

not later than 60 days after the date of the issuance of the final order of the Secretary. Review shall conform to chapter 7 of title 5. The commencement of proceedings under this subparagraph shall not, unless ordered by the court, operate as a stay of the order.

(B) No judicial review

An order of the Secretary with respect to which review could have been obtained under subparagraph (A) shall not be subject to judicial review in any criminal or other civil proceeding.

(6) Failure to comply with order

Whenever any person has failed to comply with an order issued under paragraph (3), the Secretary may file a civil action in the United States district court for the district in which the violation was found to occur, or in the United States district court for the District of Columbia, to enforce such order. In actions brought under this paragraph, the district courts shall have jurisdiction to grant all appropriate relief including, but not limited to, injunctive relief and compensatory damages.

(7) Civil action to require compliance

(A) In general

A person on whose behalf an order was issued under paragraph (3) may commence a civil action against the person to whom such order was issued to require compliance with such order. The appropriate United States district court shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce such order.

(B) Award

The court, in issuing any final order under this paragraph, may award costs of litigation (including reasonable attorneys' and expert witness fees) to any party whenever the court determines such award is appropriate.

(c) Effect of section

(1) Other laws

Nothing in this section preempts or diminishes any other safeguards against discrimination, demotion, discharge, suspension, threats, harassment, reprimand, retaliation, or any other manner of discrimination provided by Federal or State law.

(2) Rights of employees

Nothing in this section shall be construed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.

(d) Enforcement

Any nondiscretionary duty imposed by this section shall be enforceable in a mandamus proceeding brought under section 1361 of title 28.

(e) Limitation

Subsection (a) shall not apply with respect to an employee of an entity engaged in the manufacture, processing, packing, transporting, dis-

tribution, reception, holding, or importation of food who, acting without direction from such entity (or such entity's agent), deliberately causes a violation of any requirement relating to any violation or alleged violation of any order, rule, regulation, standard, or ban under this chapter.

(June 25, 1938, ch. 675, §1013, formerly §1012, as added Pub. L. 111-353, title IV, §402, Jan. 4, 2011, 124 Stat. 3968; renumbered §1013, Pub. L. 114-255, div. A, title III, §3073(b)(1), Dec. 13, 2016, 130 Stat. 1137.)

CONSTRUCTION

Nothing in this section to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2252 of this title.

§ 399e. Nanotechnology

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall intensify and expand activities related to 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;