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; $5,583,474,000: Provided, That of the amount provided under this heading, $960,568,000 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; $196,668,000 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; $501,396,000 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; $40,922,000 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; $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, and biosimilar biological product user fees that exceed the respective fiscal year 2019 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, and biosimilar biological product assessments for fiscal year 2019, including any such fees collected prior to fiscal year 2019 but credited for fiscal year 2019, shall be subject to the fiscal year 2019 limitations: Provided further, That the Secretary may accept payment during fiscal year 2019 of user fees specified under this heading and authorized for fiscal year 2020, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year 2020 for which the Secretary accepts payment in fiscal year 2019 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 animal drug review, animal generic drug review activities, and over-the-counter monograph drug activities: Provided, That fees of $30,331,000, for animal drug reviews, shall be credited to this account and remain available until expended; $18,336,000 for animal generic drug reviews, shall be credited to this account and remain available until expended; $22,000,000 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 animal drug, animal generic drug, and over-the-counter monograph drug user fees that exceed the respective fiscal year 2019 limitations are appropriated and shall be credited to this account and remain available until expended: Provided further, That fees derived from animal drug, animal generic drug, and over-the-counter monograph drug reviews for fiscal year 2019 received during fiscal year 2019, including any such fees assessed prior to fiscal year 2019 but credited for fiscal year 2019, shall be subject to the fiscal year 2019 limitations: Provided further, That the Secretary may accept payment during fiscal year 2019 of user fees specified in this paragraph and authorized for fiscal year 2020, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year 2020 for which the Secretary accepts payment in fiscal year 2019 shall not be included in amounts in this paragraph.

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", $70,000,000, 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.

FY 2019 PROPOSED GENERAL PROVISIONS

SEC. 714. None of the funds made available by this Act may be used to notify a sponsor or otherwise acknowledge receipt of a submission for an exemption for investigational use of a drug or biological product under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)) in research in which a human embryo is intentionally created or modified to include a heritable genetic modification. Any such submission shall be deemed to have not been received by the Secretary, and the exemption may not go into effect.

SEC. 725. (a) There is hereby established in the Treasury of the United States a Working Capital Fund (the Fund) to be administered by the Food and Drug Administration (FDA), without fiscal year limitation, for the payment of salaries, travel, and other expenses necessary to the maintenance and operation of (1) a supply service for the purchase, storage, handling, issuance, packing, or shipping of stationery, supplies, materials, equipment, and blank forms, for which stocks may be maintained to meet, in whole or in part, the needs of the FDA and requisitions of other Government Offices, and (2) such other services as the Commissioner of the FDA, subject to review by the Secretary of Health and Human Services, determines may be performed more advantageously as central services. The Fund shall be reimbursed from applicable discretionary resources, notwithstanding any otherwise applicable purpose limitations, available when services are performed or stock furnished, or in advance, on a basis of rates which shall include estimated or actual charges for personal services, materials, equipment, information technology, and other expenses. Charges for equipment and information technology shall include costs associated with maintenance, repair, and depreciation (including improvement and replacement).

(b) Of any discretionary resources appropriated in this Act for fiscal year 2019 for "Department of Health and Human Services - Food and Drug Administration - Salaries and Expenses", not to exceed $5,000,000 of available amounts may be transferred to and merged with the Fund established under subsection (a), notwithstanding any otherwise applicable purpose limitations.

(c) No amounts may be transferred pursuant to this section that are designated by the Congress as an emergency requirement pursuant to a concurrent resolution on the budget or the Balanced Budget and Emergency Deficit Control Act of 1985.

SEC. 715. No partially hydrogenated oils as defined in the order published by the Food and Drug Administration in the Federal Register on June 17, 2015 (80 Fed. Reg. 34650 et seq.) shall be deemed unsafe within the meaning of section 409(a) and no food that is introduced or delivered for introduction into interstate commerce that bears or contains a partially hydrogenated oil shall be deemed adulterated under sections 402(a)(1) or 402(a)(2)(C)(i) by virtue of bearing or containing a partially hydrogenated oil until the compliance date as specified in such order (June 18, 2018).

Sec. 724. 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— (a) in subparagraph (B) by striking "but shall not exceed $175 for each certification" and inserting "in an amount specified in subparagraph (E)"; and (b) 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 2018; and (ii) for each subsequent fiscal year, the prior fiscal year maximum amount multiplied by the inflation adjustment under section738(c)(2)(C), applied without regard to the limitation in clause (ii)(II) of such subparagraph. (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.".