

sultation with individuals and organizations prior to July 9, 2012.

(2) Consent required for disclosure

The Secretary shall not disclose confidential commercial or trade secret information to an expert consulted under this section without the written consent of the sponsor unless the expert is a special government employee (as defined under section 202 of title 18) or the disclosure is otherwise authorized by law.

(e) 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.

(f) No right or obligation

(1) No right to consultation

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.

(2) No altering of goals

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.

(3) No change to number of review cycles

Nothing in this section is intended to increase the number of review cycles as in effect before July 9, 2012.

(g) No delay in product review

(1) In general

Prior to a consultation with an external expert, as described in this section, relating to an investigational new drug application under section 355(i) of this title, a new drug application under section 355(b) of this title, or a biologics license application under section 262 of title 42, the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research (or appropriate Division Director), as appropriate, shall determine that—

(A) such consultation will—

(i) facilitate the Secretary's ability to complete the Secretary's review; and

(ii) address outstanding deficiencies in the application; or

(B) the sponsor authorized such consultation.

(2) Limitation

The requirements of this subsection shall apply only in instances where the consultation is undertaken solely under the authority of this section. The requirements of this subsection shall not apply to any consultation initiated under any other authority.

(June 25, 1938, ch. 675, §569, as added Pub. L. 112-144, title IX, §903, July 9, 2012, 126 Stat. 1088.)

REFERENCES IN TEXT

Section 101(b) of the Prescription Drug User Fee Amendments of 2012, referred to in subsecs. (a)(1) and (f)(2), is section 101(b) of Pub. L. 112-144, which is set out as a note under section 379g of this title.

§ 360bbb–8a. Optimizing global clinical trials

(a) In general

The Secretary shall—

(1) work with other regulatory authorities of similar standing, medical research companies, and international organizations to foster and encourage uniform, scientifically driven clinical trial standards with respect to medical products around the world; and

(2) enhance the commitment to provide consistent parallel scientific advice to manufacturers seeking simultaneous global development of new medical products in order to—

(A) enhance medical product development;

(B) facilitate the use of foreign data; and

(C) minimize the need to conduct duplicative clinical studies, preclinical studies, or nonclinical studies.

(b) Medical product

In this section, the term “medical product” means a drug, as defined in subsection (g) of section 321 of this title, a device, as defined in subsection (h) of such section, or a biological product, as defined in section 262(i) of title 42.

(c) Savings clause

Nothing in this section shall alter the criteria for evaluating the safety or effectiveness of a medical product under this chapter.

(June 25, 1938, ch. 675, §569A, as added Pub. L. 112-144, title XI, §1123, July 9, 2012, 126 Stat. 1113.)

§ 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 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 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 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.)

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

(a) 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—

(1) 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

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

(b) 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.

(c) 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.

(d) 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.

(e) Financial interest

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

(June 25, 1938, ch. 675, § 569C, as added Pub. L. 112-144, title XI, § 1137, July 9, 2012, 126 Stat. 1124.)

REFERENCES IN TEXT

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

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 sec-

tion 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—

(A) the application seeks conditional approval of a new animal drug that is contained in, or is a product of, a transgenic animal.²

(B) the person has previously filed an application for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b) of this section, or

(C) the person obtained the application, or data or other information contained therein, directly or indirectly from the person who filed for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b) of this section.

(b) Order of approval or hearing

Within 180 days after the filing of an application pursuant to subsection (a) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(1) issue an order, effective for one year, conditionally approving the application if the Secretary finds that none of the grounds for denying conditional approval, specified in subsection (c) of this section applies and publish

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

² So in original. The period probably should be a comma.