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 meet-