

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-