(1) be subject to judicial review; or

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

(f) Temporary sunset

Subsection (a) shall cease to be effective on the date that is 5 years after July 9, 2012. Subsections (b), (c), and (e) shall not be in effect during the period beginning 5 years after July 9, 2012, and ending on December 29, 2022. Subsections (b), (c), and (e) shall be in effect beginning on December 29, 2022.

(g) Coordination

The Secretary shall ensure timely and effective internal coordination and alignment among 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 regarding—

(1) the reviews of reports shared pursuant to section 374(b)(2) of this title; and

(2) any feedback or corrective or preventive actions in response to such reports.

(June 25, 1938, ch. 675, § 506D, as added Pub. L. 112–144, title X, § 1003, July 9, 2012, 126 Stat. 1103; amended Pub. L. 117–328, div. FF, title III, § 3616(a), Dec. 29, 2022, 136 Stat. 5874.)

Editorial Notes

AMENDMENTS

2022—Subsec. (f). Pub. L. 117–328, § 3616(a)(2), amended subsec. (f) generally. Prior to amendment, text read as follows: ''Subsections (a), (b), (c), and (e) shall cease to be effective on the date that is 5 years after July 9, 2012.''

Subsec. (g). Pub. L. 117–328, § 3616(a)(1), added subsec. (g).

§ 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).

(d) Interagency notification

Not later than 180 days after March 27, 2020, and every 90 days thereafter, the Secretary shall transmit a report regarding the drugs of the current drug shortage list under this section to the Administrator of the Centers for Medicare & Medicaid Services.

(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; Pub. L. 116–136, div. A, title III, § 3112(c), Mar. 27, 2020, 134 Stat. 362.)

Editorial Notes

AMENDMENTS

2020—Subsec. (d). Pub. L. 116–136 added subsec. (d).

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.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116–136 effective 180 days after Mar. 27, 2020, see section 3112(g) of Pub. L. 116–136, set out as a note under section 356c of this title.

§ 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 shortage list under section 356e of this title; and