§ 356c–1. Annual reporting on drug shortages

(a) Annual reports to Congress

Not later than March 31 of each calendar year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report, with respect to the preceding calendar year, on drug shortages that—

(1) specifies the number of manufacturers that submitted a notification to the Secretary under section 356c(a) of this title during such calendar year;

(2) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and Drug Administration's procedures for enabling and ensuring such communication;

(3)(A) lists the major actions taken by the Secretary to prevent or mitigate the drug shortages described in paragraph (7);

(B) in the list under subparagraph (A), includes—

(i) the number of applications and supplements for which the Secretary expedited review under section 356c(g)(1) of this title during such calendar year; and

(ii) the number of establishment inspections or reinspections that the Secretary expedited under section 356c(g)(2) of this title during such calendar year;

(4) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

(5) identifies the number of and describes the instances in which the Food and Drug Administration exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage;

(6) lists the names of manufacturers that were issued letters under section 356c(f) of this title; and

(7) specifies the number of drug shortages occurring during such calendar year, as identified by the Secretary.

(b) Trend analysis

The Secretary is authorized to retain a third party to conduct a study, if the Secretary believes such a study would help clarify the causes, trends, or solutions related to drug shortages.

(c) Definition

In this section, the term ''drug shortage'' or ''shortage'' has the meaning given such term in section 356c of this title.

(June 25, 1938, ch. 675, § 506C–1, as added Pub. L. 112–144, title X, § 1002, July 9, 2012, 126 Stat. 1102; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(F), Dec. 13, 2016, 130 Stat. 1153.)

AMENDMENTS

2016—Subsec. (a). Pub. L. 114–255, in introductory provisions, substituted ''Not later than March 31 of each calendar year,'' for ''Not later than the end of calendar year 2013, and not later than the end of each calendar year thereafter,'' and inserted '', with respect to the preceding calendar year,'' after ''a report''.

§ 356d. Coordination; task force and strategic plan

(a) Task force and strategic plan

(1) In general

(A) Task force

As soon as practicable after July 9, 2012, the Secretary shall establish a task force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages.

(B) Strategic plan

The strategic plan described in subparagraph (A) shall include—

(i) plans for enhanced interagency and intra-agency coordination, communication, and decisionmaking;

(ii) plans for ensuring that drug shortages are considered when the Secretary initiates a regulatory action that could precipitate a drug shortage or exacerbate an existing drug shortage;

(iii) plans for effective communication with outside stakeholders, including who the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared;

(iv) plans for considering the impact of drug shortages on research and clinical trials; and

(v) an examination of whether to establish a ''qualified manufacturing partner program'', as described in subparagraph (C).

(C) Description of program

In conducting the examination of a ''qualified manufacturing partner program'' under subparagraph (B)(v), the Secretary—

(i) shall take into account that—

(I) a ''qualified manufacturer'', for purposes of such program, would need to have the capability and capacity to supply products determined or anticipated to be in shortage; and

(II) in examining the capability and capacity to supply products in shortage, the ''qualified manufacturer'' could have a site that manufactures a drug listed under section 356e of this title or have the capacity to produce drugs in response to a shortage within a rapid timeframe; and

(ii) shall examine whether incentives are necessary to encourage the participation of ''qualified manufacturers'' in such a program.

(D) Consultation

In carrying out this paragraph, the task force shall ensure consultation with the appropriate offices within the Food and Drug Administration, including the Office of the Commissioner, the Center for Drug Evaluation and Research, the Office of Regulatory Affairs, and employees within the Depart-

ment of Health and Human Services with expertise regarding drug shortages. The Secretary shall engage external stakeholders and experts as appropriate.

(2) Timing

Not later than 1 year after July 9, 2012, the task force shall—

(A) publish the strategic plan described in paragraph (1); and

(B) submit such plan to Congress.

(b) Communication

The Secretary shall ensure that, prior to any enforcement action or issuance of a warning letter that the Secretary determines could reasonably be anticipated to lead to a meaningful disruption in the supply in the United States of a drug described under section 356c(a) of this title, there is communication with the appropriate office of the Food and Drug Administration with expertise regarding drug shortages regarding whether the action or letter could cause, or exacerbate, a shortage of the drug.

(c) Action

If the Secretary determines, after the communication described in subsection (b), that an enforcement action or a warning letter could reasonably cause or exacerbate a shortage of a drug described under section 356c(a) of this title, then the Secretary shall evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking such action or issuing such letter, unless there is imminent risk of serious adverse health consequences or death to humans.

(d) Reporting by other entities

The Secretary shall identify or establish a mechanism by which health care providers and other third-party organizations may report to the Secretary evidence of a drug shortage.

(e) Review and construction

No determination, finding, action, or omission of the Secretary under this section shall—

(1) be subject to judicial review; or

(2) be construed to establish a defense to an enforcement action by the Secretary.

(f) Sunset

Subsections (a), (b), (c), and (e) shall cease to be effective on the date that is 5 years after July 9, 2012.

(June 25, 1938, ch. 675, § 506D, as added Pub. L. 112–144, title X, § 1003, July 9, 2012, 126 Stat. 1103.)

§ 356e. Drug shortage list

(a) Establishment

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

(b) Contents

For each drug on such list, the Secretary shall include the following information:

(1) The name of the drug in shortage, including the National Drug Code number for such drug.

(2) The name of each manufacturer of such drug.

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

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

(B) Regulatory delay.

(C) Shortage of an active ingredient.

(D) Shortage of an inactive ingredient component.

(E) Discontinuance of the manufacture of the drug.

(F) Delay in shipping of the drug.

(G) Demand increase for the drug.

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

(c) Public availability

(1) In general

Subject to paragraphs (2) and (3), the Secretary shall make the information in such list publicly available.

(2) Trade secrets and confidential information

Nothing in this section alters or amends section 1905 of title 18 or section 552(b)(4) of title 5.

(3) Public health exception

The Secretary may choose not to make information collected under this section publicly available under paragraph (1) or section 356c(c) of this title 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 drug products to patients).

(June 25, 1938, ch. 675, § 506E, as added Pub. L. 112–144, title X, § 1004, July 9, 2012, 126 Stat. 1104; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(G), Dec. 13, 2016, 130 Stat. 1153.)

AMENDMENTS

2016—Subsec. (b)(3)(E). Pub. L. 114–255, which directed substitution of ''discontinuance'' for ''discontinuation'', was executed by substituting ''Discontinuance'' for ''Discontinuation'' to reflect the probable intent of Congress.

§ 356f. Hospital repackaging of drugs in shortage

(a) Definitions

In this section:

(1) Drug

The term ''drug'' excludes any controlled substance (as such term is defined in section 802 of this title).

(2) Health system

The term ''health system'' means a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

(3) Repackage

For the purposes of this section only, the term ''repackage'', with respect to a drug, means to divide the volume of a drug into smaller amounts in order to—

(A) extend the supply of a drug in response to the placement of the drug on a drug