

(d) Annual report

Not later than 18 months after September 27, 2007, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

- (1) reviewing the operations and activities of the Partnerships in the previous year; and
- (2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

(e) Definition

In this section, the term “medical product” includes a drug, a biological product as defined in section 262 of title 42, a device, and any combination of such products.

(f) Authorization of appropriations

To carry out this section, there are authorized to be appropriated \$5,000,000 for fiscal year 2008 and such sums as may be necessary for each of fiscal years 2009 through 2012.

(June 25, 1938, ch. 675, §566, as added Pub. L. 110-85, title VI, §603, Sept. 27, 2007, 121 Stat. 898.)

§ 360bbb-6. Risk communication**(a) Advisory Committee on Risk Communication****(1) In general**

The Secretary shall establish an advisory committee to be known as the “Advisory Committee on Risk Communication” (referred to in this section as the “Committee”).

(2) Duties of Committee

The Committee shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the Food and Drug Administration.

(3) Members

The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in subsection (b), and representatives of patient, consumer, and health professional organizations.

(4) Permanence of Committee

Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this subsection.

(b) Partnerships for risk communication**(1) In general**

The Secretary shall partner with professional medical societies, medical schools, academic medical centers, and other stakeholders to develop robust and multi-faceted systems for communication to health care providers about emerging postmarket drug risks.

(2) Partnerships

The systems developed under paragraph (1) shall—

- (A) account for the diversity among physicians in terms of practice, willingness to adopt technology, and medical specialty; and

(B) include the use of existing communication channels, including electronic communications, in place at the Food and Drug Administration.

(June 25, 1938, ch. 675, §567, as added Pub. L. 110-85, title IX, §917, Sept. 27, 2007, 121 Stat. 960.)

REFERENCES IN TEXT

Section 14 of the Federal Advisory Committee Act, referred to in subsec. (a)(4), is section 14 of Pub. L. 92-463, which is set out in the Appendix to Title 5, Government Organization and Employees.

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—

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

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

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