

(June 25, 1938, ch. 675, § 1002(b), (c), formerly § 902(b), (c), 52 Stat. 1059; Pub. L. 90-399, § 107, July 13, 1968, 82 Stat. 353; renumbered § 1002(b), (c), Pub. L. 111-31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784.)

Editorial Notes

REFERENCES IN TEXT

The Meat Inspection Act, approved March 4, 1907, as amended, referred to in subsec. (a), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90-201, 81 Stat. 584, which are classified generally to subchapters I to IV (§ 601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

Act of March 4, 1913, referred to in subsec. (b), is act Mar. 4, 1913, ch. 145, 37 Stat. 828. The provisions of such act referred to relating to viruses, etc., applicable to domestic animals, are contained in the eighth paragraph under the heading “Bureau of Animal Industry”, 37 Stat. 832, as amended, popularly known as the Virus-Serum-Toxin Act, which is classified generally to chapter 5 (§ 151 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 151 of this title and Tables.

The Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), referred to in subsec. (b), is act June 6, 1896, ch. 337, 29 Stat. 253, which had been classified to chapter 10 (§ 1000 et seq.) of Title 26, Internal Revenue, and included as chapter 17 (§ 2350 et seq.) of Title 26, Internal Revenue Code of 1939. Such chapter 17 was covered by section 4831 et seq. of Title 26, Internal Revenue Code, prior to the repeal of section 4831 et seq. of Title 26 by Pub. L. 93-490, § 3(a)(1), Oct. 26, 1974, 88 Stat. 1466.

The Filled Milk Act of March 4, 1923, referred to in subsec. (b), is act Mar. 4, 1923, ch. 262, 42 Stat. 1486, which is classified generally to chapter 3 (§ 61 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 61 of this title and Tables.

The Import Milk Act of February 15, 1927, referred to in subsec. (b), is act Feb. 15, 1927, ch. 155, 44 Stat. 1101, which is classified generally to subchapter IV (§ 141 et seq.) of chapter 4 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 141 of this title and Tables.

CODIFICATION

Subsecs. (a) and (b) of this section comprise respectively subsecs. (b) and (c) of section 1002 of act June 25, 1938. Subsecs. (a) and (d) of section 1002 of act June 25, 1938, which prescribed the effective date of this chapter and made appropriations available, are set out as notes under section 301 of this title and this section, respectively.

AMENDMENTS

1968—Subsec. (b). Pub. L. 90-399 substituted “section 351 of Public Health Service Act (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913 (37 Stat. 832-833);” for “the virus, serum, and toxin Act of July 1, 1902 (U.S.C., 1934 ed., title 42, chap. 4);”.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90-399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90-399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

AVAILABILITY OF APPROPRIATIONS

Act June 25, 1938, ch. 675, § 1002(d), formerly § 902(d), 52 Stat. 1059; renumbered § 1002(d), Pub. L. 111-31, div. A,

title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784, provided that: “In order to carry out the provisions of this Act which take effect [see section 1002(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title] prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended [former sections 1 to 5 and 7 to 15 of this title], appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.”

§ 393. Food and Drug Administration

(a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the “Administration”).

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

(D) cosmetics are safe and properly labeled; and

(E) public health and safety are protected from electronic product radiation;

(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

(c) Interagency collaboration

The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.

(d) Commissioner

(1) Appointment

There shall be in the Administration a Commissioner of Food and Drugs (hereinafter in this section referred to as the “Commissioner”) who shall be appointed by the President by and with the advice and consent of the Senate.

(2) General powers

The Secretary, through the Commissioner, shall be responsible for executing this chapter and for—

(A) providing overall direction to the Food and Drug Administration and establishing and implementing general policies respecting the management and operation of programs and activities of the Food and Drug Administration;

(B) coordinating and overseeing the operation of all administrative entities within the Administration;

(C) research relating to foods, drugs, cosmetics, devices, and tobacco products in carrying out this chapter;

(D) conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration; and

(E) performing such other functions as the Secretary may prescribe.

(e) Technical and scientific review groups

The Secretary through the Commissioner of Food and Drugs may, without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Administration, including functions under this chapter, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

(f) Agency plan for statutory compliance**(1) In general**

Not later than 1 year after November 21, 1997, the Secretary, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this chapter. The Secretary shall review the plan biannually and shall revise the plan as necessary, in consultation with such persons.

(2) Objectives of agency plan

The plan required by paragraph (1) shall establish objectives and mechanisms to achieve such objectives, including objectives related to—

(A) maximizing the availability and clarity of information about the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this chapter;

(B) maximizing the availability and clarity of information for consumers and patients concerning new products;

(C) implementing inspection and postmarket monitoring provisions of this chapter;

(D) ensuring access to the scientific and technical expertise needed by the Secretary to meet obligations described in paragraph (1);

(E) establishing mechanisms, by July 1, 1999, for meeting the time periods specified in this chapter for the review of all applications and submissions described in subparagraph (A) and submitted after November 21, 1997; and

(F) eliminating backlogs in the review of applications and submissions described in subparagraph (A), by January 1, 2000.

(g) Annual report

The Secretary shall annually prepare and publish in the Federal Register and solicit public comment on a report that—

(1) provides detailed statistical information on the performance of the Secretary under the plan described in subsection (f);

(2) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary; and

(3) identifies any regulatory policy that has a significant negative impact on compliance with any objective of the plan or any statutory obligation and sets forth any proposed revision to any such regulatory policy.

(h) Annual report regarding food

Not later than February 1 of each year, the Secretary shall submit to Congress a report, including efforts to coordinate and cooperate with other Federal agencies with responsibilities for food inspections, regarding—

(1) information about food facilities including—

(A) the appropriations used to inspect facilities registered pursuant to section 350d of this title in the previous fiscal year;

(B) the average cost of both a non-high-risk food facility inspection and a high-risk food facility inspection, if such a difference exists, in the previous fiscal year;

(C) the number of domestic facilities and the number of foreign facilities registered pursuant to section 350d of this title that the Secretary inspected in the previous fiscal year;

(D) the number of domestic facilities and the number of foreign facilities registered pursuant to section 350d of this title that were scheduled for inspection in the previous fiscal year and which the Secretary did not inspect in such year;

(E) the number of high-risk facilities identified pursuant to section 350j of this title that the Secretary inspected in the previous fiscal year; and

(F) the number of high-risk facilities identified pursuant to section 350j of this title that were scheduled for inspection in the previous fiscal year and which the Secretary did not inspect in such year.

(2) information about food imports including—

(A) the number of lines of food imported into the United States that the Secretary physically inspected or sampled in the previous fiscal year;

(B) the number of lines of food imported into the United States that the Secretary did not physically inspect or sample in the previous fiscal year; and

(C) the average cost of physically inspecting or sampling a line of food subject to this chapter that is imported or offered for import into the United States; and

(3) information on the foreign offices of the Food and Drug Administration including—

(A) the number of foreign offices established; and

(B) the number of personnel permanently stationed in each foreign office.

(i) Public availability of annual food reports

The Secretary shall make the reports required under subsection (h) available to the public on the Internet Web site of the Food and Drug Administration.

(June 25, 1938, ch. 675, § 1003, formerly § 903, as added Pub. L. 100-607, title V, § 503(a), Nov. 4, 1988, 102 Stat. 3121; amended Pub. L. 100-690, title II, § 2631, Nov. 18, 1988, 102 Stat. 4244; Pub. L. 105-115, title IV, §§ 406, 414, Nov. 21, 1997, 111 Stat. 2369, 2377; renumbered § 1003 and amended Pub. L. 111-31, div. A, title I, §§ 101(b)(2), 103(m), June 22, 2009, 123 Stat. 1784, 1838; Pub. L. 111-353, title II, § 201(b), Jan. 4, 2011, 124 Stat. 3925.)

Editorial Notes

AMENDMENTS

2011—Subsecs. (h), (i). Pub. L. 111-353 added subsecs. (h) and (i).

2009—Subsec. (d)(2)(C). Pub. L. 111-31, § 103(m), struck out “and” after “cosmetics,” and inserted “, and tobacco products” after “devices”.

1997—Subsec. (b). Pub. L. 105-115, § 406(a)(2), added subsec. (b). Former subsec. (b) redesignated (d).

Subsec. (c). Pub. L. 105-115, § 414, added subsec. (c). Former subsec. (c) redesignated (e).

Subsecs. (d), (e). Pub. L. 105-115, § 406(a)(1), redesignated subsecs. (b) and (c) as (d) and (e), respectively.

Subsecs. (f), (g). Pub. L. 105-115, § 406(b), added subsecs. (f) and (g).

1988—Subsec. (b)(2). Pub. L. 100-690 substituted “shall be responsible for executing this chapter and” for “shall be responsible”.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as a note under section 321 of this title.

EFFECTIVE DATE

Pub. L. 100-607, title V, § 503(c), Nov. 4, 1988, 102 Stat. 3121, provided that:

“(1) Except as provided in paragraph (2), the amendments made by this title [enacting this section and amending sections 5315 and 5316 of Title 5, Government Organization and Employees] shall take effect on the date of enactment of this Act [Nov. 4, 1988].

“(2) Section 903(b)(1) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section) [now 1003(d)(1), 21 U.S.C. 393(b)(1)] shall apply to the appointments of Commissioners of Food and Drugs made after the date of enactment of this Act.”

IMPROVING FDA GUIDANCE AND COMMUNICATION

Pub. L. 117-328, div. FF, title II, § 2505, Dec. 29, 2022, 136 Stat. 5802, provided that:

“(a) FDA REPORT AND IMPLEMENTATION OF GOOD PRACTICES.—The Secretary of Health and Human Services (referred to in this section as the ‘Secretary’) shall develop, and publish on the website of the Food and Drug Administration—

“(1) a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents, within centers, across the Food and Drug Administration, and across other applicable agencies; and

“(2) a plan for implementation of such best practices, including across other applicable agencies, which shall address—

“(A) streamlining development and review of guidance documents within centers and across the Food and Drug Administration;

“(B) streamlining processes for regulatory submissions to the Food and Drug Administration, including through the revision or issuance of guidance documents; and

“(C) implementing innovative guidance development processes and practices and transitioning or updating guidance issued during the COVID-19 public health emergency, as appropriate.

“(b) REPORT AND IMPLEMENTATION OF FDA BEST PRACTICES FOR COMMUNICATING WITH EXTERNAL STAKEHOLDERS.—The Secretary, acting through the Commissioner of Food and Drugs, shall develop and publish on the website of the Food and Drug Administration a report on the practices of the Food and Drug Administration to broadly communicate with external stakeholders, other than through guidance documents, which shall include—

“(1) a review of the types and methods of public communication that the Food and Drug Administration uses to communicate and interact with medical product sponsors and other external stakeholders;

“(2) the identification of best practices for the efficient development, issuance, and use of such communications; and

“(3) a plan for implementation of best practices for communication with external stakeholders, which shall address—

“(A) advancing the use of innovative forms of communication, including novel document types and formats, to provide increased regulatory clarity to product sponsors and other stakeholders, and advancing methods of communicating and interacting with medical product sponsors and other external stakeholders, including the use of tools such as product submission templates, webinars, and frequently asked questions communications;

“(B) streamlining processes for regulatory submissions; and

“(C) implementing innovative communication development processes and transitioning or updating communication practices used during the COVID-19 public health emergency, as appropriate.

“(c) CONSULTATION.—In developing and publishing the report and implementation plan under this section, the Secretary shall consult with stakeholders, including researchers, academic organizations, pharmaceutical, biotechnology, and medical device developers, clinical research organizations, clinical laboratories, health care providers, patient groups, and other appropriate stakeholders.

“(d) MANNER OF ISSUANCE.—For purposes of carrying out this section, the Secretary may update an existing report or plan, and may combine the reports and implementation plans described in subsections (a) and (b) into one or more documents.

“(e) TIMING.—The Secretary shall—

“(1) not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], publish a draft of the reports and plans required under this section; and

“(2) not later than 180 days after publication of the draft reports and plans under paragraph (1)—

“(A) publish a final report and plan; and

“(B) begin implementation of the best practices pursuant to such final plan.”

IMPROVING INFORMATION TECHNOLOGY SYSTEMS OF THE FOOD AND DRUG ADMINISTRATION

Pub. L. 117-328, div. FF, title III, §3627(a), Dec. 29, 2022, 136 Stat. 5888, provided that:

(a) FDA STRATEGIC INFORMATION TECHNOLOGY PLAN.—

“(1) IN GENERAL.—Not later than September 30, 2023, and at least every 4 years thereafter, the Secretary [of Health and Human Services] shall develop and submit to the appropriate committees of Congress and post on the website of the Food and Drug Administration, a coordinated information technology strategic plan to modernize the information technology systems of the Food and Drug Administration. Each such report shall be known as the ‘Food and Drug Administration Strategic Information Technology Plan’. The first such report may include the Data and Technology Modernization Strategy, as set forth in the letters described in section 1001(b) of the FDA User Fee Reauthorization Act of 2022 (division F of Public Law 117-180) [21 U.S.C. 379g note].

“(2) CONTENT OF STRATEGIC PLAN.—The Food and Drug Administration Strategic Information Technology Plan under paragraph (1) shall include—

“(A) agency-wide strategic goals and priorities for modernizing the information technology systems of the Food and Drug Administration to maximize the efficiency and effectiveness of such systems for enabling the Food and Drug Administration to fulfill its public health mission;

“(B) specific activities and strategies for achieving the goals and priorities identified under subparagraph (A), and specific milestones, metrics, and performance measures for assessing progress against such strategic goals and priorities;

“(C) specific activities and strategies for improving and streamlining internal coordination and communication within the Food and Drug Administration, including for activities and communications related to signals of potential public health concerns;

“(D) challenges and risks the Food and Drug Administration will face in meeting its strategic goals and priorities, and the activities the Food and Drug Administration will undertake to overcome those challenges and mitigate those risks;

“(E) the ways in which the Food and Drug Administration will use the Plan to guide and coordinate the projects and activities of the Food and Drug Administration across its offices and centers; and

“(F) a skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

“(3) EVALUATION OF PROGRESS.—Each Food and Drug Administration Strategic Information Technology Plan issued pursuant to this subsection, with the exception of the first such Food and Drug Administration Strategic Information Technology Plan, shall include an evaluation of—

“(A) the progress the Secretary has made, based on the metrics, benchmarks, and other milestones that measure successful development and implementation of information technology systems; and

“(B) whether actions taken in response to the previous Plan improved the capacity of the Food and Drug Administration to achieve the strategic goals and priorities set forth in such previous Plans.”

OFFICE OF MINOR USE AND MINOR SPECIES ANIMAL DRUG DEVELOPMENT

Pub. L. 108-282, title I, §102(b)(7), Aug. 2, 2004, 118 Stat. 905, provided that: “The Secretary of Health and Human Services shall establish within the Center for Veterinary Medicine (of the Food and Drug Administration), an Office of Minor Use and Minor Species Animal Drug Development that reports directly to the Director of the Center for Veterinary Medicine. This office shall

be responsible for overseeing the development and legal marketing of new animal drugs for minor uses and minor species. There is authorized to be appropriated to carry out this subsection \$1,200,000 for fiscal year 2004 and such sums as may be necessary for each fiscal year thereafter.”

REGULATIONS FOR SUNSCREEN PRODUCTS

Pub. L. 105-115, title I, §129, Nov. 21, 1997, 111 Stat. 2331, provided that: “Not later than 18 months after the date of enactment of this Act [Nov. 21, 1997], the Secretary of Health and Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.”

CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendment by Pub. L. 111-353 to be construed to apply to certain alcohol-related facilities, 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 2206, 2251, and 2252 of this title.

ADVANCING REGULATORY SCIENCE TO PROMOTE PUBLIC HEALTH INNOVATION

Pub. L. 112-144, title XI, §1124, July 9, 2012, 126 Stat. 1114, provided that:

“(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [July 9, 2012], the Secretary of Health and Human Services (referred to in this section as the ‘Secretary’) shall develop a strategy and implementation plan for advancing regulatory science for medical products in order to promote the public health and advance innovation in regulatory decisionmaking.

“(b) REQUIREMENTS.—The strategy and implementation plan developed under subsection (a) shall be consistent with the user fee performance goals in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biosimilar User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement commitment letter transmitted by the Secretary to Congress on April 20, 2012, and shall—

“(1) identify a clear vision of the fundamental role of efficient, consistent, and predictable, science-based decisions throughout regulatory decisionmaking of the Food and Drug Administration with respect to medical products;

“(2) identify the regulatory science priorities of the Food and Drug Administration directly related to fulfilling the mission of the agency with respect to decisionmaking concerning medical products and allocation of resources toward such regulatory science priorities;

“(3) identify regulatory and scientific gaps that impede the timely development and review of, and regulatory certainty with respect to, the approval, licensure, or clearance of medical products, including with respect to companion products and new technologies, and facilitating the timely introduction and adoption of new technologies and methodologies in a safe and effective manner;

“(4) identify clear, measurable metrics by which progress on the priorities identified under paragraph (2) and gaps identified under paragraph (3) will be measured by the Food and Drug Administration, including metrics specific to the integration and adoption of advances in regulatory science described in paragraph (5) and improving medical product decisionmaking, in a predictable and science-based manner; and

“(5) set forth how the Food and Drug Administration will ensure that advances in regulatory science for medical products are adopted, as appropriate, on an ongoing basis and in an [sic] manner integrated across centers, divisions, and branches of the Food and Drug Administration, including by senior managers and reviewers, including through the—

“(A) development, updating, and consistent application of guidance documents that support medical product decisionmaking; and

“(B) adoption of the tools, methods, and processes under section 566 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-5).

“(c) PERFORMANCE REPORTS.—The annual performance reports submitted to Congress under sections 736B(a) [21 U.S.C. 379h-2(a)] (as amended by section 104 of this Act), 738A(a) [21 U.S.C. 379j-1(a)] (as amended by section 204 of this Act), 744C(a) [21 U.S.C. 379j-43(a)] (as added by section 303 of this Act), and 744I(a) [21 U.S.C. 379j-53(a)] (as added by section 403 of this Act) of the Federal Food, Drug, and Cosmetic Act for each of fiscal years 2014 and 2016, shall include a report from the Secretary on the progress made with respect to—

“(1) advancing the regulatory science priorities identified under paragraph (2) of subsection (b) and resolving the gaps identified under paragraph (3) of such subsection, including reporting on specific metrics identified under paragraph (4) of such subsection;

“(2) the integration and adoption of advances in regulatory science as set forth in paragraph (5) of such subsection; and

“(3) the progress made in advancing the regulatory science goals outlined in the Prescription Drug User Fee Agreement commitment letter, the Generic Drug User Fee Agreement commitment letter, and the Biologics User Fee Agreement commitment letter transmitted by the Secretary to Congress on January 13, 2012, and the Medical Device User Fee Agreement transmitted by the Secretary to Congress on April 20, 2012.

“(d) MEDICAL PRODUCT.—In this section, the term ‘medical product’ means a drug, as defined in subsection (g) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act [42 U.S.C. 262(i)].”

INFORMATION TECHNOLOGY

Pub. L. 112-144, title XI, §1125, July 9, 2012, 126 Stat. 1115, provided that:

“(a) HHS REPORT.—Not later than 1 year after the date of enactment of this Act [July 9, 2012], the Secretary of Health and Human Services shall—

“(1) report to Congress on—

“(A) the milestones and a completion date for developing and implementing a comprehensive information technology strategic plan to align the information technology systems modernization projects with the strategic goals of the Food and Drug Administration, including results-oriented goals, strategies, milestones, performance measures;

“(B) efforts to finalize and approve a comprehensive inventory of the information technology systems of the Food and Drug Administration that includes information describing each system, such as costs, system function or purpose, and status information, and incorporate use of the system portfolio into the information investment management process of the Food and Drug Administration;

“(C) the ways in which the Food and Drug Administration uses the plan described in subparagraph (A) to guide and coordinate the modernization projects and activities of the Food and Drug Administration, including the interdependencies among projects and activities; and

“(D) the extent to which the Food and Drug Administration has fulfilled or is implementing recommendations of the Government Accountability Office with respect to the Food and Drug Administration and information technology; and

“(2) develop—

“(A) a documented enterprise architecture program management plan that includes the tasks, activities, and timeframes associated with developing and using the architecture and addresses how the

enterprise architecture program management will be performed in coordination with other management disciplines, such as organizational strategic planning, capital planning and investment control, and performance management; and

“(B) a skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

“(b) GAO REPORT.—Not later than January 1, 2016, the Comptroller General of the United States shall issue a report regarding the strategic plan described in subsection (a)(1)(A) and related actions carried out by the Food and Drug Administration. Such report shall assess the progress the Food and Drug Administration has made on—

“(1) the development and implementation of a comprehensive information technology strategic plan, including the results-oriented goals, strategies, milestones, and performance measures identified in subsection (a)(1)(A);

“(2) the effectiveness of the comprehensive information technology strategic plan described in subsection (a)(1)(A), including the results-oriented goals and performance measures; and

“(3) the extent to which the Food and Drug Administration has fulfilled recommendations of the Government Accountability Office with respect to such agency and information technology.”

FDA STUDY OF MERCURY COMPOUNDS IN DRUGS AND FOOD

Pub. L. 105-115, title IV, §413, Nov. 21, 1997, 111 Stat. 2376, provided that:

“(a) LIST AND ANALYSIS.—The Secretary of Health and Human Services shall, acting through the Food and Drug Administration—

“(1) compile a list of drugs and foods that contain intentionally introduced mercury compounds, and

“(2) provide a quantitative and qualitative analysis of the mercury compounds in the list under paragraph (1).

The Secretary shall compile the list required by paragraph (1) within 2 years after the date of enactment of the Food and Drug Administration Modernization Act of 1997 [Nov. 21, 1997] and shall provide the analysis required by paragraph (2) within 2 years after such date of enactment.

“(b) STUDY.—The Secretary of Health and Human Services, acting through the Food and Drug Administration, shall conduct a study of the effect on humans of the use of mercury compounds in nasal sprays. Such study shall include data from other studies that have been made of such use.

“(c) STUDY OF MERCURY SALES.—

“(1) STUDY.—The Secretary of Health and Human Services, acting through the Food and Drug Administration and subject to appropriations, shall conduct, or shall contract with the Institute of Medicine of the National Academy of Sciences to conduct, a study of the effect on humans of the use of elemental, organic, or inorganic mercury when offered for sale as a drug or dietary supplement. Such study shall, among other things, evaluate—

“(A) the scope of mercury use as a drug or dietary supplement; and

“(B) the adverse effects on health of children and other sensitive populations resulting from exposure to, or ingestion or inhalation of, mercury when so used.

In conducting such study, the Secretary shall consult with the Administrator of the Environmental Protection Agency, the Chair of the Consumer Product Safety Commission, and the Administrator of the Agency for Toxic Substances and Disease Registry, and, to the extent the Secretary believes necessary or appropriate, with any other Federal or private entity.

“(2) REGULATIONS.—If, in the opinion of the Secretary, the use of elemental, organic, or inorganic mercury offered for sale as a drug or dietary supple-

ment poses a threat to human health, the Secretary shall promulgate regulations restricting the sale of mercury intended for such use. At a minimum, such regulations shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from exposure to, or ingestion or inhalation of, mercury. Such regulations, to the extent feasible, should not unnecessarily interfere with the availability of mercury for use in religious ceremonies."

MANAGEMENT ACTIVITIES STUDY

Pub. L. 102-571, title II, § 205, Oct. 29, 1992, 106 Stat. 4502, directed Comptroller General to conduct a study of management of activities of the Food and Drug Administration that are related to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances and submit an interim report to Congress, not later than 6 months after Oct. 29, 1992, with a final report to be submitted not later than 12 months after Oct. 29, 1992.

CONGRESSIONAL FINDINGS

Pub. L. 100-607, title V, §502, Nov. 4, 1988, 102 Stat. 3120, provided that: "Congress finds that—

"(1) the public health has been effectively protected by the presence of the Food and Drug Administration during the last eighty years;

"(2) the presence and importance of the Food and Drug Administration must be guaranteed; and

"(3) the independence and integrity of the Food and Drug Administration need to be enhanced in order to ensure the continuing protection of the public health..."

§ 393a. Office of Pediatric Therapeutics

(a) Establishment

The Secretary of Health and Human Services shall establish an Office of Pediatric Therapeutics within the Food and Drug Administration.

(b) Duties

The Office of Pediatric Therapeutics shall be responsible for coordination and facilitation of all activities of the Food and Drug Administration that may have any effect on a pediatric population or the practice of pediatrics or may in any other way involve pediatric issues, including increasing pediatric access to medical devices.

(c) Staff

The staff of the Office of Pediatric Therapeutics shall coordinate with employees of the Department of Health and Human Services who exercise responsibilities relating to pediatric therapeutics and shall include—

(1) one or more additional individuals with expertise concerning ethical issues presented by the conduct of clinical research in the pediatric population;

(2) subject to subsection (d), one or more additional individuals with necessary expertise in a pediatric subpopulation that is, as determined through consideration of the reports and recommendations issued by the Institute of Medicine and the Comptroller General of the United States, less likely to be studied as a part of a written request issued under section 355a of this title or an assessment under section 355c of this title;

(3) one or more additional individuals with expertise in pediatric epidemiology; and

(4) one or more additional individuals with expertise in pediatrics as may be necessary to perform the activities described in subsection (b).

(d) Neonatology expertise

At least one of the individuals described in subsection (c)(2) shall have expertise in neonatology.

(Pub. L. 107-109, §6, Jan. 4, 2002, 115 Stat. 1414; Pub. L. 110-85, title III, §306(a), Sept. 27, 2007, 121 Stat. 864; Pub. L. 112-144, title V, §511, July 9, 2012, 126 Stat. 1050; Pub. L. 115-52, title V, §505(d)(1), Aug. 18, 2017, 131 Stat. 1047.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Best Pharmaceuticals for Children Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

AMENDMENTS

2017—Subsec. (d). Pub. L. 115-52 substituted “At least” for “For the 5-year period beginning on July 9, 2012, at least”.

2012—Subsec. (c)(2) to (4). Pub. L. 112-144, §511(1), added pars. (2) and (3) and redesignated former par. (2) as (4).

Subsec. (d). Pub. L. 112-144, §511(2), added subsec. (d).

2007—Subsec. (b). Pub. L. 110-85 inserted “, including increasing pediatric access to medical devices” before period at end.

§ 394. Scientific review groups

Without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Commissioner of Food and Drugs may—

(1) establish such technical and scientific review groups as are needed to carry out the functions of the Food and Drug Administration (including functions prescribed under this chapter); and

(2) appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

(June 25, 1938, ch. 675, §1004, formerly §903, as added Pub. L. 101-635, title III, §301, Nov. 28, 1990, 104 Stat. 4584; renumbered §904, Pub. L. 103-43, title XX, §2006(1), June 10, 1993, 107 Stat. 209; renumbered §1004, Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

§ 395. Loan repayment program

(a) In general

(1) Authority for program

Subject to paragraph (2), the Secretary shall carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the Food and Drug Administration, in consideration of the Federal Government agreeing to repay, for each year of such service, not more