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 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) of this section.

(d) Neonatology expertise

For the 5-year period beginning on July 9, 2012, 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.)

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

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