(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) identify 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; amended Pub. L. 115–52, title IX, § 901(b), Aug. 18, 2017, 131 Stat. 1076.)

Editorial Notes

AMENDMENTS

2017—Subsec. (b)(1)(A). Pub. L. 115–52 substituted ''identify'' for ''identity''.

Statutory Notes and Related Subsidiaries

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.''

§ 356h. Competitive generic therapies

(a) In general

The Secretary may, at the request of an applicant of a drug that is designated as a competitive generic therapy pursuant to subsection (b), expedite the development and review of an abbreviated new drug application under section 355(j) of this title for such drug.

(b) Designation process

(1) Request

The applicant may request the Secretary to designate the drug as a competitive generic therapy.

(2) Timing

A request under paragraph (1) may be made concurrently with, or at any time prior to, the submission of an abbreviated new drug application for the drug under section 355(j) of this title.

(3) Criteria

A drug is eligible for designation as a competitive generic therapy under this section if the Secretary determines that there is inadequate generic competition.

(4) Designation

Not later than 60 calendar days after the receipt of a request under paragraph (1), the Secretary may—

(A) determine whether the drug that is the subject of the request meets the criteria described in paragraph (3); and

(B) if the Secretary finds that the drug meets such criteria, designate the drug as a competitive generic therapy.

(c) Actions

In expediting the development and review of an application under subsection (a), the Secretary may, as requested by the applicant, take actions including the following:

(1) Hold meetings with the applicant and the review team throughout the development of the drug prior to submission of the application for such drug under section 355(j) of this title.

(2) Provide timely advice to, and interactive communication with, the applicant regarding the development of the drug to ensure that the development program to gather the data necessary for approval is as efficient as practicable.

(3) Involve senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review of such application, including with respect to drug-device combination products and other complex products.

(4) Assign a cross-disciplinary project lead—

(A) to facilitate an efficient review of the development program and application, including manufacturing inspections; and

(B) to serve as a scientific liaison between the review team and the applicant.

(d) Reporting requirement

Not later than one year after the date of the approval of an application under section 355(j) of this title with respect to a drug for which the development and review is expedited under this section, the sponsor of such drug shall report to the Secretary on whether the drug has been marketed in interstate commerce since the date of such approval.

(e) Definitions

In this section:

(1) The term ''generic drug'' means a drug that is approved pursuant to section 355(j) of this title.

(2) The term ''inadequate generic competition'' means, with respect to a drug, there is not more than one approved drugs[1] on the list of drugs described in section 355(j)(7)(A) of this title (not including drugs on the discontinued section of such list) that is—

(A) the reference listed drug; or

(B) a generic drug with the same reference listed drug as the drug for which designation as a competitive generic therapy is sought.

(3) The term ''reference listed drug'' means the listed drug (as such term is used in section 355(j) of this title) for the drug involved.

(June 25, 1938, ch. 675, § 506H, as added Pub. L. 115–52, title VIII, § 803(a), Aug. 18, 2017, 131 Stat. 1070.)

Statutory Notes and Related Subsidiaries

GUIDANCE; AMENDED REGULATIONS

Pub. L. 115–52, title VIII, § 803(b), Aug. 18, 2017, 131 Stat. 1071, provided that:

''(1) IN GENERAL.—

''(A) ISSUANCE.—The Secretary of Health and Human Services shall—

''(i) not later than 18 months after the date of enactment of this Act [Aug. 18, 2017], issue draft guidance on section 506H of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 356h], as added by subsection (a); and

''(ii) not later than 1 year after the close of the comment period for the draft guidance, issue final guidance on such section 506H.

''(B) CONTENTS.—The guidance issued under this paragraph shall—

''(i) specify the process and criteria by which the Secretary makes a designation under section 506H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

''(ii) specify the actions the Secretary may take to expedite the development and review of a competitive generic therapy pursuant to such a designation; and

''(iii) include good review management practices for competitive generic therapies.

''(2) AMENDED REGULATIONS.—The Secretary of Health and Human Services shall issue or revise any regulations as may be necessary to carry out this section not later than 2 years after the date of enactment of this Act [Aug. 18, 2017].''

§ 356i. Prompt reports of marketing status

(a) Notification of withdrawal

The holder of an application approved under subsection (c) or (j) of section 355 of this title or subsection (a) or (k) of section 262 of title 42 shall notify the Secretary in writing 180 days prior to withdrawing the approved drug from sale, or if 180 days is not practicable as soon as

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