APPROPRIATION LANGUAGE

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; **[**$4,665,400,000**]**[1] *$4,755,944,000: Provided,* That of the amount provided under this heading, [$851,481,000] $*865,653,000* 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; [$137,677,000] *$144,859,000* 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; [$318,363,000] *$324,085,000* shall be derived from human generic drug user fees authorized by 21 U.S.C. 379j–42, and shall be credited to this account and remain available until expended; [$21,540,000] *$22,079,000* shall be derived from biosimilar biological product user fees authorized by 21 U.S.C. 379j–52, and shall be credited to this account and remain available until expended; [$22,818,000] *$22,977,000* shall be derived from animal drug user fees authorized by 21 U.S.C. 379j–12, and shall be credited to this account and remain available until expended; [$9,705,000] *$10,367,000* shall be derived from animal generic drug user fees authorized by 21 U.S.C. 379j–21, and shall be credited to this account and remain available until expended; [$599,000,000] *$635,000,000* 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: *Provided further,* That in addition and notwithstanding any other provision under this heading, amounts collected for prescription drug user fees, medical device user fees, human generic drug user fees, biosimilar biological product user fees, animal drug user fees, and animal generic drug user fees that exceed the respective fiscal year **[**2016**]** *2017* limitations are appropriated and shall be credited to this account and remain available until expended: Provided further, That fees derived from prescription drug, medical device, human generic drug, biosimilar biological product, animal drug, and animal generic drug assessments for fiscal year **[**2016**]** *2017*, including any such fees collected prior to fiscal year **[**2016**]** *2017* but credited for fiscal year **[**2016**]** *2017*, shall be subject to the fiscal year **[**2016**]** *2017* limitations: Provided further, That the Secretary may accept payment during fiscal year **[**2016**]** *2017* of user fees specified under this heading and authorized for fiscal year **[**2017**]** *2018*, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year **[**2017**]** *2018* for which the Secretary accepts payment in fiscal year **[**2016**]** *2017* shall not be included in amounts under this heading: 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) $1,230,796 shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs; (2) $1,413,331,000 shall be for the Center for Drug Evaluation and Research and related

[1] Please note that brackets indicate deleted text and italics indicate new text.

field activities in the Office of Regulatory Affairs; (3) $361,604,000 shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) $205,383,000 shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) $470,487,000 shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) $63,331,000 shall be for the National Center for Toxicological Research; (7) $596,338,000 shall be for the Center for Tobacco Products and for related field activities in the Office of Regulatory Affairs; (8) not to exceed $154,697,000 shall be for Rent and Related activities, of which $64,461,000 is for White Oak Consolidation, other than the amounts paid to the General Services Administration for rent; (9) not to exceed $247,941,000 shall be for payments to the General Services Administration for rent; and (10) $311,031,000 shall be for other activities, including the Office of the Commissioner of Food and Drugs, the Office of Foods and Veterinary Medicine, the Office of Medical and Tobacco Products, the Office of Global and Regulatory Policy, the Office of Operations, the Office of the Chief Scientist, and central services for these offices:**]** *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: **[***Provided further,* That any transfer of funds pursuant to Section 770(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(n)) shall only be from amounts made available under this heading for other activities: *Provided further,* That of the amounts that are made available under this heading for ''other activities'', and that are not derived from user fees, $1,500,000 shall be transferred to and merged with the appropriation for ''Department of Health and Human Services—Office of Inspector General'' for oversight of the programs and operations of the Food and Drug Administration and shall be in addition to funds otherwise made available for oversight of the Food and Drug Administration:**]** *Provided further,* That funds may be transferred from one specified activity to another with the prior **[**approval**]** *notification* of the Committees on Appropriations of both Houses of Congress.

In addition, mammography user fees authorized by 42 U.S.C. 263b, export certification user fees authorized by 21 U.S.C. 381, priority review user fees authorized by 21 U.S.C. 360n and 360ff, food and feed recall fees, food reinspection fees, and voluntary qualified importer program fees authorized by 21 U.S.C. 379j-31, outsourcing facility fees authorized by 21 U.S.C. 379j-62, prescription drug wholesale distributor licensing and inspection fees authorized by 21 U.S.C. 353(e)(3), [and] third-party logistics provider licensing and inspection fees authorized by 21 U.S.C. 360eee-3(c)(1), and third-party auditor authorized by 21 U.S.C. 384d(c)(8), shall be credited to this account, to remain available until expended.

BUILDINGS AND FACILITIES

For plans, construction, repair, improvement, extension, alteration, *demolition,* and purchase of fixed equipment or facilities of or used by the Food and Drug Administration, where not otherwise provided, [$8,788,000] $11,788,000, to remain available until expended.

SALARIES AND EXPENSES (LEGISLATIVE PROPOSAL)

In addition, contingent upon the enactment of authorizing legislation, the Secretary shall assess user fees with respect to food facility registrations and inspections, food imports, food contact notification activities, cosmetic activities, and international express courier import activities, and such fees shall be credited to this account and remain available until expended.

FY 2017 PROPOSED GENERAL PROVISIONS

SEC. __. INCREASE IN EXPORT CERTIFICATION FEES.—

Section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amended—

(1) in subparagraph (B) by striking "but shall not exceed $175 for each certification" and inserting "in an amount specified in subparagraph (E)"; and

(2) by adding at the end the following new subparagraphs:

"(E) The fee for each written export certification issued by the Secretary under this paragraph shall not exceed—

"(i) $600 for fiscal year 2017; and

"(ii) for each subsequent fiscal year, the prior fiscal year maximum amount multiplied by the inflation adjustment under section 738(c)(2)(C), applied without regard to the limitation in clause (ii)(II) of such section.

"(F) The Secretary shall, for each fiscal year, publish in the Federal Register a notice of the export certification fee under this paragraph for such year, not later than 60 days before such fee takes effect."