21 USC 356j: Discontinuance or interruption in the production of medical devices
Text contains those laws in effect on December 28, 2022
Pending Updates: Pub L. 117-328 (12/29/2022), Pub L. 117-328 (12/29/2022), Pub L. 117-328 (12/29/2022) **[View Details]**

From Title 21-FOOD AND DRUGS
CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER V-DRUGS AND DEVICES
Part A-Drugs and Devices
Jump To:
Source Credit

§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 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.

(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) 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.

(i) 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 .)

[1] *So in original. Probably should be "a".*