secretary shall issue draft guidance to facilitate voluntary notifications under subsection (h) of section 506J of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j), as added by subsection (a). Such guidance shall include a description of circumstances in which a voluntary notification under such subsection (h) may be appropriate, recommended timeframes for such a notification, the process for receiving such a notification, and actions the Secretary may take to mitigate or prevent a shortage resulting from a discontinuance or

interruption in the manufacture of a device for which such notification is received. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.''

GUIDANCE ON DEVICE SHORTAGE NOTIFICATION REQUIREMENT

Pub. L. 117–328, div. FF, title II, § 2514(c), Dec. 29, 2022, 136 Stat. 5806, provided that: ''Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Secretary shall issue or revise draft guidance regarding requirements under section 506J of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j). Such guidance shall include a list of each device product code for which a manufacturer of such device is required to notify the Secretary in accordance with section 506J.''

§ 356k. Platform technologies

(a) In general

The Secretary shall establish a program for the designation of platform technologies that meet the criteria described in subsection (b).

(b) Criteria

A platform technology incorporated within or utilized by a drug or biological product is eligible for designation as a designated platform technology under this section if—

(1) the platform technology is incorporated in, or utilized by, a drug approved under section 355 of this title or a biological product licensed under section 351 of the Public Health Service Act [42 U.S.C. 262];

(2) preliminary evidence submitted by the sponsor of the approved or licensed drug described in paragraph (1), or a sponsor that has been granted a right of reference to data submitted in the application for such drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and

(3) data or information submitted by the applicable person under paragraph (2) indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process.

(c) Request for designation

A person may request the Secretary designate a platform technology as a designated platform technology concurrently with, or at any time after, submission under section 355(i) of this title or section 351(a)(3) of the Public Health Service Act [42 U.S.C. 262(a)(3)] for the investigation of a drug that incorporates or utilizes the platform technology that is the subject of the request.

(d) Designation

(1) In general

Not later than 90 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the platform technology that is the subject of the request meets the criteria described in subsection (b).

(2) Designation

If the Secretary determines that the platform technology meets the criteria described in subsection (b), the Secretary shall designate the platform technology as a designated platform technology and may expedite the development and review of any subsequent application submitted under section 355(b) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for a drug that uses or incorporates the platform technology pursuant to subsection (e), as appropriate.

(3) Determination not to designate

If the Secretary determines that the platform technology does not meet the criteria under subsection (b), the Secretary shall include with the determination not to designate the technology a written description of the rationale for such determination.

(4) Revocation of designation

The Secretary may revoke a designation made under paragraph (2), if the Secretary determines that the designated platform technology no longer meets the criteria described in subsection (b). The Secretary shall communicate the determination to revoke a designation to the requesting sponsor in writing, including a description of the rationale for such determination.

(5) Applicability

Nothing in this section shall prevent a product that uses or incorporates a designated platform technology from being eligible for expedited approval pathways if it is otherwise eligible under this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.].

(e) Actions

The Secretary may take actions to expedite the development and review of an application for a drug that incorporates or utilizes a designated platform technology, including—

(1) engaging in early interactions with the sponsor to discuss the use of the designated platform technology and what is known about such technology, including data previously submitted that is relevant to establishing, as applicable, safety or efficacy under section 355(b) of this title or safety, purity, or potency under section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)];

(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug that proposes to use the designated platform technology to ensure that the development program designed to gather data necessary for approval or licensure is as efficient as practicable, which may include holding meetings with the sponsor and the review team throughout the development of the drug; and

(3) considering inspectional findings, including prior findings, related to the manufacture of a drug that incorporates or utilizes the designated platform technology.

(f) Leveraging data from designated platform technologies

The Secretary shall, consistent with applicable standards for approval, authorization, or licensure under this chapter and section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)], allow the sponsor of an application under sec-