ly evaluated, including plant, equipment, or services.

(d) Additional authority

The Secretary may—

(1) award a grant under this section in each subsequent fiscal year without reapplication for a period of not more than 3 years, provided the requirements of subsection (c) are met for the previous fiscal year; and

(2) award a grant under this section in a fiscal year for which the requirement of subsection (c) has not been met only if such requirement was not met because such funding was diverted for response to 1 or more natural disasters or in other extenuating circumstances that the Secretary may determine appropriate.

(e) Duration of awards

The Secretary may award grants to an individual grant recipient under this section for periods of not more than 3 years. In the event the Secretary conducts a program evaluation, funding in the second year or third year of the grant, where applicable, shall be contingent on a successful program evaluation by the Secretary after the first year.

(f) Progress and evaluation

(1) In general

The Secretary shall measure the status and success of each grant program authorized under the FDA Food Safety Modernization Act (and any amendment made by such Act), including the grant program under this section. A recipient of a grant described in the preceding sentence shall, at the end of each grant year, provide the Secretary with information on how grant funds were spent and the status of the efforts by such recipient to enhance food safety. To the extent practicable, the Secretary shall take the performance of such a grant recipient into account when determining whether to continue funding for such recipient.

(2) No duplication

In carrying out paragraph (1), the Secretary shall not duplicate the efforts of the Secretary under other provisions of this chapter or the FDA Food Safety Modernization Act that require measurement and review of the activities of grant recipients under either this chapter or such Act.

(g) Supplement not supplant

Grant funds received under this section shall be used to supplement, and not supplant, non-Federal funds and any other Federal funds available to carry out the activities described in this section.

(h) Authorization of appropriations

For the purpose of making grants under this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2011 through 2015.

(June 25, 1938, ch. 675, §1009, formerly §909, as added Pub. L. 107–188, title III, §311, June 12, 2002, 116 Stat. 673; renumbered §1009 and amended Pub. L. 111–31, div. A, title I, §§101(b)(2), 103(n), June 22, 2009, 123 Stat. 1784, 1838; Pub. L. 111–353, title II, §210(a), Jan. 4, 2011, 124 Stat. 3948.)

REFERENCES IN TEXT

The FDA Food Safety Modernization Act, referred to in subsec. (f), is Pub. L. 111–353, Jan. 4, 2011, 124 Stat. 3885, which enacted chapter 27 (§2201 et seq.) and sections 350g to 350*l*–1, 379j–31, 384a to 384d, 399c, and 399d of this title, section 7625 of Title 7, Agriculture, and section 280g–16 of Title 42, The Public Health and Welfare, amended sections 331, 333, 334, 350b to 350d, 350f, 374, 381, 393, and 399 of this title and section 247b–20 of Title 42, and enacted provisions set out as notes under sections 331, 334, 342, 350b, 350d, 350e, 350g to 350j, 350*l*, and 381 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 2201 of this title and Tables.

AMENDMENTS

2011—Pub. L. 111–353 amended section generally. Prior to amendment, section related to grants to States for inspections.

2009—Subsec. (b). Pub. L. 111–31, §103(n), made technical amendment to reference in original act which appears in text as reference to section 398 of this title.

CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendment by Pub. L. 111–353 to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

§ 399a. Office of the Chief Scientist

(a) Establishment; appointment

The Secretary shall establish within the Office of the Commissioner an office to be known as the Office of the Chief Scientist. The Secretary shall appoint a Chief Scientist to lead such Office.

(b) Duties of the Office

The Office of the Chief Scientist shall—

(1) oversee, coordinate, and ensure quality and regulatory focus of the intramural research programs of the Food and Drug Administration;

(2) track and, to the extent necessary, coordinate intramural research awards made by each center of the Administration or science-based office within the Office of the Commissioner, and ensure that there is no duplication of research efforts supported by the Reagan-Udall Foundation for the Food and Drug Administration;

(3) develop and advocate for a budget to support intramural research;

(4) develop a peer review process by which intramural research can be evaluated;

(5) identify and solicit intramural research proposals from across the Food and Drug Administration through an advisory board composed of employees of the Administration that shall include—

(A) representatives of each of the centers and the science-based offices within the Office of the Commissioner; and

(B) experts on trial design, epidemiology, demographics, pharmacovigilance, basic science, and public health; and

(6) develop postmarket safety performance measures that are as measurable and rigorous

as the ones already developed for premarket review.

(June 25, 1938, ch. 675, § 1010, formerly § 910, as added Pub. L. 110–85, title VI, § 602, Sept. 27, 2007, 121 Stat. 898; renumbered § 1010, Pub. L. 111–31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784.)

§ 399b. Office of Women's Health

(a) Establishment

There is established within the Office of the Commissioner, an office to be known as the Office of Women's Health (referred to in this section as the ''Office''). The Office shall be headed by a director who shall be appointed by the Commissioner of Food and Drugs.

(b) Purpose

The Director of the Office shall—

(1) report to the Commissioner of Food and Drugs on current Food and Drug Administration (referred to in this section as the ''Administration'') levels of activity regarding women's participation in clinical trials and the analysis of data by sex in the testing of drugs, medical devices, and biological products across, where appropriate, age, biological, and sociocultural contexts;

(2) establish short-range and long-range goals and objectives within the Administration for issues of particular concern to women's health within the jurisdiction of the Administration, including, where relevant and appropriate, adequate inclusion of women and analysis of data by sex in Administration protocols and policies;

(3) provide information to women and health care providers on those areas in which differences between men and women exist;

(4) consult with pharmaceutical, biologics, and device manufacturers, health professionals with expertise in women's issues, consumer organizations, and women's health professionals on Administration policy with regard to women;

(5) make annual estimates of funds needed to monitor clinical trials and analysis of data by sex in accordance with needs that are identified; and

(6) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 237a(b)(4) of title 42).

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

(June 25, 1938, ch. 675, § 1011, as added Pub. L. 111–148, title III, § 3509(g), Mar. 23, 2010, 124 Stat. 536.)

CODIFICATION

Another section 1011 of act June 25, 1938, ch. 675, was enacted by Pub. L. 111–353, title II, § 209(a), Jan. 4, 2011, 124 Stat. 3945, and is classified to section 399c of this title.

§ 399c. Improving the training of State, local, territorial, and tribal food safety officials

(a) Training

The Secretary shall set standards and administer training and education programs for the employees of State, local, territorial, and tribal food safety officials relating to the regulatory responsibilities and policies established by this chapter, including programs for—

(1) scientific training;

(2) training to improve the skill of officers and employees authorized to conduct inspections under sections 372 and 374 of this title;

(3) training to achieve advanced product or process specialization in such inspections;

(4) training that addresses best practices;

(5) training in administrative process and procedure and integrity issues;

(6) training in appropriate sampling and laboratory analysis methodology; and

(7) training in building enforcement actions following inspections, examinations, testing, and investigations.

(b) Partnerships with State and local officials

(1) In general

The Secretary, pursuant to a contract or memorandum of understanding between the Secretary and the head of a State, local, territorial, or tribal department or agency, is authorized and encouraged to conduct examinations, testing, and investigations for the purposes of determining compliance with the food safety provisions of this chapter through the officers and employees of such State, local, territorial, or tribal department or agency.

(2) Content

A contract or memorandum described under paragraph (1) shall include provisions to ensure adequate training of such officers and employees to conduct such examinations, testing, and investigations. The contract or memorandum shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations, testing, or investigations performed pursuant to this section by the officers or employees of the State, territorial, or tribal department or agency.

(3) Effect

Nothing in this subsection shall be construed to limit the authority of the Secretary under section 372 of this title.

(c) Extension service

The Secretary shall ensure coordination with the extension activities of the National Institute of Food and Agriculture of the Department of Agriculture in advising producers and small processors transitioning into new practices required as a result of the enactment of the FDA Food Safety Modernization Act and assisting regulated industry with compliance with such Act.