APPROPRIATIONS LANGUAGE

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 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; for rental of special purpose space in the District of Columbia or elsewhere; 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; and notwithstanding section 521 of Public Law 107–188; [$1,820,849,000] *$1,881,489,000, of which $7,000,000 shall remain available until expended for plans, construction, extension, alteration, and purchase of fixed equipment or facilities*: Provided, That of the amount provided under this heading, [$284,394,000] *$305,332,000* shall be derived from prescription drug user fees authorized by 21 U.S.C. 379h, [and] shall be credited to this account and remain available until expended, Provided, That this amount shall not include any fees pursuant to 21 U.S.C. 379h(a)(2) and (a)(3) assessed for fiscal year [2006] *2007* but collected in fiscal year [2005] *2006*; [$33,938,000] *$40,300,000* shall be derived from medical device user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended; and [$8,000,000] *$11,318,000* shall be derived from animal drug user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended: Provided further, That fees derived from prescription drug, medical device, and animal drug assessments received during fiscal year [2005] *2006*, including any such fees assessed prior to the current fiscal year but credited during the current year, shall be subject to the fiscal year [2005] *2006* limitation: Provided further, That none of these shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701 [*Provided further,* That of the total amount appropriated: (1) $439,038,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $498,647,000 shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs; (3) $172,714,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) $98,964,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $235,078,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $40,530,000 shall be for the National Center for Toxicological Research; (7) $57,722,000 shall be for Rent and Related activities, other than the amounts paid to the General Services Administration for rent; (8) $129,815,000 shall be for payments to the General Services Administration for rent; and (9) $115,970,000 shall be for other activities, including the Office of the Commissioner; the Office of Management; the Office of External Relations; the Office of Policy and Planning; and central services for these offices:]

In addition, mammography user fees authorized by 42 U.S.C. 263b may be credited to this account, to remain available until expended.

In addition, export certification user fees authorized by 21 U.S.C. 381 may be credited to this account, to remain available until expended.

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

The budget provides a [$108.78] *$49,628,000* increase in budget authority over the FY [2004 Omnibus Appropriation Act] *2005 Enacted Budget*. In addition, the Budget includes an increase of [$39.85] *$31,320,000* in current law user fees over FY [2004] *2005*, which will be used to cover *non pay related* inflationary increases [as well as increases in workload for the PDUFA, MDUFMA, and ADUFA programs]. In total, the budget includes [$1.821] *$1,881,489,000* at the program level, which includes funding for counter terrorism activities that specifically relate to the protection of products or therapies regulated by the FDA (such as drugs, vaccines, foods, and animal feed), and the availability of medical products for public health preparedness in the event of an attack. Specifically, the budget requests increased funding for food defense, *medical device review, the Office of Drug Safety, GSA Rent payments, moving expenses the CDRH Engineering and Physics lab and the shared data facility at the White Oak campus, and maintenance of building and facilities.*[medical counter measures related to terrorism or other related threats to pubic health, medical device reviews, protecting the safety of the U.S. food and feed supply from Bovine Spongiform Encephalopathy (BSE), inflationary pay increases], and moving expenses for a new Human Drugs facility in White Oak, Maryland].

Salaries and Expenses - Explanatory Notes

1/ Language is retained which provides FDA with the authority to credit to this account fees that may have been collected in excess of amounts appropriated in a previous year, if any such excess collections occurred. This is the intent of section 736(g)(4) of the Food Drug and Cosmetic Act, and it exempts FDA from making small individual refunds of unanticipated excess collections. Excess fees from previous years, if any, would be used to reduce the amount of fees FDA would collect in a subsequent year--in effect lowering the fees that FDA would otherwise assess and collect. This is intended to make appropriation language consistent with authorizing language.
2/ Important language is added that enables FDA to collect user fees for drug establishments and products, as set forth in the Prescription Drug User Fee Act (PDUFA), but that such fees collected during fiscal year [2005] *2006* year and assessed for fiscal year [2006] *2007*, not count against the FY [2005] 2006 collection ceiling established in the FY [2005] *2006* appropriation law.