

Congress on the role of the Food and Drug Administration in supporting advanced and continuous pharmaceutical manufacturing, including—

(A) a national framework of principles related to the implementation of advanced and continuous pharmaceutical manufacturing;

(B) a plan for the development of Federal regulations and guidance to support and facilitate the incorporation of advanced or continuous manufacturing into the development of pharmaceuticals;

(C) a plan for development of Federal regulations or guidance related to the review of advanced and continuous pharmaceutical manufacturing, including how such manufacturing practices may be incorporated into the review of medical product applications; and

(D) a summary of relevant feedback related to improving advanced and continuous pharmaceutical manufacturing solicited from the public, which may include other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, and contract manufacturers, and other relevant entities.

(h) Definitions

In this section:

(1) Advanced and continuous pharmaceutical manufacturing

The term “advanced and continuous pharmaceutical manufacturing” refers to a method of pharmaceutical manufacturing, or a combination of pharmaceutical manufacturing methods—

(A) that incorporates a novel technology, or uses an established technique or technology in a new or innovative way, that enhances drug quality or improves the manufacturing process for a drug, including processes that may apply to advanced therapies and the production of biological products, such as cell and gene therapies; or

(B) for which the input materials are continuously fed into and transformed within the process, and the output materials are continuously removed from the system, utilizing an integrated manufacturing process that consists of a series of 2 or more simultaneous unit operations.

(2) Biological product

The term “biological product” has the meaning given such term in section 262(i) of title 42.

(3) Drug

The term “drug” has the meaning given such term in section 321(g) of this title.

(4) Institution of higher education

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

(5) Secretary

The term “Secretary” means the Secretary of Health and Human Services.

(i) Authorization of appropriations

(1) In general

There is authorized to be appropriated to carry out this section \$100,000,000 for the period of fiscal years 2023 through 2027.

(2) Federal administrative expenses

Of the amounts made available to carry out this section for a fiscal year, the Secretary shall not use more than 8 percent for Federal administrative expenses, including training, technical assistance, reporting, and evaluation.

(Pub. L. 114–255, div. A, title III, §3016, Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5815.)

Editorial Notes

REFERENCES IN TEXT

This Act, referred to in subsec. (f)(3), is Pub. L. 114–255, Dec. 13, 2016, 130 Stat. 1033, known as the 21st Century Cures Act. For complete classification of this Act to the Code, see Short Title of 2016 Amendment note set out under section 201 of Title 42, The Public Health and Welfare, and Tables.

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.

AMENDMENTS

2022—Pub. L. 117–328 amended section generally. Prior to amendment, section related to grants for studying continuous drug manufacturing.

Statutory Notes and Related Subsidiaries

TRANSITION RULE

Pub. L. 117–328, div. FF, title III, §3204(b), Dec. 29, 2022, 136 Stat. 5819, provided that: “Section 3016 of the 21st Century Cures Act (21 U.S.C. 399h), as in effect on the day before the date of the enactment of this section [Dec. 29, 2022], shall apply with respect to grants awarded under such section before such date of enactment.”

§ 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 information 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.)

Editorial Notes

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

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- 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.
- 473. Grants for improvements to meat and poultry facilities to allow for interstate shipment.

§ 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.