

**TITLE IV  
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; \$4,256,673,000: Provided, That of the amount provided under this heading, \$856,041,000 shall be derived from prescription drug user fees authorized by 21 U.S.C. 379h, shall be credited to this account and remain available until expended, and shall not include any fees pursuant to 21 U.S.C. 379h(a)(2) and (a)(3) assessed for fiscal year 2013 but collected in fiscal year 2012; \$67,118,000 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; \$21,768,000 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; \$5,706,000 shall be derived from animal generic drug user fees authorized by 21 U.S.C. 379f, and shall be credited to this account and shall*

*remain available until expended; \$477,000,000 shall be derived from tobacco product user fees authorized by 21 U.S.C. 387s and shall be credited to this account and remain available until expended; \$12,364,000 shall be derived from food and feed recall fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act (Public Law 75-717), as added by the FDA Food Safety Modernization Act (Public Law 111-353), and shall be credited to this account and remain available until expended; \$14,700,000 shall be derived from food reinspection fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act, as added by the FDA Food Safety Modernization Act, and shall be credited to this account and remain available until expended; and \$71,066,000 shall be derived from voluntary qualified importer program fees authorized by section 743 of the Federal Food, Drug, and Cosmetic Act, as added by the FDA Food Safety Modernization Act, and shall be credited to this account and remain available until expended: Provided further, That in addition and notwithstanding any other provision under this heading, amounts collected for prescription drug user fees that exceed the fiscal year 2012 limitation are appropriated and shall be credited to this account and remain available until expended: Provided further, That fees derived from prescription drug, medical device, animal drug, animal generic drug, and tobacco product assessments for fiscal year 2012 received during fiscal year 2012, including any such fees assessed prior to fiscal year 2012 but credited for fiscal year 2012, shall be subject to the fiscal year 2012 limitations: Provided further, That not to exceed \$25,000 of this amount shall be*

*for official reception and representation expenses, not otherwise provided for, as determined by the Commissioner.*

*In addition, mammography user fees authorized by 42 U.S.C. 263b, export certification user fees authorized by 21 U.S.C. 381, and priority review user fees authorized by 21 U.S.C. 360n may be credited to this account, to remain available until expended.*

### **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, \$13,055,000, to remain available until expended.*

### **SALARIES AND EXPENSES**

*Contingent upon the enactment of authorizing legislation, the Secretary shall charge fees for generic drug review activities: Provided, That such fees, in an amount not to exceed \$40,122,000, shall be credited to this account, to remain available until expended, for generic drug review activities.*

*In addition, contingent upon the enactment of authorizing legislation to charge reinspection fees for products other than food, the Secretary shall charge fees for such reinspections: Provided, That such fees, in an amount not to exceed \$14,108,000, shall be credited to this account, to remain available until expended, for reinspections.*

*In addition, contingent upon the enactment of authorizing legislation, the Secretary shall charge fees for international express courier import activities: Provided, That such fees, in an amount not to exceed \$5,338,000, shall be credited to this account, to remain available until expended, for international express couriers import activities.*

<b>Language Provision</b>	<b>Explanation</b>
Generic Drug Review User Fee	The Administration will propose legislation to allow FDA to collect fees to support generic drug review. The additional resources, estimated at \$40,122,000 in 2012, will enable FDA to reduce review times and respond to the growing number of generic drug applications.
Medical Products Reinspection User Fee	The Administration will propose legislation to allow FDA to collect fees to cover the costs of medical re-inspections and associated follow-up work. The additional resources, estimated at \$14,108,000 in 2012, will ensure that facilities that fail to comply with health and safety standards bear the cost of reinspection.
International Express Couriers User Fees	The Administration will propose legislation to allow FDA to collect fees to cover the costs of increased surveillance at express courier hubs. The additional resources, estimated at \$5,338,000 in 2012, will support FDA import operations to support international courier activities.