ditions on persons who carry out any activity pursuant to an authorization under this section.

(June 25, 1938, ch. 675, § 564, as added Pub. L. 108–136, div. A, title XVI, § 1603(a), Nov. 24, 2003, 117 Stat. 1684; amended Pub. L. 108–276, § 4(a), July 21, 2004, 118 Stat. 853.)

AMENDMENTS

2004—Pub. L. 108–276 amended section generally, substituting provisions of subsecs. (a) to (*l*) for similar former provisions, except for additional provisions in subsec. (b)(1) allowing Secretary to authorize use of medical products in actual or potential domestic and public health emergencies in addition to actual or potential military emergencies.

§ 360bbb–4. Technical assistance

The Secretary, in consultation with the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration a team of experts on manufacturing and regulatory activities (including compliance with current Good Manufacturing Practice) to provide both off-site and on-site technical assistance to the manufacturers of qualified countermeasures (as defined in section 247d–6a of title 42), security countermeasures (as defined in section 247d–6b of title 42), or vaccines, at the request of such a manufacturer and at the discretion of the Secretary, if the Secretary determines that a shortage or potential shortage may occur in the United States in the supply of such vaccines or countermeasures and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.

(June 25, 1938, ch. 675, § 565, as added Pub. L. 109–417, title IV, § 404, Dec. 19, 2006, 120 Stat. 2875.)

§ 360bbb–5. Critical Path Public-Private Partnerships

(a) Establishment

The Secretary, acting through the Commissioner of Food and Drugs, may enter into collaborative agreements, to be known as Critical Path Public-Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, manufacturing, and translational therapeutics, and enhancing medical product safety.

(b) Eligible entity

In this section, the term ''eligible entity'' means an entity that meets each of the following:

(1) The entity is—

(A) an institution of higher education (as such term is defined in section 1001 of title 20) or a consortium of such institutions; or

(B) an organization described in section 501(c)(3) of title 26 and exempt from tax under section 501(a) of such title.

(2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include graduate training programs in areas relevant to priorities of the Critical Path Initiative.

(3) The entity demonstrates to the Secretary's satisfaction that the entity is capable of—

(A) developing and critically evaluating tools, methods, and processes—

(i) to increase efficiency, predictability, and productivity of medical product development; and

(ii) to more accurately identify the benefits and risks of new and existing medical products;

(B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and

(C) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

(c) Funding

The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

(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]

(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.