sideration 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.)

Editorial Notes

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.)

Editorial Notes

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. National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing

(a) In general

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs—

(1) may, to support the advancement, development, and implementation of advanced and continuous pharmaceutical manufacturing—

(A) solicit requests for designation as National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing (in this section referred to as a ''National Center of Excellence'');

(B) beginning not later than one year after December 29, 2022, designate as National Centers of Excellence institutions of higher education or consortia of institutions of higher education that—

(i) request such designation; and

(ii) meet the eligibility criteria specified in subsection (c); and

(C) award grants to such institutions or consortia of institutions; and

(2) shall so designate not more than 5 institutions of higher education or consortia of such institutions.

(b) Request for designation

A request for designation under subsection (a) shall be made to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(c) Eligibility criteria for designation

To be eligible to receive a designation under this section, an institution of higher education or consortium of institutions of higher education shall include in its request for designation a description of the institution's or consortium's—

(1) physical capacity and technical capabilities to conduct advanced research on, and to develop and implement, advanced and continuous pharmaceutical manufacturing;

(2) collaboration or partnerships with other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, contract manufacturers, and other relevant entities;

(3) proven capacity to design, develop, implement, and demonstrate new, highly effective technologies for use in advanced and continuous pharmaceutical manufacturing;

(4) proven ability to facilitate training of a qualified workforce for advanced research on, and development and implementation of, advanced and continuous pharmaceutical manufacturing; and

(5)(A) experience in participating in and leading advanced and continuous pharmaceutical manufacturing technology partnerships with other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, contract manufacturers, and other relevant entities to—

(i) support the implementation of advanced or continuous pharmaceutical manufacturing for companies manufacturing or seeking to manufacture in the United States;

(ii) support Federal agencies with technical assistance and workforce training, which may include regulatory and quality metric guidance as applicable, and hands-on training, for advanced and continuous pharmaceutical manufacturing;

(iii) organize and conduct advanced research and development activities, with respect to advanced or continuous pharmaceutical manufacturing, needed to develop new and more effective technology, and to develop and support technological leadership;

(iv) develop best practices for designing, developing, and implementing advanced and continuous pharmaceutical manufacturing processes; and

(v) identify and assess workforce needs for advanced and continuous pharmaceutical manufacturing, and address such workforce needs, which may include the development and implementing of training programs; or

(B) a plan, to be implemented within 2 years, to establish partnerships described in subparagraph (A).

(d) Termination of designation

The Secretary may terminate the designation of any National Center of Excellence designated