

site of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate Internet Web site, and seek public comment on the communication plan.

(Pub. L. 112-144, title XI, §1138, July 9, 2012, 126 Stat. 1125.)

CODIFICATION

Section was enacted as part of the Food and Drug Administration Safety and Innovation Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 399g. Food and Drug Administration Intercenter Institutes

(a) In general

The Secretary shall establish one or more Intercenter Institutes within the Food and Drug Administration (referred to in this section as an “Institute”) for a major disease area or areas. With respect to the major disease area of focus of an Institute, such Institute shall develop and implement processes for coordination of activities, as applicable to such major disease area or areas, among the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health (for the purposes of this section, referred to as the “Centers”). Such activities may include—

(1) coordination of staff from the Centers with diverse product expertise in the diagnosis, cure, mitigation, treatment, or prevention of the specific diseases relevant to the major disease area of focus of the Institute;

(2) streamlining, where appropriate, the review of medical products to diagnose, cure, mitigate, treat, or prevent the specific diseases relevant to the major disease area of focus of the Institute, applying relevant standards under sections 355, 360(k), 360c(f)(2), and 360e of this title and section 262 of title 42, and other applicable authorities;

(3) promotion of scientific programs within the Centers related to the major disease area of focus of the Institute;

(4) development of programs and enhancement of strategies to recruit, train, and provide continuing education opportunities for the personnel of the Centers with expertise related to the major disease area of focus of the Institute;

(5) enhancement of the interactions of the Centers with patients, sponsors, and the external biomedical community regarding the major disease area of focus of the Institute; and

(6) facilitation of the collaborative relationships of the Centers with other agencies within the Department of Health and Human Services regarding the major disease area of focus of the Institute.

(b) Public process

The Secretary shall provide a period for public comment during the time that each Institute is being implemented.

(c) Timing

The Secretary shall establish at least one Institute under subsection (a) before the date that is 1 year after December 13, 2016.

(d) Termination of Institutes

The Secretary may terminate any Institute established pursuant to this section if the Secretary determines such Institute is no longer benefitting the public health. Not less than 60 days prior to so terminating an Institute, the Secretary shall provide public notice, including the rationale for such termination.

(June 25, 1938, ch. 675, §1014, as added Pub. L. 114-255, div. A, title III, §3073(a), Dec. 13, 2016, 130 Stat. 1136.)

§ 399h. Grants for studying continuous drug manufacturing

(a) In general

The Secretary of Health and Human Services may award grants to institutions of higher education and nonprofit organizations for the purpose of studying and recommending improvements to the process of continuous manufacturing of drugs and biological products and similar innovative monitoring and control techniques.

(b) Definitions

In this section—

(1) the term “drug” has the meaning given such term in section 321 of this title;

(2) the term “biological product” has the meaning given such term in section 262(i) of title 42; and

(3) the term “institution of higher education” has the meaning given such term in section 1001(a) of title 20.

(Pub. L. 114-255, div. A, title III, §3016, Dec. 13, 2016, 130 Stat. 1095.)

CODIFICATION

Section was enacted as part of the 21st Century Cures Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 399i. Food and Drug Administration Working Capital Fund

(a) In general

There is hereby established in the Treasury of the United States a Working Capital Fund (the Fund) to be administered by the Food and Drug Administration (FDA), without fiscal year limitation, for the payment of salaries, travel, and other expenses necessary to the maintenance and operation of (1) a supply service for the purchase, storage, handling, issuance, packing, or shipping of stationery, supplies, materials, equipment, and blank forms, for which stocks may be maintained to meet, in whole or in part, the needs of the FDA and requisitions of other Government Offices, and (2) such other services as the Commissioner of the FDA, subject to review by the Secretary of Health and Human Services, determines may be performed more advantageously as central services. The Fund shall be reimbursed from applicable discretionary resources, notwithstanding any otherwise applicable purpose limitations, available when services are performed or stock furnished, or in advance, on a basis of rates which shall include estimated or actual charges for personal services, materials, equipment, information technology, and other expenses. Charges for equipment and in-

formation technology shall include costs associated with maintenance, repair, and depreciation (including improvement and replacement).

(b) Appropriations

Of any discretionary resources appropriated in this Act for fiscal year 2018 for “Department of Health and Human Services, Food and Drug Administration, Salaries and Expenses”, not to exceed \$5,000,000 of amounts available as of September 30 may be transferred to and merged with the Fund established under subsection (a), notwithstanding any otherwise applicable purpose limitations.

(c) Emergency funds excluded

No amounts may be transferred pursuant to this section that are designated by the Congress as an emergency requirement pursuant to a concurrent resolution on the budget or the Balanced Budget and Emergency Deficit Control Act of 1985.

(Pub. L. 115-141, div. A, title VII, §722, Mar. 23, 2018, 132 Stat. 387.)

REFERENCES IN TEXT

This Act, referred to in subsec. (b), is div. A of Pub. L. 115-141, Mar. 23, 2018, 132 Stat. 351, known as the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2018. For complete classification of this Act to the Code, see Tables.

The Balanced Budget and Emergency Deficit Control Act of 1985, referred to in subsec. (c), is title II of Pub. L. 99-177, Dec. 12, 1985, 99 Stat. 1038, which enacted chapter 20 (§900 et seq.) and sections 654 to 656 of Title 2, The Congress, amended sections 602, 622, 631 to 642, and 651 to 653 of Title 2, sections 1104 to 1106, and 1109 of Title 31, Money and Finance, and section 911 of Title 42, The Public Health and Welfare, repealed section 661 of Title 2, enacted provisions set out as notes under section 900 of Title 2 and section 911 of Title 42, and amended provisions set out as a note under section 621 of Title 2. For complete classification of this Act to the Code, see Short Title note set out under section 900 of Title 2 and Tables.

CODIFICATION

Section was enacted as part of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2018, and also as part of the Consolidated Appropriations Act, 2018, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

CHAPTER 10—POULTRY AND POULTRY PRODUCTS INSPECTION

- Sec. 451. Congressional statement of findings.
- 452. Congressional declaration of policy.
- 453. Definitions.
- 454. Federal and State cooperation in development and administration of State poultry product inspection programs.
- 455. Inspection in official establishments.
- 456. Operation of premises, facilities and equipment.
- 457. Labeling and container standards.
- 458. Prohibited acts.
- 459. Compliance by all establishments.
- 460. Miscellaneous activities subject to regulation.
- 461. Offenses and punishment.
- 462. Reporting of violations; notice; opportunity to present views.
- 463. Rules and regulations.

- Sec. 464. Exemptions.
- 465. Limitations upon entry of poultry products and other materials into official establishments.
- 466. Imports.
- 467. Inspection services.
- 467a. Administrative detention; duration; pending judicial proceedings; notification of government authorities; release; removal of official marks.
- 467b. Seizure and condemnation.
- 467c. Federal court jurisdiction of enforcement and injunction proceedings and other kinds of cases; limitations; United States as plaintiff; subpoenas.
- 467d. Administration and enforcement; applicability of penalty provisions; conduct of inquiries; power and jurisdiction of courts.
- 467e. Non-Federal jurisdiction of federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters.
- 467f. Federal Food, Drug, and Cosmetic Act applications.
- 468. Cost of inspection; overtime.
- 469. Authorization of appropriations.
- 470. Omitted.
- 471. Safe Meat and Poultry Inspection Panel.
- 472. Interstate shipment of poultry inspected by Federal and State agencies for certain small establishments.

§ 451. Congressional statement of findings

Poultry and poultry products are an important source of the Nation’s total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded poultry products impair the effective regulation of poultry products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged poultry products, and result in sundry losses to poultry producers and processors of poultry and poultry products, as well as injury to consumers. It is hereby found that all articles and poultry which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary of Agriculture and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

(Pub. L. 85-172, §2, Aug. 28, 1957, 71 Stat. 441; Pub. L. 90-492, §2, Aug. 18, 1968, 82 Stat. 791.)

AMENDMENTS

1968—Pub. L. 90-492 inserted provisions stating it to be necessary that the health and welfare of consumers