

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.

CHAPTER 10—POULTRY AND POULTRY PRODUCTS INSPECTION

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- 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.
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469. Authorization of appropriations.
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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 be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged, provisions that misbranded poultry products impair the effective regulation of poultry products and 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, and provisions that all articles and poultry which are regulated by 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 serve the specified aims, and struck out provisions that all poultry and poultry products which have or are required to have inspection under this chapter are either in the current of interstate or foreign commerce or directly affect such commerce, provisions that that part entering directly into the current of interstate or foreign commerce cannot be effectively inspected and regulated without also inspecting and regulating all poultry and poultry products in the same establishment, and provisions authorizing the Secretary to designate major consuming areas.

EFFECTIVE DATE OF 1968 AMENDMENT

Pub. L. 90-492, § 20, Aug. 18, 1968, 82 Stat. 808, provided that: "This Act [see Short Title of 1968 Amendment note below] shall become effective upon enactment [Aug. 18, 1968] except as provided in paragraphs (a) through (c):

"(a) The provisions of subparagraphs (a)(2)(A) and (a)(3) of section 9 of the Poultry Products Inspection Act, as amended by section 9 of this Act [section 458(a)(2)(A) and (a)(3) of this title], shall become effective upon the expiration of sixty days after enactment hereof [Aug. 18, 1968].

"(b) Section 14 of this Act, amending section 15 of the Poultry Products Inspection Act [section 464 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Aug. 18, 1968].

"(c) Paragraph 11(d) of the Poultry Products Inspection Act, as added by section 11 of this Act [section 460(d) of this title], shall become effective upon the expiration of sixty days after enactment hereof [Aug. 18, 1968]."

EFFECTIVE DATE

Pub. L. 85-172, § 29, formerly § 22, Aug. 28, 1957, 71 Stat. 449, as renumbered by Pub. L. 90-492, § 17, Aug. 18, 1968, 82 Stat. 805, provided that: "This Act [this chapter] shall take effect upon enactment [Aug. 28, 1957], except that no person shall be subject to the provisions of this Act [this chapter] prior to January 1, 1959, unless such person after January 1, 1958, applies for and receives inspection for poultry or poultry products in accordance with the provisions of this Act [this chapter] and pursuant to regulations promulgated by the Secretary hereunder, in any establishment processing poultry or poultry products in commerce or in a designated major consuming area. Any person who voluntarily applies for and receives such inspection after January 1, 1958, shall be subject, on and after the date he commences to receive such inspection, to all of the provisions and penalties provided for in this Act [this chapter] with respect to all poultry or poultry products handled in the establishment for which such said application for inspection is made."

SHORT TITLE OF 1968 AMENDMENT

Pub. L. 90-492, § 1, Aug. 18, 1968, 82 Stat. 791, provided: "That this Act [enacting sections 467a to 467f and 470 of this title, amending this section and sections 452 to 461, 463 to 465, and 467 of this title, and enacting provisions set out as notes under this section] may be cited as the 'Wholesome Poultry Products Act'."

SHORT TITLE

Pub. L. 85-172, § 1, Aug. 28, 1957, 71 Stat. 441, provided: "That this Act [enacting this chapter and provisions set out as notes under this section] may be cited as the 'Poultry Products Inspection Act'."

SEPARABILITY

Pub. L. 90-492, § 19, Aug. 18, 1968, 82 Stat. 808, provided that: "If any provisions of this Act or of the amendments made hereby [see Short Title of 1968 Amendment note above] or the application thereof to any person or