

enhancing scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or other statutes administered by the Food and Drug Administration, to address issues relevant to the regulation of those products, including the potential toxicology of such nanomaterials, the potential benefit of new therapies derived from nanotechnology, the effects of such nanomaterials on biological systems, and the interaction of such nanomaterials with biological systems.

(b) Activities

In conducting activities related to nanotechnology, the Secretary may—

(1) assess scientific literature and data on general nanomaterials interactions with biological systems and on specific nanomaterials of concern to the Food and Drug Administration;

(2) in cooperation with other Federal agencies, develop and organize information using databases and models that will facilitate the identification of generalized principles and characteristics regarding the behavior of classes of nanomaterials with biological systems;

(3) promote Food and Drug Administration programs and participate in collaborative efforts, to further the understanding of the science of novel properties of nanomaterials that might contribute to toxicity;

(4) promote and participate in collaborative efforts to further the understanding of measurement and detection methods for nanomaterials;

(5) collect, synthesize, interpret, and disseminate scientific information and data related to the interactions of nanomaterials with biological systems;

(6) build scientific expertise on nanomaterials within the Food and Drug Administration, including field and laboratory expertise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under this Act;

(7) ensure ongoing training, as well as dissemination of new information within the centers of the Food and Drug Administration, and more broadly across the Food and Drug Administration, to ensure timely, informed consideration of the most current science pertaining to nanomaterials;

(8) encourage the Food and Drug Administration to participate in international and national consensus standards activities pertaining to nanomaterials; and

(9) carry out other activities that the Secretary determines are necessary and consistent with the purposes described in paragraphs (1) through (8).

(Pub. L. 112-144, title XI, §1126, July 9, 2012, 126 Stat. 1116.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This Act, referred to in subsec. (b)(6), is Pub. L. 112-144, July 9, 2012, 126 Stat. 993, known as the Food and Drug Administration Safety and Innovation Act. For complete classification of this Act to the Code, see Tables.

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.

§ 399f. Ensuring adequate information regarding pharmaceuticals for all populations, particularly underrepresented subpopulations, including racial subgroups

(a) Communication plan

The Secretary of Health and Human Services (referred to in this section as the “Secretary”), acting through the Commissioner of Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration’s communication plan to inform and educate health care providers and patients on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) Content

The communication plan described under subsection (a)—

(1) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within such Department, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black-box warnings, health advisories, health and safety benefits and risks), particular actions to be taken by health care professionals and patients, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

(3) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(c) Issuance and posting of communication plan

(1) Communication plan

Not later than 1 year after July 9, 2012, the Secretary, acting through the Commissioner of Food and Drugs, shall issue the communication plan described under this section.

(2) Posting of communication plan on the office of minority health web site

The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the Internet Web

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-