

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

Section 503(c) of title V of Pub. L. 100-607 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 [21 U.S.C. 393(b)(1)] (as added by subsection (a) of this section) shall apply to the appointments of Commissioners of Food and Drugs made after the date of enactment of this Act.”

REGULATIONS FOR SUNSCREEN PRODUCTS

Section 129 of Pub. L. 105-115 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.”

FDA STUDY OF MERCURY COMPOUNDS IN DRUGS AND FOOD

Section 413 of Pub. L. 105-115 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 Protec-

tion 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

Section 502 of Pub. L. 100-607 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.”

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360m of this title.

§ 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, §904, 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.)

REFERENCES IN TEXT

The provisions of title 5 governing appointments in the competitive service, referred to in text, are classified generally to section 3301 et seq. of Title 5, Government Organization and Employees.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 355 of this title.

§ 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. 254f 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, §905, as added Pub. L. 103-43, title XX, §2006(2), June 10, 1993, 107 Stat. 210.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended. Subpart III of part D of title III of the Act is classified generally to subpart III [§254f 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 con-

dition 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, §906, as added Pub. L. 105-115, title II, §214, Nov. 21, 1997, 111 Stat. 2348.)

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) of this section 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