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

than $20,000 of the principal and interest of the educational loans of such health professionals.

(2) Limitation

The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the Food and Drug Administration for purposes of paragraph (1) for a period of not less than 3 years.

(b) Applicability of certain provisions

With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III of the Public Health Service Act [42 U.S.C. 254*l* et seq.], the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

(June 25, 1938, ch. 675, §1005, formerly §905, as added Pub. L. 103–43, title XX, §2006(2), June 10, 1993, 107 Stat. 210; renumbered §1005, Pub. L. 111–31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b), is act July 1, 1944, ch. 373, 58 Stat. 682. Subpart III of part D of title III of the Act is classified generally to subpart III [§254*l* et seq.] of part D of subchapter II of chapter 6A of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

§ 396. Practice of medicine

Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

(June 25, 1938, ch. 675, §1006, formerly §906, as added Pub. L. 105–115, title II, §214, Nov. 21, 1997, 111 Stat. 2348; renumbered §1006, Pub. L. 111–31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

§ 397. Contracts for expert review

(a) In general

(1) Authority

The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with relevant expertise, to review and evaluate, for the purpose of making recommendations to the Secretary on, part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this chapter for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 379 of this title relating to the confidentiality of information.

(2) Increased efficiency and expertise through contracts

The Secretary may use the authority granted in paragraph (1) whenever the Secretary determines that use of a contract described in paragraph (1) will improve the timeliness of the review of an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. The Secretary may use such authority whenever the Secretary determines that use of such a contract will improve the quality of the review of an application or submission described in paragraph (1), unless using such authority would unduly increase the cost of such review. Such improvement in timeliness or quality may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

(b) Review of expert review

(1) In general

Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter in a timely manner.

(2) Limitation

A final decision by the Secretary on any such application or submission shall be made within the applicable prescribed time period for review of the matter as set forth in this chapter or in the Public Health Service Act (42 U.S.C. 201 et seq.).

(June 25, 1938, ch. 675, §1007, formerly §907, as added Pub. L. 105–115, title IV, §415, Nov. 21, 1997, 111 Stat. 2377; renumbered §1007, Pub. L. 111–31,