FY 2008 Proposed Appropriation Language

Primary Exhibit [1]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
Federal Funds

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; $1,649,405,000: Provided, That of the amount provided under this heading, $13,696,000 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 animal drug assessments received during fiscal year 2008, including any such fees assessed prior to the current fiscal year but credited during the current year, shall be subject to the fiscal year 2008 limitation.

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.

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, $4,950,000, to remain available until expended.

SALARIES AND EXPENSES
(Legislative proposal, not subject to PAYGO)

Contingent upon the enactment of authorizing legislation, the Secretary shall charge a fee for generic drug review activities: Provided, That such fees, in an amount not to exceed $15,701,000, shall be credited as an offsetting collection to this account, to remain available until expended for the purpose of such generic drug review activities. In addition, contingent upon the enactment of authorizing legislation, the Secretary shall charge a fee for prescription drug review and medical device review activities: Provided, That such fees, in an amount not to exceed $339,195,000, for prescription drug reviews, shall be credited to this amount and remain available until expended for the purpose of such prescription drug reviews, and shall not include any prescription drug review fees assessed for fiscal year 2009 but collected in fiscal year 2008; and $47,500,000 for medical device reviews, shall be credited to this amount, to remain available until expended for the purpose of such medical device review activities: Provided further, That fees derived from prescription drug and medical device review assessments received during fiscal year 2008, including any such fees assessed prior to the current fiscal year but credited during the current year, shall be subject to the fiscal year 2008 limitation.

[1] The FY 2008 President's Budget Appendix and OMB MAX A-11 database incorrectly identifies MQSA as legislation that must be re-authorized in FY 2008 in order for FDA to continue collecting mammography user fees.

Supplementary Exhibit

Comparison of Proposed FY 2008 Appropriations Language to Most Recently Enacted Full-Year Appropriation (FY 2006)

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; ~~$1,838,567,000:~~ **$1,649,405,000:** ~~*Provided*, That of the amount provided under this heading, $305,332,000 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 2007 but collected in fiscal year 2006; $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 $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 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 2006 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: *Provided further*, That of the total amount appropriated: (1) $443,153,000 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $520,564,000 shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs; (3) $178,714,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) $99,787,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $245,770,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $41,152,000 shall be for the National Center for Toxicological Research; (7) $58,515,000 shall be for Rent and Related activities, of which $21,974,000 is for White Oak Consolidation, other than the amounts paid to the General Services Administration for rent; (8) $134,853,000 shall be for payments to the General Services Administration for rent; and (9) $116,059,000 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: *Provided further*, That funds may be transferred from one specified activity to another with the prior approval of the Committees on Appropriations of both Houses of Congress.~~ In addition, mammography user fees authorized by 42 U.S.C. 263b may be credited to this account, to remain available until expended. **Provided, That of the amount provided under this heading, $13,696,000 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 animal drug assessments received during fiscal year 2008, including any such fees assessed prior to the current fiscal year but credited during the current year, shall be subject to the fiscal year 2008 limitation.

In addition, export certification user fees authorized by 21 U.S.C. 381 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, ~~$8,000,000~~ **$4,950,000**, to remain available until expended.

SALARIES AND EXPENSES
(Legislative proposal, not subject to PAYGO)

Contingent upon the enactment of authorizing legislation, the Secretary shall charge a fee for generic drug review activities. Provided, That such fees, in an amount not to exceed $15,701,000, shall be credited to this account, to remain available until expended for the purpose of generic drug review activities.

In addition, contingent upon the enactment of authorizing legislation, the Secretary shall charge a fee for prescription drug review and medical device review: Provided, That fees, in an amount not to exceed $339,195,000 for prescription drug reviews, shall be credited to this amount and remain available until expended for the purpose of prescription drug reviews, and shall not include any prescription drug review fees assessed for fiscal year 2009 but collected in fiscal year 2008;

Provided, That fees, in an amount not to exceed $47,500,000 for medical device reviews, shall be credited to this amount, to remain available until expended for the purpose of such medical device review activities; Provided further: That fees derived from prescription drug and medical device review assessments received during fiscal year 2008, including any such fees assessed prior to the current fiscal year but credited during the current year, shall be subject to the fiscal year 2008 limitation.

Language Analysis

Language Provision	Explanation
Reauthorization of FY 2007 Current Law User Fees – PDUFA, MDUFMA	The FY 2006 enacted appropriations language for the PDUFA and MDUFMA user fee programs is struck because collecting these fees is subject to re-authorization in FY 2008. The Administration will propose authorizing legislation to reauthorize the collection and spending of fees, subject to appropriation language.
Animal Drug User Fee (ADUFA)	The budget includes $13,696,000 derived from current law animal drug user fees authorized by 21 U.S.C. 379j, but also includes an FY 2008 fiscal year 2008 limitation.
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 $15,701,000 in 2008, will enable FDA to reduce review times and respond to the growing number of generic drug applications.
Prescription Drug User Fee – Reauthorization	The authority to collect fees under PDUFA expires on September 30, 2007. The terms of legislation to reauthorize PDUFA are currently under discussion. Contingent on reauthorization by FY 2008, the budget requests $339,195,000 in spending authority from PDUFA user fees. This amount is subject to change depending on the reauthorization statute.
Medical Device User Fee and Modernization Act – Reauthorization	The authority to collect fees under MDUFMA expires on September 30, 2007. The terms of legislation to reauthorize MDUFMA are currently under discussion. Contingent on reauthorization by FY 2008, the budget requests $47,500,000 in spending authority from MDUFMA fees. This amount is subject to change depending on the reauthorization statute.