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

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.)

§ 356g. Standards for regenerative medicine and regenerative advanced therapies

(a) In general

Not later than 2 years after December 13, 2016, the Secretary, in consultation with the National Institute of Standards and Technology and stakeholders (including regenerative medicine and advanced therapies manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, practicing clinicians, regenerative medicine and advanced therapies industry organizations, and standard setting organizations), shall facilitate an effort to coordinate and prioritize the development of standards and consensus definition of terms, through a public process, to support, through regulatory predictability, the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies, including with respect to the manufacturing processes and controls of such products.

(b) Activities

(1) In general

In carrying out this section, the Secretary shall continue to—

(A) identity[1] opportunities to help advance the development of regenerative medicine therapies and regenerative advanced therapies;

(B) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would help support the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies through regulatory predictability; and

(C) work with stakeholders, such as those described in subsection (a), as appropriate, in the development of such standards.

(2) Regulations and guidance

Not later than 1 year after the development of standards as described in subsection (a), the Secretary shall review relevant regulations and guidance and, through a public process, update such regulations and guidance as the Secretary determines appropriate.

(c) Definitions

For purposes of this section, the terms ''regenerative medicine therapy'' and ''regenerative advanced therapy'' have the meanings given such terms in section 356(g) of this title.

(June 25, 1938, ch. 675, § 506G, as added Pub. L. 114–255, div. A, title III, § 3036, Dec. 13, 2016, 130 Stat. 1104.)

GUIDANCE REGARDING DEVICES USED IN THE RECOVERY, ISOLATION, OR DELIVERY OF REGENERATIVE ADVANCED THERAPIES

Pub. L. 114–255, div. A, title III, § 3034, Dec. 13, 2016, 130 Stat. 1103, provided that:

''(a) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of the 21st Century Cures Act [Dec. 13, 2016], the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance clarifying how, in the context of regenerative advanced therapies, the Secretary will evaluate devices used in the recovery, isolation, or delivery of regenerative advanced therapies. In doing so, the Secretary shall specifically address—

''(1) how the Food and Drug Administration intends to simplify and streamline regulatory requirements for combination device and cell or tissue products;

''(2) what, if any, intended uses or specific attributes would result in a device used with a regenerative therapy product to be classified as a class III device;

''(3) when the Food and Drug Administration considers it is necessary, if ever, for the intended use of a device to be limited to a specific intended use with only one particular type of cell; and

''(4) application of the least burdensome approach to demonstrate how a device may be used with more than one cell type.

''(b) FINAL GUIDANCE.—Not later than 12 months after the close of the period for public comment on the draft guidance under subsection (a), the Secretary of Health and Human Services shall finalize such guidance.''

[1] So in original. Probably should be ''identify''.