(C) other relevant information, as determined by the Secretary.

(c) Patient experience data

For purposes of this section, the term ''patient experience data'' includes data that—

(1) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

(2) are intended to provide information about patients' experiences with a disease or condition, including—

(A) the impact (including physical and psychosocial impacts) of such disease or condition, or a related therapy or clinical investigation on patients' lives; and

(B) patient preferences with respect to treatment of such disease or condition.

(June 25, 1938, ch. 675, § 569C, as added Pub. L. 112–144, title XI, § 1137, July 9, 2012, 126 Stat. 1124; amended Pub. L. 114–255, div. A, title III, § 3001, Dec. 13, 2016, 130 Stat. 1083; Pub. L. 115–52, title VI, § 605, Aug. 18, 2017, 131 Stat. 1048.)

Editorial Notes

REFERENCES IN TEXT

Section 101(b) of the Prescription Drug User Fee Amendments of 2012, referred to in subsec. (a)(4), is section 101(b) of Pub. L. 112–144, which is set out as a note under section 379g of this title.

AMENDMENTS

2017—Subsec. (c)(2)(A). Pub. L. 115–52 substituted ''impact (including physical and psychosocial impacts) of such disease or condition, or a related therapy or clinical investigation'' for ''impact of such disease or condition, or a related therapy,''.

2016—Subsec. (a). Pub. L. 114–255, § 3001(1), (2), substituted ''Patient engagement in drugs and devices'' for ''In general'' in subsec. heading, designated existing provisions as par. (1) and inserted par. heading, redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, of par. (1), redesignated subsecs. (b) to (e) as as pars. (2) to (5), respectively, and realigned margins.

Subsecs. (b), (c). Pub. L. 114–255, § 3001(3), added subsecs. (b) and (c). Former subsecs. (b) and (c) redesignated pars. (2) and (3), respectively, of subsec. (a).

Subsecs. (d), (e). Pub. L. 114–255, § 3001(2), redesignated subsecs. (d) and (e) as pars. (4) and (5), respectively, of subsec. (a).

Statutory Notes and Related Subsidiaries

PATIENT-FOCUSED DRUG DEVELOPMENT GUIDANCE

Pub. L. 114–255, div. A, title III, § 3002, Dec. 13, 2016, 130 Stat. 1084, provided that:

''(a) PUBLICATION OF GUIDANCE DOCUMENTS.—Not later than 180 days after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services (referred to in this section as the 'Secretary'), acting through the Commissioner of Food and Drugs, shall develop a plan to issue draft and final versions of one or more guidance documents, over a period of 5 years, regarding the collection of patient experience data, and the use of such data and related information in drug development. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue a draft version of at least one such guidance document. Not later than 18 months after the public comment period on the draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

''(b) PATIENT EXPERIENCE DATA.—For purposes of this section, the term 'patient experience data' has the meaning given such term in section 569C of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–8c] (as added by section 3001).

''(c) CONTENTS.—The guidance documents described in subsection (a) shall address—

''(1) methodological approaches that a person seeking to collect patient experience data for submission to, and proposed use by, the Secretary in regulatory decisionmaking may use, that are relevant and objective and ensure that such data are accurate and representative of the intended population, including methods to collect meaningful patient input throughout the drug development process and methodological considerations for data collection, reporting, management, and analysis;

''(2) methodological approaches that may be used to develop and identify what is most important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease;

''(3) approaches to identifying and developing methods to measure impacts to patients that will help facilitate collection of patient experience data in clinical trials;

''(4) methodologies, standards, and technologies to collect and analyze clinical outcome assessments for purposes of regulatory decisionmaking;

''(5) how a person seeking to develop and submit proposed draft guidance relating to patient experience data for consideration by the Secretary may submit such proposed draft guidance to the Secretary;

''(6) the format and content required for submissions under this section to the Secretary, including with respect to the information described in paragraph (1);

''(7) how the Secretary intends to respond to submissions of information described in paragraph (1), if applicable, including any timeframe for response when such submission is not part of a regulatory application or other submission that has an associated timeframe for response; and

''(8) how the Secretary, if appropriate, anticipates using relevant patient experience data and related information, including with respect to the structured risk-benefit assessment framework described in section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)), to inform regulatory decisionmaking.''

STREAMLINING PATIENT INPUT

Pub. L. 114–255, div. A, title III, § 3003, Dec. 13, 2016, 130 Stat. 1085, provided that: ''Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary, that is initiated by the Secretary under section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended by section 3001) or section 3002 [set out as a note above].''

§ 360bbb–8d. Notification, nondistribution, and recall of controlled substances

(a) Order to cease distribution and recall

(1) In general

If the Secretary determines there is a reasonable probability that a controlled substance would cause serious adverse health consequences or death, the Secretary may, after providing the appropriate person with an opportunity to consult with the agency, issue an order requiring manufacturers, importers, distributors, or pharmacists, who distribute such controlled substance to immediately cease distribution of such controlled substance.

(2) Hearing

An order under paragraph (1) shall provide the person subject to the order with an oppor-

tunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify an amendment to the order, and what actions are required by such amended order pursuant to subparagraph (3).

(3) Order resolution

After an order is issued according to the process under paragraphs (1) and (2), the Secretary shall, except as provided in paragraph (4)—

(A) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order;

(B) continue the order ceasing distribution of the controlled substance until a date specified in such order; or

(C) amend the order to require a recall of the controlled substance, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding such recall.

(4) Risk assessment

If the Secretary determines that the risk of recalling a controlled substance presents a greater health risk than the health risk of not recalling such controlled substance from use, an amended order under subparagraph (B) or (C) of paragraph (3) shall not include either a recall order for, or an order to cease distribution of, such controlled substance, as applicable.

(5) Action following order

Any person who is subject to an order pursuant to subparagraph (B) or (C) of paragraph (3) shall immediately cease distribution of or recall, as applicable, the controlled substance and provide notification as required by such order.

(b) Notice to persons affected

If the Secretary determines necessary, the Secretary may require the person subject to an order pursuant to paragraph (1) or an amended order pursuant to subparagraph (B) or (C) of paragraph (3) to provide either a notice of a recall order for, or an order to cease distribution of, such controlled substance, as applicable, under this section to appropriate persons, including persons who manufacture, distribute, import, or offer for sale such product that is the subject of an order and to the public. In providing such notice, the Secretary may use the assistance of health professionals who prescribed or dispensed such controlled substances.

(c) Nondelegation

An order described in subsection (a)(3) shall be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated under this section unless the official is the Director of the Center for Drug Evaluation and Research or an official senior to such Director.

(d) Savings clause

Nothing contained in this section shall be construed as limiting—

(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, any drug under any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.]; or

(2) the ability of the Secretary to request any person to perform a voluntary activity related to any drug subject to this chapter or the Public Health Service Act.

(June 25, 1938, ch. 675, § 569D, as added Pub. L. 115–271, title III, § 3012(b), Oct. 24, 2018, 132 Stat. 3935.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (d), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

PART F—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

§ 360ccc. Conditional approval of new animal drugs for minor use and minor species and certain new animal drugs

(a) Application requirements

(1)(A) Except as provided in paragraph (3), any person may file with the Secretary an application for conditional approval of—

(i) a new animal drug intended for a minor use or a minor species; or

(ii) a new animal drug not intended for a minor use or minor species—

(I) that is intended to treat a serious or life-threatening disease or condition or addresses an unmet animal or human health need; and

(II) for which the Secretary determines that a demonstration of effectiveness would require a complex or particularly difficult study or studies.

(B) The Secretary shall, not later than September 30, 2019, issue guidance or regulations further clarifying the criteria specified in subparagraph (A)(ii).

(C) An application under this paragraph shall comply in all respects with the provisions of section 360b of this title except for subsections (a)(4), (b)(2), (c)(1), (c)(2), (c)(3), (d)(1), (e), (h), and (n) of such section unless otherwise stated in this section, and any additional provisions of this section.

(D) New animal drugs for which conditional approval is sought under this section are subject to the same safety standards that would be applied to new animal drugs under section 360b(d) of this title (including, for antimicrobial new animal drugs, with respect to antimicrobial resistance).

(2) The applicant shall submit to the Secretary as part of an application for the conditional approval of a new animal drug—

(A) all information necessary to meet the requirements of section 360b(b)(1) of this title except section 360b(b)(1)(A) of this title;

(B) full reports of investigations which have been made to show whether or not such drug is safe under section 360b(d) of this title (in-