

sified 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.

AMENDMENTS

2016—Subsec. (c). Pub. L. 114–255 inserted “or under the Public Health Service Act” before period at end.

§ 360bbb–8b. Use of clinical investigation data from outside the United States

(a) In general

In determining whether to approve, license, or clear a drug, biological product, or device pursuant to an application submitted under this subchapter, the Secretary shall accept data from clinical investigations conducted outside of the United States, including the European Union, if the applicant demonstrates that such data are adequate under applicable standards to support approval, licensure, or clearance of the drug, biological product, or device in the United States.

(b) Notice to sponsor

If the Secretary finds under subsection (a) that the data from clinical investigations conducted outside the United States, including in the European Union, are inadequate for the purpose of making a determination on approval, clearance, or licensure of a drug, biological product, or device pursuant to an application submitted under this subchapter, the Secretary shall provide written notice to the sponsor of the application of such finding and include the rationale for such finding.

(June 25, 1938, ch. 675, §569B, as added Pub. L. 112–144, title XI, §1123, July 9, 2012, 126 Stat. 1113; amended Pub. L. 114–255, div. A, title III, §3101(a)(2)(Q), Dec. 13, 2016, 130 Stat. 1155.)

AMENDMENTS

2016—Pub. L. 114–255 substituted “drug, biological product, or device” for “drug or device” wherever appearing.

§ 360bbb–8c. Patient participation in medical product discussion

(a) Patient engagement in drugs and devices

(1) In general

The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

(A) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and

(B) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

(2) Protection of proprietary information

Nothing in this section shall be construed to alter the protections offered by laws, regulations, or policies governing disclosure of confidential commercial or trade secret information and any other information exempt from disclosure pursuant to section 552(b) of title 5

as such laws, regulations, or policies would apply to consultation with individuals and organizations prior to July 9, 2012.

(3) Other consultation

Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to July 9, 2012.

(4) No right or obligation

Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder. Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012. Nothing in this section is intended to increase the number of review cycles as in effect before July 9, 2012.

(5) Financial interest

In this section, the term “financial interest” means a financial interest under section 208(a) of title 18.

(b) Statement of patient experience

(1) In general

Following the approval of an application that was submitted under section 355(b) of this title or section 262(a) of title 42 at least 180 days after December 13, 2016, the Secretary shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of such application.

(2) Data and information

The data and information referred to in paragraph (1) are—

(A) patient experience data;

(B) information on patient-focused drug development tools; and

(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 of such disease or condition, or a related therapy, 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.)

REFERENCES IN TEXT

Section 101(b) of the Prescription Drug User Fee Amendments of 2012, referred to in subsec. (a)(4), is sec-

tion 101(b) of Pub. L. 112-144, which is set out as a note under section 379g of this title.

AMENDMENTS

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).

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 decision-making.”

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].”

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

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

(a) Application requirements; contents; restrictions

(1) Except as provided in paragraph (3) of this section,¹ any person may file with the Secretary an application for conditional approval of a new animal drug intended for a minor use or a minor species. Such an application may not be a supplement to an application approved under section 360b of this title. Such application must comply in all respects with the provisions of section 360b of this title except sections 360b(a)(4), 360b(b)(2), 360b(c)(1), 360b(c)(2), 360b(c)(3), 360b(d)(1), 360b(e), 360b(h), and 360b(n) of this title unless otherwise stated in this section, and any additional provisions of this section. New animal drugs are subject to application of the same safety standards that would be applied to such 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 (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance) and there is a reasonable expectation of effectiveness for use;

(C) data for establishing a conditional dose;

(D) projections of expected need and the justification for that expectation based on the best information available;

(E) information regarding the quantity of drug expected to be distributed on an annual basis to meet the expected need; and

(F) a commitment that the applicant will conduct additional investigations to meet the requirements for the full demonstration of effectiveness under section 360b(d)(1)(E) of this title within 5 years.

(3) A person may not file an application under paragraph (1) if—

¹ So in original. Probably should be “this subsection.”.