

the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

(June 25, 1938, ch. 675, §1006, formerly §906, as added Pub. L. 105-115, title II, §214, Nov. 21, 1997, 111 Stat. 2348; renumbered §1006, Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

#### EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

### § 397. Contracts for expert review

#### (a) In general

##### (1) Authority

The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with relevant expertise, to review and evaluate, for the purpose of making recommendations to the Secretary on, part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this chapter for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 379 of this title relating to the confidentiality of information.

##### (2) Increased efficiency and expertise through contracts

The Secretary may use the authority granted in paragraph (1) whenever the Secretary determines that use of a contract described in paragraph (1) will improve the timeliness of the review of an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. The Secretary may use such authority whenever the Secretary determines that use of such a contract will improve the quality of the review of an application or submission described in paragraph (1), unless using such authority would unduly increase the cost of such review. Such improvement in timeliness or quality may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

#### (b) Review of expert review

##### (1) In general

Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) of this section shall review the recommendations of the organization or individual who conducted the expert

review and shall make a final decision regarding the matter in a timely manner.

#### (2) Limitation

A final decision by the Secretary on any such application or submission shall be made within the applicable prescribed time period for review of the matter as set forth in this chapter or in the Public Health Service Act (42 U.S.C. 201 et seq.).

(June 25, 1938, ch. 675, §1007, formerly §907, as added Pub. L. 105-115, title IV, §415, Nov. 21, 1997, 111 Stat. 2377; renumbered §1007, Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

#### REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b)(2), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

#### EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

### § 398. Notices to States regarding imported food

#### (a) In general

If the Secretary has credible evidence or information indicating that a shipment of imported food or portion thereof presents a threat of serious adverse health consequences or death to humans or animals, the Secretary shall provide notice regarding such threat to the States in which the food is held or will be held, and to the States in which the manufacturer, packer, or distributor of the food is located, to the extent that the Secretary has knowledge of which States are so involved. In providing notice to a State, the Secretary shall request the State to take such action as the State considers appropriate, if any, to protect the public health regarding the food involved.

#### (b) Rule of construction

Subsection (a) of this section may not be construed as limiting the authority of the Secretary with respect to food under any other provision of this chapter.

(June 25, 1938, ch. 675, §1008, formerly §908, as added Pub. L. 107-188, title III, §310, June 12, 2002, 116 Stat. 673; renumbered §1008, Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

### § 399. Grants to enhance food safety

#### (a) In general

The Secretary is authorized to make grants to eligible entities to—

(1) undertake examinations, inspections, and investigations, and related food safety activities under section 372 of this title;

(2) train to the standards of the Secretary for the examination, inspection, and investigation of food manufacturing, processing, packing, holding, distribution, and importation, in-

cluding as such examination, inspection, and investigation relate to retail food establishments;

(3) build the food safety capacity of the laboratories of such eligible entity, including the detection of zoonotic diseases;

(4) build the infrastructure and capacity of the food safety programs of such eligible entity to meet the standards as outlined in the grant application; and

(5) take appropriate action to protect the public health in response to—

(A) a notification under section 398 of this title, including planning and otherwise preparing to take such action; or

(B) a recall of food under this chapter.

**(b) Eligible entities; application**

**(1) In general**

In this section, the term “eligible entity” means an entity—

(A) that is—

- (i) a State;
- (ii) a locality;
- (iii) a territory;
- (iv) an Indian tribe (as defined in section 450b(e) of title 25); or
- (v) a nonprofit food safety training entity that collaborates with 1 or more institutions of higher education; and

(B) that submits an application to the Secretary at such time, in such manner, and including such information as the Secretary may reasonably require.

**(2) Contents**

Each application submitted under paragraph (1) shall include—

- (A) an assurance that the eligible entity has developed plans to engage in the types of activities described in subsection (a);
- (B) a description of the types of activities to be funded by the grant;
- (C) an itemization of how grant funds received under this section will be expended;
- (D) a description of how grant activities will be monitored; and
- (E) an agreement by the eligible entity to report information required by the Secretary to conduct evaluations under this section.

**(c) Limitations**

The funds provided under subsection (a) shall be available to an eligible entity that receives a grant under this section only to the extent such entity funds the food safety programs of such entity independently of any grant under this section in each year of the grant at a level equal to the level of such funding in the previous year, increased by the Consumer Price Index. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly 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 sec-

tions 350g to 350l-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, 350l, 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—