BUDGET EXHIBITS

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; $5,833,942,000: Provided, That of the amount provided under this heading, $1,062,367,000 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; $219,527,000 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; $511,682,000 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; $39,618,000 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; $30,524,000 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; $18,700,000 shall be derived from generic new animal drug user fees authorized by 21 U.S.C. 379j-21, and shall be credited to this account and remain available until expended; $712,000,000 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 to 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 generic animal drug user fees that exceed the respective fiscal year 2020 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 generic animal drug assessments for fiscal year 2020, including any such fees collected prior to fiscal year 2020 but credited for fiscal year 2020, shall be subject to the fiscal year 2020 limitations: Provided further, That the Secretary may accept payment during fiscal year 2020 of user fees specified under this heading and authorized for fiscal year 2021, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year 2021 for which the Secretary accepts payment in fiscal year 2020 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 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 funds may be transferred from one specified activity to another with the prior 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), third-party logistics provider licensing and inspection fees authorized by 21 U.S.C. 360eee-3(c)(1), third-party auditor fees authorized by 21 U.S.C. 384d(c)(8), and Medical Countermeasure Priority Review Voucher User Fees authorized by 21 U.S.C. 360bbb-4a, 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, $11,788,000, to remain available until expended.

Salaries and Expenses (Legislative Proposal)

Contingent upon the enactment of authorizing legislation, the Secretary shall charge a fee for innovative food products activities and over-the-counter monograph drug activities: Provided, That fees of $28,000,000 for innovative food products, shall be credited to this account and remain available until expended; $28,400,000 for over-the-counter monograph drug activities, shall be credited to this account and remain available until expended: Provided further, That, in addition to and notwithstanding any other provision under this heading, amounts collected for innovative food products and over-the-counter monograph drug user fees that exceed the respective fiscal year 2020 limitations are appropriated and shall be credited to this account and remain available until expended: Provided further, That fees derived from innovative food products, and over-the-counter monograph drug reviews for fiscal year 2020 received during fiscal year 2020, including any such fees assessed prior to fiscal year 2020 but credited for fiscal year 2020, shall be subject to the fiscal year 2020 limitations: Provided further, That the Secretary may accept payment during fiscal year 2020 of user fees specified in this paragraph and authorized for fiscal year 2021, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year 2021 for which the Secretary accepts payment in fiscal year 2020 shall not be included in amounts in this paragraph.
In addition, contingent upon the enactment of authorizing legislation establishing fees under 21 U.S.C. 387s with respect to products deemed under 21 U.S.C. 387a(b) but not specified in 21 U.S.C. 387s(b)(2)(B), the Secretary shall assess and collect such fees: Provided, That $100,000,000 shall be derived from such fees, which shall be credited to this account and remain available until expended, in addition to amounts otherwise derived from fees authorized under 21 U.S.C. 387s.

FDA Innovation, Cures Act

For necessary expenses to carry out the purposes described under section 1002(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes under the heading "Salaries and Expenses", $75,000,000, to remain available until expended: Provided, That amounts appropriated in this paragraph are appropriated pursuant to section 1002(b)(3) of the 21st Century Cures Act, are to be derived from amounts transferred under section 1002(b)(2)(A) of such Act, and may be transferred by the Secretary of Health and Human Services to other accounts of the Department solely for the purposes provided in such Act: Provided further, That such transfer authority is in addition to any other transfer authority provided by law.

Note.—A full-year 2019 appropriation for this account was not enacted at the time the budget was prepared; therefore, the budget assumes this account is operating under the Continuing Appropriations Act, 2019 (Division C of P.L. 115–245, as amended). The amounts included for 2019 reflect the annualized level provided by the continuing resolution.