The Secretary shall establish 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.

(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, §1011, as added Pub. L. 111–353, title II, §1209(a), Jan. 4, 2011, 124 Stat. 3945, and is classified to section 399c of this title.)

CONSIDERATION

Another section 1011 of act June 25, 1938, ch. 675, was enacted by Pub. L. 111–353, title II, §1209(a), Jan. 4, 2011, 124 Stat. 3945, and is classified to section 399c of this title.
(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.

d) National Food Safety Training, Education, Extension, Outreach and Technical Assistance Program

(1) In general
In order to improve food safety and reduce the incidence of foodborne illness, the Secretary shall, not later than 180 days after January 4, 2011, enter into one or more memorandum of understanding, or enter into other cooperative agreements, with the Secretary of Agriculture to establish a competitive grant program within the National Institute for Food and Agriculture to provide food safety training, education, extension, outreach, and technical assistance to—
(A) owners and operators of farms;
(B) small food processors; and
(C) small fruit and vegetable merchant wholesalers.

(2) Implementation
The competitive grant program established under paragraph (1) shall be carried out in accordance with section 7625 of title 7.

e) Authorization of appropriations
There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal years 2011 through 2015.


REFERENCES IN TEXT
The FDA Food Safety Modernization Act, referred to in subsec. (c), is Pub. L. 111–135, title II, Jan. 22, 2011, 124 Stat. 396, which enacted chapter 27 (§2201 et seq.) and sections 350k to 350–1, 379–1, 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, 332, 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.

CONSTRUCTION
Another section 1011 of act June 25, 1938, ch. 675, was enacted by Pub. L. 111–135, title II, §3509(g), Mar. 23, 2010, 124 Stat. 536, and is classified to section 399b of this title.

§ 399d. Employee protections

(a) In general
No entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food may discharge an employee or otherwise discriminate against an employee with respect to compensation, terms, conditions, or privileges of employment because the employee, whether at the employee’s initiative or in the ordinary course of the employee’s duties (or any person acting pursuant to a request of the employee)—

(1) provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of this chapter or any order, rule, regulation, standard, or ban under this chapter, or any order, rule, regulation, standard, or ban under this chapter; 1

1 So in original.