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) Discontinuation 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.)

§ 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

(B) facilitate access to the drug by hospitals within the same health system.

(b) Exclusion from registration

Notwithstanding any other provision of this chapter, a hospital shall not be considered an establishment for which registration is required under section 360 of this title solely because it repackages a drug and transfers it to another hospital within the same health system in accordance with the conditions in subsection (c)—

(1) during any period in which the drug is listed on the drug shortage list under section 356e of this title; or

(2) during the 60-day period following any period described in paragraph (1).

(c) Conditions

Subsection (b) shall only apply to a hospital, with respect to the repackaging of a drug for transfer to another hospital within the same health system, if the following conditions are met:

(1) Drug for intrasystem use only

In no case may a drug that has been repackaged in accordance with this section be sold or otherwise distributed by the health system or a hospital within the system to an entity or

individual that is not a hospital within such health system.

(2) Compliance with State rules

Repackaging of a drug under this section shall be done in compliance with applicable State requirements of each State in which the drug is repackaged and received.

(d) Termination

This section shall not apply on or after the date on which the Secretary issues final guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transferring repackaged drugs to other hospitals within the same health system during a drug shortage.

(June 25, 1938, ch. 675, § 506F, as added Pub. L. 112–144, title X, § 1007, July 9, 2012, 126 Stat. 1106.)

§ 357. Repealed. Pub. L. 105–115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325

Section, act June 25, 1938, ch. 675, § 507, as added July 6, 1945, ch. 281, § 3, 59 Stat. 463; amended Mar. 10, 1947, ch. 16, § 3, 61 Stat. 12; July 13, 1949, ch. 305, § 2, 63 Stat. 409; Aug. 5, 1953, ch. 334, § 2, 67 Stat. 389; Pub. L. 87–781, title I, §§ 105(a), (b), (d)–(f), 106(a), (b), Oct. 10, 1962, 76 Stat. 785, 786, 787; Pub. L. 90–399, § 105(b), July 13, 1968, 82 Stat. 352; Pub. L. 102–300, § 6(b)(2), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, § 3(p), Aug. 13, 1993, 107 Stat. 777, related to certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug.

§ 358. Authority to designate official names

(a) Necessity or desirability; use in official compendiums; infringement of trademarks

The Secretary may designate an official name for any drug or device if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Any official name designated under this section for any drug or device shall be the only official name of that drug or device used in any official compendium published after such name has been prescribed or for any other purpose of this chapter. In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark.

(b) Review of names in official compendiums

Within a reasonable time after October 10, 1962, and at such other times as he may deem necessary, the Secretary shall cause a review to be made of the official names by which drugs are identified in the official United States Pharmacopoeia, the official Homoeopathic Pharmacopoeia of the United States, and the official National Formulary, and all supplements thereto, and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto) to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

(c) Determinations of complexity, usefulness, multiplicity, or lack of name; designation by Secretary

Whenever he determines after any such review that (1) any such official name is unduly complex or is not useful for any other reason, (2) two or more official names have been applied to a single drug or device, or to two or more drugs which are identical in chemical structure and pharmacological action and which are substantially identical in strength, quality, and purity, or to two or more devices which are substantially equivalent in design and purpose or (3) no official name has been applied to a medically useful drug or device, he shall transmit in writing to the compiler of each official compendium in which that drug or drugs or device are identified and recognized his request for the recommendation of a single official name for such drug or drugs or device which will have usefulness and simplicity. Whenever such a single official name has not been recommended within one hundred and eighty days after such request, or the Secretary determines that any name so recommended is not useful for any reason, he shall designate a single official name for such drug or drugs or device. Whenever he determines that the name so recommended is useful, he shall designate that name as the official name of such drug or drugs or device. Such designation shall be made as a regulation upon public notice and in accordance with the procedure set forth in section 553 of title 5.

(d) Revised official names; compilation, publication, and public distribution of listings

After each such review, and at such other times as the Secretary may determine to be necessary or desirable, the Secretary shall cause to be compiled, published, and publicly distributed a list which shall list all revised official names of drugs or devices designated under this section and shall contain such descriptive and explanatory matter as the Secretary may determine to be required for the effective use of those names.

(e) Request by compiler of official compendium for designation of name

Upon a request in writing by any compiler of an official compendium that the Secretary exercise the authority granted to him under subsection (a) of this section, he shall upon public notice and in accordance with the procedure set forth in section 553 of title 5 designate the official name of the drug or device for which the request is made.

(June 25, 1938, ch. 675, § 508, as added Pub. L. 87–781, title I, § 111(a), Oct. 10, 1962, 76 Stat. 789; amended Pub. L. 94–295, § 5(b), May 28, 1976, 90 Stat. 581; Pub. L. 103–80, § 3(q), Aug. 13, 1993, 107 Stat. 777.)

AMENDMENTS

1993—Subsecs. (c), (e). Pub. L. 103–80 substituted reference to section 553 of title 5 for ''section 4 of the Administrative Procedure Act (5 U.S.C. 1003)''.

1976—Subsec. (a). Pub. L. 94–295 substituted ''drug or device'' for ''drug'' wherever appearing.

Subsec. (b). Pub. L. 94–295 substituted ''National Formulary, and all supplements thereto, and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto)'' for ''National Formulary, and all supplements thereto,''.

Subsec. (c)(2). Pub. L. 94–295 inserted ''or device'' after ''single drug'', and ''or to two or more devices which are substantially equivalent in design and purpose'' after ''purity,''.