

tion of an article of food that was the subject of a recall under section 350(b) of this title or a public health advisory described in paragraph (1).

(Pub. L. 111-353, title II, §206(f), Jan. 4, 2011, 124 Stat. 3943.)

#### Editorial Notes

##### REFERENCES IN TEXT

Subsection (a), referred to in par. (1), means subsec. (a) of section 206 of Pub. L. 111-353.

##### CODIFICATION

Section was enacted as part of the FDA Food Safety Modernization Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

#### Statutory Notes and Related Subsidiaries

##### CONSTRUCTION

Nothing in this section to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2252 of this title.

#### § 350m. Requirements for critical food

##### (a) Notification of meaningful disruption for critical food

###### (1) In general

A manufacturer of a critical food (as defined in section 321(ss) of this title) shall notify the Secretary of a permanent discontinuance in the manufacture or an interruption of the manufacture of such food that is likely to lead to a meaningful disruption in the supply of such food in the United States, and the reasons for such discontinuance or interruption, as soon as practicable, but not later than 5 business days after such discontinuance or such interruption.

###### (2) Distribution of information

Not later than 5 calendar days after receiving a notification under paragraph (1), if the Secretary has determined that such discontinuance or interruption has resulted, or is likely to result, in a shortage of such critical food, the Secretary shall distribute, to the Secretary of Agriculture and to the maximum extent practicable to the appropriate entities, as determined by the Secretary through such means as the Secretary determines appropriate, information on such shortage.

###### (3) Confidentiality

Nothing in this subsection authorizes 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.

###### (4) Meaningful disruption

In this subsection, the term “meaningful disruption”—

(A) means a change in production that is reasonably likely to lead to a significant reduction in the supply of a critical food by a manufacturer that affects the ability of the manufacturer to meet expected demand for its product; and

(B) does not include interruptions in manufacturing due to matters such as routine maintenance, changes or discontinuance of flavors, colors, or other insignificant formulation characteristics, or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

##### (b) Risk management plans

Each manufacturer of a critical food shall develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates risks to the supply of the food, as applicable, for each establishment in which such food is manufactured. A risk management plan under this subsection—

(1) may identify and evaluate risks to the supply of more than one critical food, or critical food category, manufactured at the same establishment;

(2) may identify mechanisms by which the manufacturer would mitigate the impacts of a supply disruption through alternative production sites, alternative suppliers, stockpiling of inventory, or other means; and

(3) shall be subject to inspection and copying by the Secretary pursuant to an inspection under section 374 of this title.

##### (c) Failure to meet requirements

###### (1) In general

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

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

(B) not later than 45 calendar days after the issuance of a letter under subparagraph (A), subject to paragraph (2), the Secretary shall make available to the public on the website of the Food and Drug Administration, with appropriate redactions made to protect the information described in subsection (a)(3)—

(i) the letter issued under subparagraph (A); and

(ii) at the request of such person, any response to such letter such person submitted to the Secretary.

###### (2) Exception

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 submitting a notification as required under subsection (a), the requirements of paragraph (1)(B) shall not apply.

(June 25, 1938, ch. 675, §424, as added Pub. L. 117-328, div. FF, title III, §3401(k), Dec. 29, 2022, 136 Stat. 5844.)

#### SUBCHAPTER V—DRUGS AND DEVICES

##### PART A—DRUGS AND DEVICES

#### § 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—