Public Law 101-635 101st Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revitalize the Food and Drug Administration, and for other purposes.

Nov. 28, 1990 [S. 845]

Food and Drug

Administration

21 USC 301 note.

Revitalization

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Food and Drug Administration Revitalization Act"

Act

(b) Table of Contents.—The table of contents is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. References to the Federal Food, Drug, and Cosmetic Act.

TITLE I—CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACILITY

Sec. 101. Consolidated administrative and laboratory facility.

TITLE II—RECOVERY AND RETENTION OF FEES FOR FOIA REQUESTS

Sec. 201. Recovery and retention of fees for FOIA requests.

TITLE III-SCIENTIFIC REVIEW GROUPS

Sec. 301. Scientific review groups.

TITLE IV-AUTOMATION OF FDA

Sec. 401. Automation of FDA.

SEC. 2. REFERENCES TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

I—CONSOLIDATED ADMINISTRA-TITLE TIVE AND LABORATORY FACILITY

SEC. 101. CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACILITY.

Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 710. CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACIL-ITY.

Government contracts. 21 USC 379b.

"(a) AUTHORITY.—The Secretary, in consultation with the Administrator of the General Services Administration, shall enter into contracts for the design, construction, and operation of a consolidated Food and Drug Administration administrative and laboratory facility.

"(b) AWARDING OF CONTRACT.—The Secretary shall solicit contract proposals under subsection (a) from interested parties. In awarding contracts under such subsection, the Secretary shall review such

proposals and give priority to those alternatives that are the most cost effective for the Federal Government and that allow for the use of donated land, federally owned property, or lease-purchase arrangements. A contract under this subsection shall not be entered into unless such contract results in a net cost savings to the Federal Government over the duration of the contract, as compared to the Government purchase price including borrowing by the Secretary of the Treasury.

Government property.

"(c) Donations.—In carrying out this section, the Secretary shall have the power, in connection with real property, buildings, and facilities, to accept on behalf of the Food and Drug Administration gifts or donations of services or property, real or personal, as the Secretary determines to be necessary.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section \$100,000,000 for fiscal year 1991, and such sums as may be necessary for each of the subsequent

fiscal years, to remain available until expended.".

TITLE II—RECOVERY AND RETENTION OF FEES FOR FOIA REQUESTS

SEC. 201. RECOVERY AND RETENTION OF FEES FOR FOIA REQUESTS.

Chapter VII (21 U.S.C. 371 et seq.) (as amended by section 101 of this Act) is further amended by adding at the end thereof the following new section:

21 USC 379c.

"SEC. 711. RECOVERY AND RETENTION OF FEES FOR FREEDOM OF INFORMATION REQUESTS.

"(a) In General.—The Secretary, acting through the Commis-

sioner of Food and Drugs, may-

"(1) set and charge fees, in accordance with section 552(a)(4)(A) of title 5, United States Code, to recover all reasonable costs incurred in processing requests made under section 552 of title 5, United States Code, for records obtained or created under this Act or any other Federal law for which responsibility for administration has been delegated to the Commissioner by the Secretary;

"(2) retain all fees charged for such requests; and

"(3) establish an accounting system and procedures to control receipts and expenditures of fees received under this section. "(b) USE OF FEES.—The Secretary and the Commissioner of Food and Drugs shall not use fees received under this section for any

and Drugs shall not use fees received under this section for any purpose other than funding the processing of requests described in subsection (a)(1). Such fees shall not be used to reduce the amount of funds made to carry out other provisions of this Act.

"(c) WAIVER OF FEES.—Nothing in this section shall supersede the right of a requester to obtain a waiver of fees pursuant to section

552(a)(4)(A) of title 5, United States Code.".

TITLE III—SCIENTIFIC REVIEW GROUPS

SEC. 301. SCIENTIFIC REVIEW GROUPS.

Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 903. SCIENTIFIC REVIEW GROUPS.

21 USC 394.

Without regard to the provisions of title 5, United States Code, 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 Act);

"(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.".

TITLE IV—AUTOMATION OF FDA

SEC. 401. AUTOMATION OF FDA.

Chapter VII (21 U.S.C. 371 et seq.) (as amended by sections 101 and 201 of this Act) is further amended by adding at the end thereof the following new section:

"SEC. 712. AUTOMATION OF FOOD AND DRUG ADMINISTRATION.

21 USC 379d.

"(a) In General.—The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this Act.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated each fiscal year such sums as are necessary to carry

out this section.".

Approved November 28, 1990.

LEGISLATIVE HISTORY—S. 845:

SENATE REPORTS: No. 101–242 (Comm. on Labor and Human Resources). CONGRESSIONAL RECORD, Vol. 136 (1990);
Oct. 24, considered and passed Senate.
Oct. 27, considered and passed House.