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) of this section;

(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.)

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''.

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.''

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 Biosimilar 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 supplement 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 sec-