

risk than the health risk of not recalling the device from use, and

(ii) shall provide for notice to individuals subject to the risks associated with the use of such device.

In providing the notice required by clause (ii), the Secretary may use the assistance of health professionals who prescribed or used such a device for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 375(b) of this title.

(3) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).

(June 25, 1938, ch. 675, §518, as added Pub. L. 94-295, §2, May 28, 1976, 90 Stat. 562; amended Pub. L. 101-629, §8, Nov. 28, 1990, 104 Stat. 4520; Pub. L. 102-300, §4, June 16, 1992, 106 Stat. 239.)

AMENDMENTS

1992—Subsec. (b)(1)(A)(ii). Pub. L. 102-300 substituted “or” for “and” after “properly designed” and “time of its design”.

1990—Subsec. (e). Pub. L. 101-629 added subsec. (e).

§ 360h-1. Program to improve the device recall system

(a) In general

The Secretary shall—

(1) establish a program to routinely and systematically assess information relating to device recalls and use such information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices;

(2) clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform those checks in a consistent manner;

(3) develop detailed criteria for assessing whether a person performing a device recall has performed an effective correction or action plan for the recall; and

(4) document the basis for each termination by the Food and Drug Administration of a device recall.

(b) Assessment content

The program established under subsection (a)(1) shall, at a minimum, identify—

(1) trends in the number and types of device recalls;

(2) devices that are most frequently the subject of a recall; and

(3) underlying causes of device recalls.

(c) Definition

In this section, the term “recall” means—

(1) the removal from the market of a device pursuant to an order of the Secretary under subsection (b) or (e) of section 360h of this title; or

(2) the correction or removal from the market of a device at the initiative of the manufacturer or importer of the device that is required to be reported to the Secretary under section 360i(g) of this title.

(June 25, 1938, ch. 675, §518A, as added Pub. L. 112-144, title VI, §605, July 9, 2012, 126 Stat. 1053;

amended Pub. L. 114-255, div. A, title III, §3101(a)(2)(K), Dec. 13, 2016, 130 Stat. 1154.)

AMENDMENTS

2016—Subsecs. (c), (d). Pub. L. 114-255 redesignated subsec. (d) as (c) and struck out former subsec. (c). Prior to amendment, text read as follows: “The Secretary shall document the basis for the termination by the Food and Drug Administration of a device recall.”

§ 360i. Records and reports on devices

(a) General rule

Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

(1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—

(A) may have caused or contributed to a death or serious injury, or

(B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, which report under this subparagraph—

(i) shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations), unless the Secretary grants an exemption or variance from, or an alternative to, a requirement under such regulations pursuant to section 803.19 of such part, if the device involved is—

(I) a class III device;

(II) a class II device that is permanently implantable, is life supporting, or is life sustaining; or

(III) a type of device which the Secretary has, by notice published in the Federal Register or letter to the person who is the manufacturer or importer of the device, indicated should be subject to such part 803 in order to protect the public health;

(ii) shall, if the device is not subject to clause (i), be submitted in accordance with criteria established by the Secretary for reports made pursuant to this clause, which criteria shall require the reports to be in summary form and made on a quarterly basis; or

(iii) shall, if the device is imported into the United States and for which part 803 of title 21, Code of Federal Regulations (or successor regulations) requires an importer to submit a report to the manufacturer, be submitted by the importer to the manufacturer in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations)¹

¹ So in original. Probably should be followed by a semicolon.