TITLE VI

RELATED AGENCIES AND FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

SALARIES AND EXPENSES

For necessary expenses of the Food and Drug Administration, including hire and purchase of passenger motor vehicles; for rental of special purpose space in the District of Columbia or elsewhere; and for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary's certificate, not to exceed $25,000; $907,499,000, of which not to exceed $87,528,000 in fees pursuant to section 736 of the Federal Food, Drug, and Cosmetic Act may be credited to this appropriation and remain available until expended: *Provided,* That fees derived from applications received during fiscal year 1997 shall be subject to the fiscal year 1997 limitation: *Provided further,* That none of these funds shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701.

In addition, fees pursuant to section 354 of the Public Health Service Act may be credited to this account, to remain available until expended.

In addition, fees pursuant to section 801 of the Federal Food, Drug, and Cosmetic Act may be credited to this account, to remain available until expended.

GENERAL PROVISIONS

SEC. 601. EFFECTIVE MEDICATION GUIDES.— 21 USC 353 note.

(a) IN GENERAL.—Not later than 30 days after the date of enactment of this Act, the Secretary of the Department of Health and Human Services shall request that national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, patient drug information database companies, and other relevant parties collaborate to develop a long-range comprehensive action plan to achieve goals consistent with the goals of the proposed rule of the Food and Drug Administration on "Prescription Drug Product Labeling: Medication Guide Requirements" (60 Fed. Reg. 44182; relating to the provision of oral and written prescription information to consumers).

(b) GOALS.—Goals consistent with the proposed rule described in subsection (a) are the distribution of useful written information to 75 percent of individuals receiving new precriptions by the year 2000 and to 95 percent by the year 2006.

(c) PLAN.—The plan described in subsection (a) shall—

(1) identify the plan goals;

(2) assess the effectiveness of the current private-sector approaches used to provide oral and written prescription information to consumers;

Guidelines.

(3) develop guidelines for providing effective oral and written prescription information consistent with the findings of any such assessment;

(4) contain elements necessary to ensure the transmittal of useful information to the consuming public, including being scientifically accurate, non-promotional in tone and content, sufficiently specific and comprehensive as to adequately inform consumers about the use of the product, and in an understandable, legible format that is readily comprehensible and not confusing to consumers expected to use the product.

(5) develop a mechanism to assess periodically the quality of the oral and written prescription information and the frequency with which the information is provided to consumers; and

(6) provide for compliance with relevant State board regulations.

(d) LIMITATION ON THE AUTHORITY OF THE SECRETARY.—The Secretary of the Department of Health and Human Services shall have no authority to implement the proposed rule described in subsection (a), or to develop any similar regulation, policy statement, or other guideline specifying a uniform content or format for written information voluntarily provided to consumers about prescription drugs if, (1) not later than 120 days after the date of enactment of this Act, the national organizations described in subsection (a) develop and submit to the Secretary for Health and Human Services a comprehensive, long-range action plan (as described in subsection (a)) which shall be acceptable to the Secretary of Health and Human Services; (2) the aforementioned plan is submitted to the Secretary of Health and Human Services for review and acceptance: *Provided,* That the Secretary shall give due consideration to the submitted plan and that any such acceptance shall not be arbitrarily withheld; and (3) the implementation of (a) a plan accepted by the Secretary commences within 30 days of the Secretary's acceptance of such plan, or (b) the plan submitted to the Secretary commences within 60 days of the submission of such plan if the Secretary fails to take any action on the plan within 30 days of the submission of the plan. The Secretary shall accept, reject or suggest modifications to the plan submitted within 30 days of its submission. The Secretary may confer with and assist private parties in the development of the plan described in subsections (a) and (b).

(e) SECRETARY REVIEW.—Not later than January 1, 2001, the Secretary of the Department of Health and Human Services shall review the status of private-sector initiatives designed to achieve the goals of the plan described in subsection (a), and if such goals are not achieved, the limitation in subsection (d) shall not apply, and the Secretary shall seek public comment on other initiatives that may be carried out to meet such goals.

SEC. 602. Section 3 of the Saccharin Study and Labeling Act (21 U.S.C 348 note) is amended by striking out "May 1, 1997" and inserting in lieu thereof "May 1, 2002".

SEC. 603. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

21 USC 381.

(a) IMPORTS FOR EXPORT.—Section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act is amended—

(1) by striking "accessory of a device which is ready" and inserting "accessory of a device, or other article of device requiring further processing, which is ready";

(2) in subparagraph (A), by striking "is intended to be" and inserting "is intended to be further processed by the initial owner or consignee, or"; and

(3) in subparagraph (C)—

(A) by striking "part," and inserting "part, article,"; and

(B) by striking "incorporated" and inserting "incorporated or further processed".

(b) LABELING OF EXPORTED DRUGS.—Section 801(f) of the Federal Food, Drug, and Cosmetic Act is amended— 21 USC 381.

(1) in paragraph (1), by striking "If a drug" and inserting "If a drug (other than insulin, an antibiotic drug, an animal drug, or a drug exported under section 802)"; and

(2) in paragraph (2), by adding at the end the following new sentence: "A drug exported under section 802 is exempt from this section.".

(c) EXPORT OF CERTAIN UNAPPROVED DRUGS AND DEVICES.—Section 802(f)(5) of the Federal Food, Drug, and Cosmetic Act is amended by striking "if the drug or device is not labeled" and inserting "if the labeling of the drug or device is not". 21 USC 382.

BUILDINGS AND FACILITIES

For plans, construction, repair, improvement, extension, alteration, and purchase of fixed equipment or facilities of or used by the Food and Drug Administration, where not otherwise provided, $21,350,000, to remain available until expended (7 U.S.C. 2209b).

RENTAL PAYMENTS (FDA)

(INCLUDING TRANSFERS OF FUNDS)

For payment of space rental and related costs pursuant to Public Law 92–313 for programs and activities of the Food and Drug Administration which are included in this Act, $46,294,000: *Provided,* That in the event the Food and Drug Administration should require modification of space needs, a share of the salaries and expenses appropriation may be transferred to this appropriation, or a share of this appropriation may be transferred to the salaries and expenses appropriation, but such transfers shall not exceed 5 percent of the funds made available for rental payments (FDA) to or from this account.

DEPARTMENT OF THE TREASURY

FINANCIAL MANAGEMENT SERVICE

PAYMENTS TO THE FARM CREDIT SYSTEM FINANCIAL ASSISTANCE CORPORATION

For necessary payments to the Farm Credit System Financial Assistance Corporation by the Secretary of the Treasury, as authorized by section 6.28(c) of the Farm Credit Act of 1971, as amended, for reimbursement of interest expenses incurred by the Financial