for Fiscal Year 2014 (Public Law 113–66; 127 Stat. 881).''; and

(10) by redesignating subsections (d) through (h) as subsections (c) through (g), respectively.

SA 5742. Mr. PADILLA (for himself and Mrs. FEINSTEIN) submitted an amendment intended to be proposed to amendment SA 5499 submitted by Mr. REED (for himself and Mr. INHOFE) and intended to be proposed to the bill H.R. 7900, to authorize appropriations for fiscal year 2023 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle G of title X, add the following:

SEC. 10___. LAND HELD IN TRUST FOR THE KARUK TRIBE.

(a) FINDINGS.—Congress finds that—

(1) the Katimiîn and Ameekyáaraam land is located in the ancestral territory of the Karuk Tribe; and

(2) the Karuk Tribe has historically used, and has an ongoing relationship with, the Katimiîn and Ameekyáaraam land.

(b) DEFINITIONS.—In this section:

(1) KATIMIÎN AND AMEEKYÁARAAM LAND.—The term ''Katimiîn and Ameekyáaraam land'' means the approximately 1,031 acres of Federal land, including improvements and appurtenances to the Federal land, located in Siskiyou County, California, and Humboldt County, California, and generally depicted as ''Proposed Area'' on the map of the Forest Service entitled ''Katimiîn Area Boundary Proposal'' and dated August 9, 2021.

(2) SECRETARY.—The term ''Secretary'' means the Secretary of the Interior.

(c) ADMINISTRATIVE TRANSFER.—Administrative jurisdiction of the Katimiîn and Ameekyáaraam land is hereby transferred from the Secretary of Agriculture to the Secretary, subject to the condition that the Chief of the Forest Service shall continue to manage the component of the National Wild and Scenic Rivers System that flows through the Katimiîn and Ameekyáaraam land.

(d) LAND HELD IN TRUST.—The Katimiîn and Ameekyáaraam land is hereby taken into trust by the Secretary for the benefit of the Karuk Tribe, subject to—

(1) valid existing rights, contracts, and management agreements relating to easements and rights-of-way; and

(2) continued access by the Chief of the Forest Service for the purpose of managing the component of the National Wild and Scenic Rivers System that flows through the Katimiîn and Ameekyáaraam land.

(e) SURVEY.—Not later than 180 days after the date of enactment of this Act, the Secretary of Agriculture shall provide to the Secretary a complete survey of the land taken into trust under subsection (d).

(f) USE OF LAND.—

(1) IN GENERAL.—Land taken into trust under subsection (d) may be used for traditional and customary uses for the benefit of the Karuk Tribe.

(2) GAMING.—Class II and class III gaming under the Indian Gaming Regulatory Act (25 U.S.C. 2701 et seq.) shall not be allowed on the land taken into trust under subsection (d).

(g) WILD AND SCENIC RIVERS MANAGEMENT.—

(1) IN GENERAL.—Nothing in this section affects the status or administration of any component of the National Wild and Scenic Rivers System, including any component that flows through the land taken into trust under subsection (d).

(2) MEMORANDUM OF UNDERSTANDING.—The Secretary of Agriculture shall enter into a memorandum of understanding with the Karuk Tribe, consistent with the obligations of the Secretary of Agriculture under subsection (c), to establish mutual goals for the protection and enhancement of the river values of any component of the National Wild and Scenic Rivers System that flows through the land taken into trust under subsection (d).

SA 5743. Mr. PADILLA (for himself and Mrs. FEINSTEIN) submitted an amendment intended to be proposed to amendment SA 5499 submitted by Mr. REED (for himself and Mr. INHOFE) and intended to be proposed to the bill H.R. 7900, to authorize appropriations for fiscal year 2023 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle G of title X, add the following:

SEC. 10___. LAND TO BE TAKEN INTO TRUST FOR THE BENEFIT OF THE AGUA CALIENTE BAND OF CAHUILLA INDIANS.

(a) IN GENERAL.—The approximately 2,560 acres of land owned by the Agua Caliente Band of Cahuilla Indians generally depicted as ''Lands to be Taken into Trust'' on the map entitled ''Agua Caliente Band of Cahuilla Indians Land to be Taken into Trust'' and dated November 17, 2021, is hereby taken into trust by the United States for the benefit of the Agua Caliente Band of Cahuilla Indians.

(b) ADMINISTRATION.—Land taken into trust by subsection (a) shall be—

(1) part of the reservation of the Agua Caliente Band of Cahuilla Indians; and

(2) administered in accordance with the laws and regulations generally applicable to property held in trust by the United States for the benefit of an Indian Tribe.

(c) GAMING PROHIBITED.—Land taken into trust by subsection (a) shall not be eligible for gaming under the Indian Gaming Regulatory Act (25 U.S.C. 2701 et seq.).

SA 5744. Mr. DURBIN (for himself and Mr. LEE) submitted an amendment intended to be proposed to amendment SA 5499 submitted by Mr. REED (for himself and Mr. INHOFE) and intended to be proposed to the bill H.R. 7900, to authorize appropriations for fiscal year 2023 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. INVESTIGATIONS OF DEPARTMENT OF JUSTICE PERSONNEL.

Section 8E of the Inspector General Act of 1978 (5 U.S.C. App.) is amended—

(1) in subsection (b)—

(A) in paragraph (2), by striking ''and paragraph (3)'';

(B) by striking paragraph (3);

(C) by redesignating paragraphs (4) and (5) as paragraphs (3) and (4), respectively; and

(D) in paragraph (4), as redesignated, by striking ''paragraph (4)'' and inserting ''paragraph (3)''; and

(2) in subsection (d), by striking '', except with respect to allegations described in subsection (b)(3),''.

SA 5745. Mr. SCHUMER submitted an amendment intended to be proposed by him to the bill H.R. 6833, to amend title XXVII of the Public Health Service Act, the Internal Revenue Code of 1986, and the Employee Retirement Income Security Act of 1974 to establish requirements with respect to cost-sharing for certain insulin products, and for other purposes; which was ordered to lie on the table; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023''.

SEC. 2. TABLE OF CONTENTS.

Sec. 1. Short Title.
Sec. 2. Table of Contents.
Sec. 3. References.
Sec. 4. Payment to Widows and Heirs of Deceased Members of Congress.

DIVISION A—CONTINUING APPROPRIATIONS ACT, 2023

DIVISION B—UKRAINE SUPPLEMENTAL APPROPRIATIONS ACT, 2023

DIVISION C—OTHER MATTERS

Title I—Extensions, Technical Corrections, and Other Matters
Title II—Budgetary Effects

DIVISION D—HEALTH AND HUMAN SERVICES EXTENSIONS

Title I—Medicare and Medicaid
Title II—Human Services
Title III—Public Health
Title IV—Indian Health

DIVISION E—VETERANS AFFAIRS EXTENSIONS

Title I—Extensions of authorities relating to health care
Title II—Extensions of authorities relating to benefits
Title III—Extensions of authorities relating to homeless veterans
Title IV—Extensions of other authorities

DIVISION F—FDA USER FEE REAUTHORIZATION ACT OF 2022

DIVISION G—HERMIT'S PEAK/CALF CANYON FIRE ASSISTANCE ACT

SEC. 3. REFERENCES.

Except as expressly provided otherwise, any reference to ''this Act'' contained in any division of this Act shall be treated as referring only to the provisions of that division.

SEC. 4. PAYMENT TO WIDOWS AND HEIRS OF DECEASED MEMBERS OF CONGRESS.

There is hereby appropriated for fiscal year 2023, out of any money in the Treasury not otherwise appropriated, for payment to Dean Swihart, beneficiary of Jacqueline Walorski-Swihart, late a Representative from the State of Indiana, $174,000.

DIVISION A—CONTINUING APPROPRIATIONS ACT, 2023

The following sums are hereby appropriated, out of any money in the Treasury not otherwise appropriated, and out of applicable corporate or other revenues, receipts, and funds, for the several departments, agencies, corporations, and other organizational units of Government for fiscal year 2023, and for other purposes, namely:

SEC. 101. Such amounts as may be necessary, at a rate for operations as provided in the applicable appropriations Acts for fiscal year 2022 and under the authority and conditions provided in such Acts, for continuing projects or activities (including the costs of direct loans and loan guarantees) that are not otherwise specifically provided for in this Act, that were conducted in fiscal year 2022, and for which appropriations, funds, or other authority were made available in the following appropriations Acts:

(1) The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2022 (division A of Public Law 117–103), except section 783, and except that section 785 shall be applied by substituting ''$125,000,000'' for ''$250,000,000''.

(2) The Commerce, Justice, Science, and Related Agencies Appropriations Act, 2022 (division B of Public Law 117–103), except section 521(c)(1).

(3) The Department of Defense Appropriations Act, 2022 (division C of Public Law 117–103).

(4) The Energy and Water Development and Related Agencies Appropriations Act, 2022 (division D of Public Law 117–103).

(5) The Financial Services and General Government Appropriations Act, 2022 (division E of Public Law 117–103), except the matter under the heading ''Postal Regulatory Commission'' in title V.

(6) The Department of Homeland Security Appropriations Act, 2022 (division F of Public Law 117–103), except sections 544 and 545, and including title II of division O of Public Law 117–103.

(7) The Department of the Interior, Environment, and Related Agencies Appropriations Act, 2022 (division G of Public Law 117–103).

(8) The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2022 (division H of Public Law 117–103), and section 162 of division A of Public Law 117–43.

(9) The Legislative Branch Appropriations Act, 2022 (division I of Public Law 117–103), and section 6 in the matter preceding division A of Public Law 117–103.

(10) The Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2022 (division J of Public Law 117–103).

(11) The Department of State, Foreign Operations, and Related Programs Appropriations Act, 2022 (division K of Public Law 117–103), except the first proviso of section 7069(e).

(12) The Transportation, Housing and Urban Development, and Related Agencies Appropriations Act, 2022 (division L of Public Law 117–103).

SEC. 102. (a) No appropriation or funds made available or authority granted pursuant to section 101 for the Department of Defense shall be used for:

(1) the new production of items not funded for production in fiscal year 2022 or prior years;

(2) the increase in production rates above those sustained with fiscal year 2022 funds; or

(3) the initiation, resumption, or continuation of any project, activity, operation, or organization (defined as any project, subproject, activity, budget activity, program element, and subprogram within a program element, and for any investment items defined as a P–1 line item in a budget activity within an appropriation account and an R–1 line item that includes a program element and subprogram element within an appropriation account) for which appropriations, funds, or other authority were not available during fiscal year 2022.

(b) No appropriation or funds made available or authority granted pursuant to section 101 for the Department of Defense shall be used to initiate multi-year procurements utilizing advance procurement funding for economic order quantity procurement unless specifically appropriated later.

SEC. 103. Appropriations made by section 101 shall be available to the extent and in the manner that would be provided by the pertinent appropriations Act.

SEC. 104. Except as otherwise provided in section 102, no appropriation or funds made available or authority granted pursuant to section 101 shall be used to initiate or resume any project or activity for which appropriations, funds, or other authority were not available during fiscal year 2022.

SEC. 105. Appropriations made and authority granted pursuant to this Act shall cover all obligations or expenditures incurred for any project or activity during the period for which funds or authority for such project or activity are available under this Act.

SEC. 106. Unless otherwise provided for in this Act or in the applicable appropriations Act for fiscal year 2023, appropriations and funds made available and authority granted pursuant to this Act shall be available until whichever of the following first occurs:

(1) The enactment into law of an appropriation for any project or activity provided for in this Act.

(2) The enactment into law of the applicable appropriations Act for fiscal year 2023 without any provision for such project or activity.

(3) December 16, 2022.

SEC. 107. Expenditures made pursuant to this Act shall be charged to the applicable appropriation, fund, or authorization whenever a bill in which such applicable appropriation, fund, or authorization is contained is enacted into law.

SEC. 108. Appropriations made and funds made available by or authority granted pursuant to this Act may be used without regard to the time limitations for submission and approval of apportionments set forth in section 1513 of title 31, United States Code, but nothing in this Act may be construed to waive any other provision of law governing the apportionment of funds.

SEC. 109. Notwithstanding any other provision of this Act, except section 106, for those programs that would otherwise have high initial rates of operation or complete distribution of appropriations at the beginning of fiscal year 2023 because of distributions of funding to States, foreign countries, grantees, or others, such high initial rates of operation or complete distribution shall not be made, and no grants shall be awarded for such programs funded by this Act that would impinge on final funding prerogatives.

SEC. 110. This Act shall be implemented so that only the most limited funding action of that permitted in the Act shall be taken in order to provide for continuation of projects and activities.

SEC. 111. (a) For entitlements and other mandatory payments whose budget authority was provided in appropriations Acts for fiscal year 2022, and for activities under the Food and Nutrition Act of 2008, activities shall be continued at the rate to maintain program levels under current law, under the authority and conditions provided in the applicable appropriations Act for fiscal year 2022, to be continued through the date specified in section 106(3).

(b) Notwithstanding section 106, obligations for mandatory payments due on or about the first day of any month that begins after October 2022 but not later than 30 days after the date specified in section 106(3) may continue to be made, and funds shall be available for such payments.

SEC. 112. Amounts made available under section 101 for civilian personnel compensation and benefits in each department and agency may be apportioned up to the rate for operations necessary to avoid furloughs within such department or agency, consistent with the applicable appropriations Act for fiscal year 2022, except that such authority provided under this section shall not be used until after the department or agency has taken all necessary actions to reduce or defer non-personnel-related administrative expenses.

SEC. 113. Funds appropriated by this Act may be obligated and expended notwithstanding section 10 of Public Law 91–672 (22 U.S.C. 2412), section 15 of the State Department Basic Authorities Act of 1956 (22 U.S.C. 2680), section 313 of the Foreign Relations Authorization Act, Fiscal Years 1994 and 1995 (22 U.S.C. 6212), and section 504(a)(1) of the National Security Act of 1947 (50 U.S.C. 3094(a)(1)).

SEC. 114. Each amount incorporated by reference in this Act that was previously designated by the Congress as an emergency requirement pursuant to sections 4001(a)(1) and 4001(b) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, or as being for disaster relief pursuant to section 4005(f) of such concurrent resolution, is designated as being an emergency requirement pursuant to section 4001(a)(1) of such concurrent resolution and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022, or as being for disaster relief pursuant to section 1(f) of such House resolution, respectively.

SEC. 115. (a) Rescissions or cancellations of discretionary budget authority that continue pursuant to section 101 in Treasury Appropriations Fund Symbols (TAFS)—

(1) to which other appropriations are not provided by this Act, but for which there is a current applicable TAFS that does receive an appropriation in this Act; or

(2) which are no-year TAFS and receive other appropriations in this Act,

may be continued instead by reducing the rate for operations otherwise provided by section 101 for such current applicable TAFS, as long as doing so does not impinge on the final funding prerogatives of the Congress.

(b) Rescissions or cancellations described in subsection (a) shall continue in an amount equal to the lesser of—

(1) the amount specified for rescission or cancellation in the applicable appropriations Act referenced in section 101 of this Act; or

(2) the amount of balances available, as of October 1, 2022, from the funds specified for rescission or cancellation in the applicable appropriations Act referenced in section 101 of this Act.

(c) No later than November 21, 2022, the Director of the Office of Management and Budget shall provide to the Committees on Appropriations of the House of Representatives and the Senate a comprehensive list of the rescissions or cancellations that will continue pursuant to section 101: *Provided*, That the information in such comprehensive list shall be periodically updated to reflect any subsequent changes in the amount of balances available, as of October 1, 2022, from the funds specified for rescission or cancellation in the applicable appropriations Act referenced in section 101, and such updates shall be transmitted to the Committees on Appropriations of the House of Representatives and the Senate upon request.

SEC. 116. Amounts made available by section 101 for ''Farm Service Agency—Agricultural Credit Insurance Fund Program Account'' may be apportioned up to the rate for

operations necessary to accommodate approved applications for direct and guaranteed farm ownership loans, as authorized by 7 U.S.C. 1922 et seq.

SEC. 117. Amounts made available by section 101 to the Department of Agriculture for ''Rural Business—Cooperative Service—Rural Microentrepreneur Assistance Program'' may be used for the costs of loans, including the cost of modifying such loans, as defined in section 502 of the Congressional Budget Act of 1974, under the same terms and conditions as authorized by section 379E of the Consolidated Farm and Rural Development Act (7 U.S.C. 2008s).

SEC. 118. Section 260 of the Agricultural Marketing Act of 1946 (7 U.S.C. 1636i) and section 942 of the Livestock Mandatory Reporting Act of 1999 (7 U.S.C. 1635 note; Public Law 106–78) shall be applied by substituting the date specified in section 106(3) of this Act for ''September 30, 2022''.

SEC. 119. Amounts made available by section 101 to the Department of Commerce for ''Economic Development Administration—Salaries and Expenses'' may be apportioned up to the rate for operations necessary to maintain agency operations.

SEC. 120. Amounts made available by section 101 for ''Department of Commerce—National Telecommunications and Information Administration—Salaries and Expenses'' may be apportioned up to the rate for operations necessary to ensure continued oversight of public safety communications programs.

SEC. 121. In addition to amounts otherwise provided by section 101, for ''Department of Justice—Federal Bureau of Investigation—Salaries and Expenses'', there is appropriated $15,300,000, for an additional amount for fiscal year 2023, to remain available until September 30, 2023, for investigative activities associated with Afghan resettlement operations: *Provided*, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022.

SEC. 122. (a) Notwithstanding sections 101 and 106, through September 30, 2023, the Secretary of Defense may transfer up to $3,000,000,000 from unobligated balances from amounts made available under the heading ''Department of Defense—Operation and Maintenance—Overseas Humanitarian, Disaster, and Civic Aid'' in division C of Public Law 117–43 and division B of Public Law 117–70 to any appropriation account under the headings ''Department of State and Related Agency—Department of State—Administration of Foreign Affairs'', ''Bilateral Economic Assistance—Department of State—Migration and Refugee Assistance'', and ''Bilateral Economic Assistance—Department of State—United States Emergency Refugee and Migration Assistance Fund'' for support of Operation Allies Welcome or any successor operation: *Provided*, That upon transfer, such funds shall be merged with the appropriation to which such funds are transferred except that such funds may be made available for such purposes notwithstanding any requirement or limitation applicable to the appropriation to which transferred, including sections 2(c)(1) and 2(c)(2) of the Migration and Refugee Assistance Act of 1962 with respect to the United States Emergency Refugee and Migration Assistance Fund and in sections 4(a) and 4(b) of the State Department Basic Authorities Act of 1956 with respect to funds transferred to the Emergencies in the Diplomatic and Consular Service account: *Provided further*, That section 2215 of title 10, United States Code, shall not apply to a transfer of funds under this subsection: *Provided further*, That the exercise of the authority of this subsection shall be subject to prior consultation with, and the regular notification procedures of, the Committees on Appropriations of the House of Representatives and the Senate: *Provided further*, That any funds transferred pursuant to this subsection that were previously designated by the Congress as an emergency requirement pursuant to the concurrent resolution on the budget are designated by the Congress as being for an emergency requirement pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022.

(b) Not later than November 1, 2022 and prior to any transfer of funds pursuant to subsection (a), the Director of the Office of Management and Budget shall provide to the Committees on Appropriations of the House of Representatives and the Senate a written report on Operation Allies Welcome or any successor operation: *Provided*, That such report shall describe the number and status of Afghans residing at Department of Defense and Department of State-managed facilities and any anticipated future arrivals at such facilities; the strategy and plan, including timeline, for adjudicating and relocating all Afghans residing at Department of Defense or overseas civilian facilities and for the transition of operations and responsibilities under Operation Allies Welcome or any successor operation from the Department of Defense to the Department of State during fiscal year 2023; the activities and responsibilities assigned to each Federal agency involved in such strategy and plan; and a spend plan, containing an estimate of the costs, including additional construction and security costs, to be incurred by each such agency for carrying out such strategy and plan, and the sources of funds: *Provided further*, That prior to the initial obligation of funds transferred to the Department of State pursuant to subsection (a), the Secretary of State shall submit a report to such Committees detailing the roles and responsibilities of Department of State bureaus and offices in Operation Allies Welcome or any successor operation.

SEC. 123. During the period covered by this Act, section 714(b)(2)(B) of title 10, United States Code, shall be applied by substituting ''three years'' for ''two years''.

SEC. 124. (a) Of the remaining unobligated balances, as of September 30, 2022, from amounts provided under the heading ''Afghanistan Security Forces Fund'' in title IX of division C of Public Law 116–260, $100,000,000 is hereby permanently rescinded, and in addition to amounts otherwise provided by section 101, an amount of additional new budget authority equivalent to the amount rescinded pursuant to this subsection is hereby appropriated on September 30, 2022, for an additional amount for fiscal year 2022, to remain available until September 30, 2025, for the same purposes and under the same authorities provided under such heading in Public Law 116–260, in addition to other funds as may be available for such purposes.

(b)(1) Subject to paragraph (2), this section shall become effective immediately upon enactment of this Act.

(2) If this Act is enacted after September 30, 2022, this section shall be applied as if it were in effect on September 30, 2022.

SEC. 125. In addition to amounts otherwise provided by section 101, for ''Corps of Engineers—Civil—Construction'', there is appropriated $20,000,000, for an additional amount for fiscal year 2023, to remain available until expended, for necessary expenses related to water and wastewater infrastructure under section 219 of the Water Resources Development Act of 1992 (106 Stat. 4835): *Provided*, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022.

SEC. 126. (a) During the period covered by this Act, title I of Public Law 108–361 (the Calfed Bay-Delta Authorization Act) (118 Stat. 1681), as amended by section 204 of division D of Public Law 117–103, shall be applied by substituting ''2023'' for ''2022'' each place it appears.

(b) During the period covered by this Act, section 103(f)(4)(A) of title I of Public Law 108–361 (the Calfed Bay-Delta Authorization Act) (118 Stat. 1696) shall be applied by substituting ''$25,650,000'' for ''$25,000,000''.

SEC. 127. (a) During the period covered by this Act, section 9106(g)(2) of Public Law 111–11 (Omnibus Public Land Management Act of 2009) shall be applied by substituting ''2023'' for ''2022''.

(b) During the period covered by this Act, section 104(c) of the Reclamation States Emergency Drought Relief Act of 1991 (43 U.S.C. 2214(c)) shall be applied by substituting ''2023'' for ''2022''.

(c) During the period covered by this Act, section 301 of the Reclamation States Emergency Drought Relief Act of 1991 (43 U.S.C. 2241) shall be applied by substituting ''2023'' for ''2022''.

SEC. 128. In addition to amounts otherwise provided by section 101, amounts are provided for ''Department of the Treasury—Alcohol and Tobacco Tax and Trade Bureau—Salaries and Expenses'' at a rate for operations of $14,929,000, for an additional amount to administer the Craft Beverage Modernization Act import claims program, as required by the Taxpayer Certainty and Disaster Tax Relief Act of 2020, and such amounts may be apportioned up to the rate for operations necessary to establish and implement a new import claims program.

SEC. 129. Notwithstanding section 101, title II of division E of Public Law 117–103 shall be applied by adding the following new heading and appropriation language under the heading ''Executive Office of the President and Funds Appropriated to the President'':

''OFFICE OF THE NATIONAL CYBER DIRECTOR

''SALARIES AND EXPENSES

''For necessary expenses of the Office of the National Cyber Director, as authorized by section 1752 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116–283), $21,000,000, of which not to exceed $5,000 shall be available for official reception and representation expenses.''.

SEC. 130. Notwithstanding section 101, amounts are provided for ''The Judiciary—Courts of Appeals, District Courts, and Other Judicial Services—Fees of Jurors and Commissioners'' at a rate for operations of $59,565,000.

SEC. 131. In addition to amounts otherwise provided by section 101, for ''The Judiciary—Courts of Appeals, District Courts, and Other Judicial Services—Court Security'', there is appropriated $112,500,000, for an additional amount for fiscal year 2023, to remain available until expended, for security improvements at United States courthouses and Federal court facilities: *Provided*, That not later than 90 days after the date of enactment of this Act, and every 90 days thereafter until all funds provided by this section have been expended, the Director of the Administrative Office of the United States Courts shall provide, in an appropriate format, quarterly reports on the obligations and expenditures of

the funds provided under this section to the Committees on Appropriations of the House of Representatives and the Senate: *Provided further*, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022.

SEC. 132. Notwithstanding any other provision of this Act, except section 106, the District of Columbia may expend local funds made available under the heading ''District of Columbia—District of Columbia Funds'' for such programs and activities under the District of Columbia Appropriations Act, 2022 (title IV of division E of Public Law 117–103) at the rate set forth in the Fiscal Year 2023 Local Budget Act of 2022 (D.C. Act 24–486), as modified as of the date of enactment of this Act.

SEC. 133. In addition to amounts otherwise provided by section 101, amounts are provided for ''Small Business Administration—Salaries and Expenses'' at a rate for operations of $20,000,000, for an additional amount for costs associated with the establishment and implementation of a Government-wide service-disabled veteran-owned small business certification program within the Small Business Administration, as required by section 36 of the Small Business Act (15 U.S.C. 657f) and section 862 of Public Law 116–283: *Provided*, That such amounts may be apportioned up to the rate for operations necessary to establish and implement such certification program: *Provided further*, That such amounts may be obligated in the account and budget structure set forth in H.R. 8294, as passed by the House of Representatives on July 20, 2022.

SEC. 134. Amounts made available by section 101 for ''Small Business Administration—Business Loans Program Account'' may be apportioned up to the rate for operations necessary to accommodate increased demand for commitments for general business loans authorized under paragraphs (1) through (35) of section 7(a) of the Small Business Act (15 U.S.C. 636(a)), for guarantees of trust certificates authorized by section 5(g) of the Small Business Act (15 U.S.C. 634(g)), for commitments to guarantee loans under section 503 of the Small Business Investment Act of 1958 (15 U.S.C. 697), and for commitments to guarantee loans for debentures under section 303(b) of the Small Business Investment Act of 1958 (15 U.S.C. 683(b)).

SEC. 135. Amounts made available by section 101 to the Department of Homeland Security under the heading ''Federal Emergency Management Agency—Disaster Relief Fund'' may be apportioned up to the rate for operations necessary to carry out response and recovery activities under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.).

SEC. 136. Notwithstanding sections 101, 104, and 106, to carry out the Hermit's Peak/Calf Canyon Fire Assistance Act, there is appropriated $2,500,000,000, to remain available until expended, to the Department of Homeland Security for ''Federal Emergency Management Agency—Hermit's Peak/Calf Canyon Fire Assistance Account'', which shall be derived by transfer from amounts made available under the heading ''Federal Emergency Management Agency—Disaster Relief Fund'' in title VI of division B of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136), of which $1,000,000 shall be transferred to ''Office of the Inspector General—Operations and Support'' for oversight of activities authorized by the Hermit's Peak/Calf Canyon Fire Assistance Act: *Provided*, That no amounts may be derived from amounts made available for major disasters declared pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.): *Provided further*, That amounts provided by this section shall be subject to the same authorities and conditions as if such amounts were provided by title III of the Department of Homeland Security Appropriations Act, 2022 (division F of Public Law 117–103): *Provided further*, That not later than 90 days after the date of enactment of this Act, and every 90 days thereafter until all funds provided by this section have been expended, the Administrator of the Federal Emergency Management Agency shall provide, in an appropriate format, quarterly reports to the Committees on Appropriations of the Senate and the House of Representatives on the obligations and expenditures of the funds made available by this section: *Provided further*, That amounts transferred by this section that were previously designated by the Congress as an emergency requirement pursuant to the Balanced Budget and Emergency Deficit Control Act of 1985 or a concurrent resolution on the budget are designated as an emergency requirement pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022.

SEC. 137. Section 708(b)(13) of the Homeland Security Act of 2002 (6 U.S.C. 348(b)(13)) shall be applied by substituting the date specified in section 106(3) of this Act for ''September 30, 2022''.

SEC. 138. During the period covered by this Act, section 822(a) of the Homeland Security Act of 2002 (6 U.S.C. 383(a)) shall be applied by substituting ''2023'' for ''2022''.

SEC. 139. (a) Sections 1309(a) and 1319 of the National Flood Insurance Act of 1968 (42 U.S.C. 4016(a) and 4026) shall be applied by substituting the date specified in section 106(3) of this Act for ''September 30, 2022''.

(b)(1) Subject to paragraph (2), this section shall become effective immediately upon enactment of this Act.

(2) If this Act is enacted after September 30, 2022, this section shall be applied as if it were in effect on September 30, 2022.

SEC. 140. Section 880(g) of the National Defense Authorization Act for Fiscal Year 2017 (Public Law 114–328) shall be applied by substituting the date specified in section 106(3) of this Act for ''September 30, 2022''.

SEC. 141. Section 210G(i) of the Homeland Security Act of 2002 (6 U.S.C. 124n(i)) shall be applied by substituting the date specified in section 106(3) of this Act for ''the date that is 4 years after the date of enactment of this section''.

SEC. 142. Amounts made available by section 101 for ''Department of the Interior—National Park Service—National Recreation and Preservation'' for heritage partnership programs may be used to provide financial assistance to any national heritage area, national heritage corridor, cultural heritage corridor, national heritage partnership, national heritage route, national heritage canalway, and battlefields national historic district established as of September 1, 2022, notwithstanding any statutory sunset provision terminating the Secretary's authority to provide assistance to any such area and notwithstanding any limitation on amounts authorized to be appropriated with respect to any such area.

SEC. 143. Amounts made available by section 101 to the Department of the Interior under the heading ''Working Capital Fund'' may be apportioned up to the rate for operations necessary to implement enterprise cybersecurity safeguards.

SEC. 144. (a) In addition to amounts otherwise provided by section 101, amounts are provided for ''Department of Health and Human Services—Indian Health Service—Indian Health Services'' at a rate for operations of $16,721,000, for an additional amount for costs of staffing and operating facilities that were opened, renovated, or expanded in fiscal years 2022 and 2023, and such amounts may be apportioned up to the rate for operations necessary to staff and operate such facilities.

(b) In addition to amounts otherwise provided by section 101, amounts are provided for ''Department of Health and Human Services—Indian Health Service—Indian Health Facilities'' at a rate for operations of $1,201,000, for an additional amount for costs of staffing and operating facilities that were opened, renovated, or expanded in fiscal years 2022 and 2023, and such amounts may be apportioned up to the rate for operations necessary to staff and operate such facilities.

SEC. 145. In addition to amounts otherwise provided by section 101, for ''Department of Health and Human Services—Substance Abuse and Mental Health Services Administration—Mental Health'', there is appropriated $62,000,000, for an additional amount for fiscal year 2023, to remain available until September 30, 2023, for carrying out 988 Suicide Lifeline activities and behavioral health crisis services.

SEC. 146. In addition to amounts otherwise provided by section 101, for ''Department of Health and Human Services—Administration for Children and Families—Low Income Home Energy Assistance'', there is appropriated $1,000,000,000, for an additional amount for fiscal year 2023, to remain available until September 30, 2023, for making payments under subsection (b) of section 2602 of the Low-Income Home Energy Assistance Act of 1981 (42 U.S.C. 8621 et seq.): *Provided*, That of the funds made available by this section, $500,000,000 shall be allocated as though the total appropriation for such payments for fiscal year 2023 was less than $1,975,000,000: *Provided further*, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022.

SEC. 147. In addition to amounts otherwise provided by section 101, for ''Department of Health and Human Services—Administration for Children and Families—Refugee and Entrant Assistance'', there is appropriated $1,775,000,000, for an additional amount for fiscal year 2023, to remain available until September 30, 2025, to carry out section 462 of the Homeland Security Act of 2002 and section 235 of the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, and for refugee and entrant assistance activities authorized by section 414 of the Immigration and Nationality Act and section 501 of the Refugee Education Assistance Act of 1980: *Provided*, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022.

SEC. 148. Notwithstanding section 101, the first paragraph under the heading ''Social Security Administration—Limitation on Administrative Expenses'' in title IV of division H of Public Law 117–103 shall be applied by substituting ''$13,602,945,000'' for ''$13,202,945,000''.

SEC. 149. (a) During the period covered by this Act, subsection (a)(1)(A) of section 2502 of the Afghanistan Supplemental Appropriations Act, 2022 (division C of Public Law 117–

43) shall be applied by substituting the date specified in section 106(3) for ''September 30, 2022''.

(b) The amount provided by this section is designated as an emergency requirement pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022.

SEC. 150. Activities authorized by part A of title IV (other than under section 403(c) or 418) and section 1108(b) of the Social Security Act shall continue through the date specified in section 106(3), in the manner authorized for fiscal year 2022, and out of any money in the Treasury of the United States not otherwise appropriated, there are hereby appropriated such sums as may be necessary for such purpose.

SEC. 151. Notwithstanding section 101, section 126 of division J of Public Law 117–103 shall be applied during the period covered by this Act by substituting ''fiscal year 2017 and fiscal year 2018'' for ''fiscal year 2017''.

SEC. 152. Notwithstanding section 101, amounts are provided for—

(1) ''Department of State and Related Agency—Department of State—Administration of Foreign Affairs—Diplomatic Programs'' at a rate for operations of $9,228,789,000;

(2) ''Bilateral Economic Assistance—Funds Appropriated to the President—International Disaster Assistance'' at a rate for operations of $4,555,460,000;

(3) ''Bilateral Economic Assistance—Funds Appropriated to the President—Transition Initiatives'' at a rate for operations of $100,000,000;

(4) ''Bilateral Economic Assistance—Funds Appropriated to the President—Assistance for Europe, Eurasia and Central Asia'' at a rate for operations of $850,000,000;

(5) ''Bilateral Economic Assistance—Department of State—Migration and Refugee Assistance'' at a rate for operations of $3,562,188,000;

(6) ''International Security Assistance—Department of State—International Narcotics Control and Law Enforcement'' at a rate for operations of $1,421,004,000; and

(7) ''International Security Assistance—Funds Appropriated to the President—Foreign Military Financing Program'' at a rate for operations of $6,190,424,000.

SEC. 153. During the period covered by this Act, section 579 of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (42 U.S.C. 1437f note) shall be applied by substituting ''2023'' for ''2022'' each place it appears.

SEC. 154. Amounts made available by section 101 to the Department of Housing and Urban Development for ''Public and Indian Housing—Native Hawaiian Housing Loan Guarantee Fund Program Account'' may be apportioned up to the rate for operations necessary to accommodate demand for commitments to guarantee loans as authorized by section 184A of the Housing and Community Development Act of 1992 (12 U.S.C. 1715z–13b).

SEC. 155. In addition to amounts otherwise provided by section 101, for ''Department of Housing and Urban Development—Community Planning and Development—Community Development Fund'', there is appropriated $2,000,000,000, for an additional amount for fiscal year 2023, to remain available until expended, for the same purposes and under the same terms and conditions as funds appropriated under such heading in title VIII of the Disaster Relief Supplemental Appropriations Act, 2022 (division B of Public Law 117–43), except that such amounts shall be for major disasters that occurred in 2021 or 2022 and the fourth, twentieth, and twenty-first provisos under such heading in such Act shall not apply: *Provided*, That amounts made available under this section and under such heading in such Act may be used by a grantee to assist utilities as part of a disaster-related eligible activity under section 105(a) of the Housing and Community Development Act of 1974 (42 U.S.C. 5305(a)): *Provided further*, That such amount is designated by the Congress as being for an emergency requirement pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022.

SEC. 156. Notwithstanding section 106 of this Act, at any time during fiscal year 2023, the Secretary of Housing and Urban Development may transfer up to $1,300,000 in unobligated balances from amounts made available in prior Acts under the heading ''Housing Programs—Project-Based Rental Assistance'' to Treasury Appropriation Fund Symbol 86 X 0148 for the liquidation of obligations incurred in fiscal year 2018 in connection with the continued provision of interest reduction payments authorized under section 236 of the National Housing Act (12 U.S.C. 1715z–1).

SEC. 157. (a) The remaining unobligated balances, as of September 30, 2022, from amounts made available for ''Department of Transportation—Office of the Secretary—National Infrastructure Investments'' in title I of division H of the Further Consolidated Appropriations Act, 2020 (Public Law 116–94) are hereby permanently rescinded, and in addition to amounts otherwise provided by section 101, an amount of additional new budget authority equivalent to the amount rescinded pursuant to this subsection is hereby appropriated on September 30, 2022, for an additional amount for fiscal year 2022, to remain available until September 30, 2023, and shall be available, without additional competition, for completing the funding of awards made pursuant to the fiscal year 2020 national infrastructure investments program, in addition to other funds as may be available for such purposes.

(b) The remaining unobligated balances, as of September 30, 2022, from amounts made available to the Department of Transportation in section 105 of division L of the Consolidated Appropriations Act, 2021 (Public Law 116–260) are hereby permanently rescinded, and in addition to amounts otherwise provided by section 101, an amount of additional new budget authority equivalent to the amount rescinded pursuant to this subsection is hereby appropriated on September 30, 2022, for an additional amount for fiscal year 2022, to remain available until September 30, 2023, and shall be available, without additional competition, for completing the funding of awards made pursuant to the fiscal year 2019 national infrastructure investments program, in addition to other funds as may be available for such purposes.

(c)(1) Subject to paragraph (2), this section shall become effective immediately upon enactment of this Act.

(2) If this Act is enacted after September 30, 2022, this section shall be applied as if it were in effect on September 30, 2022.

This division may be cited as the ''Continuing Appropriations Act, 2023''.

DIVISION B—UKRAINE SUPPLEMENTAL APPROPRIATIONS ACT, 2023

The following sums are appropriated, out of any money in the Treasury not otherwise appropriated, for the fiscal year ending September 30, 2023, and for other purposes, namely:

TITLE I

DEPARTMENT OF DEFENSE

MILITARY PERSONNEL

MILITARY PERSONNEL, ARMY

For an additional amount for ''Military Personnel, Army'', $110,107,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses.

MILITARY PERSONNEL, NAVY

For an additional amount for ''Military Personnel, Navy'', $462,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses.

MILITARY PERSONNEL, MARINE CORPS

For an additional amount for ''Military Personnel, Marine Corps'', $600,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses.

MILITARY PERSONNEL, AIR FORCE

For an additional amount for ''Military Personnel, Air Force'', $11,582,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses.

OPERATION AND MAINTENANCE

OPERATION AND MAINTENANCE, ARMY

For an additional amount for ''Operation and Maintenance, Army'', $654,696,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses.

OPERATION AND MAINTENANCE, NAVY

For an additional amount for ''Operation and Maintenance, Navy'', $433,035,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses.

OPERATION AND MAINTENANCE, MARINE CORPS

For an additional amount for ''Operation and Maintenance, Marine Corps'', $34,984,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses.

OPERATION AND MAINTENANCE, AIR FORCE

For an additional amount for ''Operation and Maintenance, Air Force'', $267,084,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses.

OPERATION AND MAINTENANCE, SPACE FORCE

For an additional amount for ''Operation and Maintenance, Space Force'', $1,771,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses.

OPERATION AND MAINTENANCE, DEFENSE-WIDE

(INCLUDING TRANSFER OF FUNDS)

For an additional amount for ''Operation and Maintenance, Defense-Wide'', $4,713,544,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses: *Provided*, That of the total amount provided under this heading in this Act, $3,000,000,000, to remain available until September 30, 2024, shall be for the Ukraine Security Assistance Initiative: *Provided further*, That such funds for the Ukraine Security Assistance Initiative shall be available to the Secretary of Defense under the same terms and conditions as are provided for in section 8139 of the Department of Defense Appropriations Act, 2022 (division C of Public Law 117–103): *Provided further*, That of the total amount provided under this heading in this Act, up to $1,500,000,000, to remain available until September 30, 2024, may be transferred to accounts under the headings ''Operation and Maintenance'' and ''Procurement'' for replacement of defense articles from the

stocks of the Department of Defense, and for reimbursement for defense services of the Department of Defense and military education and training, provided to the government of Ukraine or to foreign countries that have provided support to Ukraine at the request of the United States: *Provided further*, That funds transferred pursuant to a transfer authority provided under this heading in this Act shall be merged with and available for the same purposes and for the same time period as the appropriations to which the funds are transferred: *Provided further*, That the Secretary of Defense shall notify the congressional defense committees of the details of such transfers not less than 15 days before any such transfer: *Provided further*, That upon a determination that all or part of the funds transferred from this appropriation are not necessary for the purposes provided herein, such amounts may be transferred back and merged with this appropriation: *Provided further*, That the transfer authority provided under this heading in this Act is in addition to any other transfer authority provided by law.

PROCUREMENT

MISSILE PROCUREMENT, ARMY

For an additional amount for ''Missile Procurement, Army'', $450,000,000, to remain available until September 30, 2025, to respond to the situation in Ukraine and for related expenses.

PROCUREMENT OF AMMUNITION, ARMY

For an additional amount for ''Procurement of Ammunition, Army'', $540,000,000, to remain available until September 30, 2025, for expansion of public and private plants, including the land necessary therefor, and procurement and installation of equipment, appliances, and machine tools in such plants, for the purpose of increasing production of critical munitions to replace defense articles provided to the Government of Ukraine or foreign countries that have provided support to Ukraine at the request of the United States.

OTHER PROCUREMENT, ARMY

For an additional amount for ''Other Procurement, Army'', $3,890,000, to remain available until September 30, 2025, to respond to the situation in Ukraine and for related expenses.

OTHER PROCUREMENT, NAVY

For an additional amount for ''Other Procurement, Navy'', $2,170,000, to remain available until September 30, 2025, to respond to the situation in Ukraine and for related expenses.

OTHER PROCUREMENT, AIR FORCE

For an additional amount for ''Other Procurement, Air Force'', $437,991,000, to remain available until September 30, 2025, to respond to the situation in Ukraine and for other expenses.

PROCUREMENT, DEFENSE-WIDE

For an additional amount for ''Procurement, Defense-Wide'', $9,770,000, to remain available until September 30, 2025, to respond to the situation in Ukraine and for related expenses.

RESEARCH, DEVELOPMENT, TEST AND EVALUATION

RESEARCH, DEVELOPMENT, TEST AND EVALUATION, ARMY

For an additional amount for ''Research, Development, Test and Evaluation, Army'', $3,300,000, to remain available until September 30, 2024, to respond to the situation in Ukraine and for related expenses.

RESEARCH, DEVELOPMENT, TEST AND EVALUATION, NAVY

For an additional amount for ''Research, Development, Test and Evaluation, Navy'', $2,077,000, to remain available until September 30, 2024, to respond to the situation in Ukraine and for related expenses.

RESEARCH, DEVELOPMENT, TEST AND EVALUATION, AIR FORCE

For an additional amount for ''Research, Development, Test and Evaluation, Air Force'', $99,704,000, to remain available until September 30, 2024, to respond to the situation in Ukraine and for related expenses.

RESEARCH, DEVELOPMENT, TEST AND EVALUATION, DEFENSE-WIDE

For an additional amount for ''Research, Development, Test and Evaluation, Defense-Wide'', $31,230,000, to remain available until September 30, 2024, to respond to the situation in Ukraine and for related expenses.

OTHER DEPARTMENT OF DEFENSE PROGRAMS

OFFICE OF THE INSPECTOR GENERAL

For an additional amount for ''Office of the Inspector General'', $2,000,000, to remain available until September 30, 2023, to carry out reviews of the activities of the Department of Defense to execute funds appropriated in this title, including assistance provided to Ukraine: *Provided*, That the Inspector General of the Department of Defense shall provide to the congressional defense committees a briefing not later than 90 days after the date of enactment of this Act.

RELATED AGENCIES

INTELLIGENCE COMMUNITY MANAGEMENT ACCOUNT

For an additional amount for ''Intelligence Community Management Account'', $500,000, to remain available until September 30, 2023, to respond to the situation in Ukraine and for related expenses.

GENERAL PROVISIONS—THIS TITLE

SEC. 1101. Not later than 60 days after the date of enactment of this Act, the Secretary of Defense, in coordination with the Secretary of State, shall submit a report to the Committees on Appropriations, Armed Services, and Foreign Affairs of the House of Representatives and the Committees on Appropriations, Armed Services, and Foreign Relations of the Senate on measures being taken to account for United States defense articles designated for Ukraine since the February 24, 2022, Russian invasion of Ukraine, particularly measures with regard to such articles that require enhanced end-use monitoring; measures to ensure that such articles reach their intended recipients and are used for their intended purposes; and any other measures to promote accountability for the use of such articles: *Provided*, That such report shall include a description of any occurrences of articles not reaching their intended recipients or used for their intended purposes and a description of any remedies taken: *Provided further*, That such report shall be submitted in unclassified form, but may be accompanied by a classified annex.

SEC. 1102. Not later than 30 days after the date of enactment of this Act, and every 30 days thereafter through fiscal year 2023, the Secretary of Defense, in coordination with the Secretary of State, shall provide a written report to the Committees on Appropriations, Armed Services, and Foreign Affairs of the House of Representatives and the Committees on Appropriations, Armed Services, and Foreign Relations of the Senate describing United States security assistance provided to Ukraine since the February 24, 2022, Russian invasion of Ukraine, including a comprehensive list of the defense articles and services provided to Ukraine and the associated authority and funding used to provide such articles and services: *Provided*, That such report shall be submitted in unclassified form, but may be accompanied by a classified annex.

TITLE II

DEPARTMENT OF ENERGY

ATOMIC ENERGY DEFENSE ACTIVITIES

NATIONAL NUCLEAR SECURITY ADMINISTRATION

DEFENSE NUCLEAR NONPROLIFERATION

For an additional amount for ''Defense Nuclear Nonproliferation'', $35,000,000, to remain available until expended, to respond to the situation in Ukraine and for related expenses.

TITLE III

BILATERAL ECONOMIC ASSISTANCE

FUNDS APPROPRIATED TO THE PRESIDENT

ECONOMIC SUPPORT FUND

For an additional amount for ''Economic Support Fund'', $4,500,000,000, to remain available until September 30, 2024, for assistance for Ukraine: *Provided*, That funds appropriated under this heading in this Act may be made available notwithstanding any other provision of law that restricts assistance to foreign countries and may be made available as contributions.

GENERAL PROVISIONS—THIS TITLE

SEC. 1301. During fiscal year 2023, section 506(a)(1) of the Foreign Assistance Act of 1961 (22 U.S.C. 2318(a)(1)) shall be applied by substituting ''$3,700,000,000'' for ''$100,000,000''.

SEC. 1302. (a) Funds appropriated by this title shall be made available for direct financial support for the Government of Ukraine, including for Ukrainian first responders, and may be made available as a cash transfer subject to the requirements of subsection (b): *Provided*, That such funds shall be provided on a reimbursable basis and matched by sources other than the United States Government, to the maximum extent practicable: *Provided further*, That the Secretary of State or the Administrator of the United States Agency for International Development, as appropriate, shall ensure third-party monitoring of such funds: *Provided further*, That at least 15 days prior to the initial obligation of such funds, the Secretary of State, following consultation with the Administrator of the United States Agency for International Development, shall certify and report to the appropriate congressional committees that mechanisms for monitoring and oversight of such funds are in place and functioning and that the Government of Ukraine has in place substantial safeguards to prevent corruption and ensure accountability of such funds: *Provided further*, That not less than 45 days after the initial obligation of such funds, the Inspectors General of the Department of State and the United States Agency for International Development shall submit a report to the appropriate congressional committees detailing and assessing the mechanisms for monitoring and safeguards described in the previous proviso.

(b) Funds made available to the Government of Ukraine as a cash transfer under subsection (a) shall be subject to a memorandum of understanding between the Governments of the United States and Ukraine that describes how the funds proposed to be made available will be used and the appropriate safeguards to ensure transparency and accountability: *Provided*, That such assistance shall be maintained in a separate, auditable account and may not be comingled with any other funds.

(c) The Secretary of State or the Administrator of the United States Agency for International Development, as appropriate, shall report to the appropriate congressional committees on the uses of funds provided for direct financial support to the Government of Ukraine pursuant to subsection (a) not later than 45 days after the date of enactment of this Act and every 45 days thereafter until

all such funds have been expended: *Provided*, That such report shall include a detailed description of the use of such funds, including categories and amounts, the intended results and the results achieved, a summary of other donor contributions, and a description of the efforts undertaken by the Secretary and Administrator to increase other donor contributions for direct financial support: *Provided further*, That such report shall also include the metrics established to measure such results.

(d) Funds made available for the purposes of subsection (a) shall be subject to the regular notification procedures of the Committees on Appropriations of the House of Representatives and the Senate.

TITLE IV

GENERAL PROVISIONS—THIS ACT

SEC. 1401. Each amount appropriated or made available by this Act is in addition to amounts otherwise appropriated for the fiscal year involved.

SEC. 1402. No part of any appropriation contained in this Act shall remain available for obligation beyond the current fiscal year unless expressly so provided herein.

SEC. 1403. Unless otherwise provided for by this Act, the additional amounts appropriated by this Act to appropriations accounts shall be available under the authorities and conditions applicable to such appropriations accounts for fiscal year 2023.

SEC. 1404. Each amount provided by this division is designated by the Congress as being for an emergency requirement pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th Congress), the concurrent resolution on the budget for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th Congress), as engrossed in the House of Representatives on June 8, 2022.

This division may be cited as the ''Ukraine Supplemental Appropriations Act, 2023''.

DIVISION C—OTHER MATTERS

TITLE I—EXTENSIONS, TECHNICAL CORRECTIONS, AND OTHER MATTERS

SEC. 101. EXTENSION OF FCC AUCTION AUTHORITY.

Section 309(j)(11) of the Communications Act of 1934 (47 U.S.C. 309(j)(11)) is amended by striking ''September 30, 2022'' and inserting ''December 16, 2022''.

SEC. 102. EXTENSION OF AUTHORIZATION FOR SPECIAL ASSESSMENT FOR DOMESTIC TRAFFICKING VICTIMS' FUND.

Section 3014(a) of title 18, United States Code, is amended, in the matter preceding paragraph (1), by striking ''September 30, 2022'' and inserting ''December 16, 2022''.

SEC. 103. UNITED STATES PAROLE COMMISSION EXTENSION.

(a) SHORT TITLE.—This section may be cited as the ''United States Parole Commission Extension Act of 2022''.

(b) AMENDMENT OF SENTENCING REFORM ACT OF 1984.—For purposes of section 235(b) of the Sentencing Reform Act of 1984 (18 U.S.C. 3551 note; Public Law 98–473; 98 Stat. 2032), as such section relates to chapter 311 of title 18, United States Code, and the United States Parole Commission, each reference in such section to ''35 years'' or ''35-year period'' shall be deemed a reference to ''35 years and 46 days'' or ''35-year and 46-day period'', respectively.

SEC. 104. EXTENSION OF COMMODITY FUTURES TRADING COMMISSION CUSTOMER PROTECTION FUND EXPENSES ACCOUNT.

Section 1(b) of Public Law 117–25 (135 Stat. 297) is amended by striking ''October 1, 2022'' each place it appears and inserting ''December 16, 2022''.

TITLE II—BUDGETARY EFFECTS

SEC. 201. BUDGETARY EFFECTS.

(a) STATUTORY PAYGO SCORECARDS.—The budgetary effects of this division and each succeeding division shall not be entered on either PAYGO scorecard maintained pursuant to section 4(d) of the Statutory Pay-As-You-Go Act of 2010.

(b) SENATE PAYGO SCORECARDS.—The budgetary effects of this division and each succeeding division shall not be entered on any PAYGO scorecard maintained for purposes of section 4106 of H. Con. Res. 71 (115th Congress).

(c) CLASSIFICATION OF BUDGETARY EFFECTS.—Notwithstanding Rule 3 of the Budget Scorekeeping Guidelines set forth in the joint explanatory statement of the committee of conference accompanying Conference Report 105–217 and section 250(c)(8) of the Balanced Budget and Emergency Deficit Control Act of 1985, the budgetary effects of this division and each succeeding division shall not be estimated—

(1) for purposes of section 251 of such Act;

(2) for purposes of an allocation to the Committee on Appropriations pursuant to section 302(a) of the Congressional Budget Act of 1974; and

(3) for purposes of paragraph (4)(C) of section 3 of the Statutory Pay-As-You-Go Act of 2010 as being included in an appropriation Act.

DIVISION D—HEALTH AND HUMAN SERVICES EXTENSIONS

TITLE I—MEDICARE AND MEDICAID

SEC. 101. EXTENSION OF INCREASED INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR CERTAIN LOW-VOLUME HOSPITALS.

(a) IN GENERAL.—Section 1886(d)(12) of the Social Security Act (42 U.S.C. 1395ww(d)(12)) is amended—

(1) in subparagraph (B), in the matter preceding clause (i), by striking ''in fiscal year 2023 and subsequent fiscal years'' and inserting ''during the portion of fiscal year 2023 beginning on December 17, 2022, and ending on September 30, 2023, and in fiscal year 2024 and subsequent fiscal years'';

(2) in subparagraph (C)(i)—

(A) in the matter preceding subclause (I)—

(i) by inserting ''or portion of a fiscal year'' after ''for a fiscal year''; and

(ii) by inserting ''and the portion of fiscal year 2023 beginning on October 1, 2022, and ending on December 16, 2022'' after ''through 2022'';

(B) in subclause (III), by inserting ''and the portion of fiscal year 2023 beginning on October 1, 2022, and ending on December 16, 2022'' after ''through 2022''; and

(C) in subclause (IV), by striking ''fiscal year 2023'' and inserting ''the portion of fiscal year 2023 beginning on December 17, 2022, and ending on September 30, 2023, and fiscal year 2024''; and

(3) in subparagraph (D)—

(A) in the matter preceding clause (i), by inserting ''or during the portion of fiscal year 2023 beginning on October 1, 2022, and ending on December 16, 2022'' after ''through 2022''; and

(B) in clause (ii), by inserting ''and the portion of fiscal year 2023 beginning on October 1, 2022, and ending on December 16, 2022'' after ''through 2022''.

(b) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the provisions of, including the amendments made by, this section by program instruction or otherwise.

SEC. 102. EXTENSION OF THE MEDICARE-DEPENDENT HOSPITAL (MDH) PROGRAM.

(a) IN GENERAL.—Section 1886(d)(5)(G) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amended—

(1) in clause (i), by striking ''October 1, 2022'' and inserting ''December 17, 2022''; and

(2) in clause (ii)(II), by striking ''October 1, 2022'' and inserting ''December 17, 2022''.

(b) CONFORMING AMENDMENTS.—

(1) EXTENSION OF TARGET AMOUNT.—Section 1886(b)(3)(D) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(D)) is amended—

(A) in the matter preceding clause (i), by striking ''October 1, 2022'' and inserting ''December 17, 2022''; and

(B) in clause (iv), by inserting ''and the portion of fiscal year 2023 beginning on October 1, 2022, and ending on December 16, 2022,'' after ''through fiscal year 2022''.

(2) PERMITTING HOSPITALS TO DECLINE RECLASSIFICATION.—Section 13501(e)(2) of the Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. 1395ww note) is amended by striking ''or fiscal year 2000 through fiscal year 2022,'' and inserting ''fiscal year 2000 through fiscal year 2022, or the portion of fiscal year 2023 beginning on October 1, 2022, and ending on December 16, 2022''.

SEC. 103. EXTENSION OF INCREASED FMAPS FOR THE TERRITORIES.

Section 1905(ff) of the Social Security Act (42 U.S.C. 1396d(ff)) is amended by striking ''December 13'' each place it appears and inserting ''December 16'' in each such place.

SEC. 104. REDUCTION OF MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking ''$7,500,000,000'' and inserting ''$7,308,000,000''.

TITLE II—HUMAN SERVICES

SEC. 201. EXTENSION OF MATERNAL, INFANT, AND EARLY CHILDHOOD HOME VISITING PROGRAMS.

Activities authorized by section 511 of the Social Security Act shall continue through December 16, 2022, in the manner authorized for fiscal year 2022, and out of any money in the Treasury of the United States not otherwise appropriated, there is hereby appropriated for such purpose an amount equal to the pro rata portion of the amount appropriated for such activities for fiscal year 2022.

SEC. 202. EXTENSION OF CHILD AND FAMILY SERVICES PROGRAMS.

Activities authorized by part B of title IV of the Social Security Act shall continue through December 16, 2022, in the manner authorized for fiscal year 2022, and out of any money in the Treasury of the United States not otherwise appropriated, there are hereby appropriated such sums as may be necessary for such purpose.

TITLE III—PUBLIC HEALTH

SEC. 301. EXTENSION OF THE PROGRAM TO DEEM CERTAIN HEALTH PROFESSIONAL VOLUNTEERS EMPLOYEES OF THE PUBLIC HEALTH SERVICE UNDER CERTAIN CIRCUMSTANCES.

(a) IN GENERAL.—Section 224(q) of the Public Health Service Act (42 U.S.C. 233(q)) is amended by striking paragraph (6).

(b) TECHNICAL CORRECTIONS.—Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended—

(1) in subsection (g)(1)(H)(iv), by striking ''this section.'' and inserting ''this section).'';

(2) in subsection (k)(3), by inserting ''governing board members,'' after ''officers,'';

(3) in subsection (p)(7)(A)(i), by moving the margin of subclause (II) 2 ems to the left; and

(4) in subsection (q)(5)(A), by striking ''and paragraph (6)''.

SEC. 302. EXTENSION OF AUTHORIZATION FOR A COMMISSIONED OFFICER OF THE PUBLIC HEALTH SERVICE TO ACCUMULATE EXCESS ANNUAL LEAVE.

For purposes of annual leave accumulated in fiscal year 2022, the authority provided in section 2106 of division C of Public Law 116–

159 (42 U.S.C. 210–1 note) shall apply to such leave by substituting ''2022'' for ''2020'' in subsections (a) and (d)(2).

TITLE IV—INDIAN HEALTH

SEC. 401. EXTENSION OF MORATORIUM.

Section 424(a) of title IV of division G of Public Law 113–76 is amended by striking ''October 1, 2019'' and inserting ''December 16, 2022''.

DIVISION E—VETERANS AFFAIRS EXTENSIONS

TITLE I—EXTENSIONS OF AUTHORITIES RELATING TO HEALTH CARE

SEC. 101. EXTENSION OF AUTHORITY FOR COLLECTION OF COPAYMENTS FOR HOSPITAL CARE AND NURSING HOME CARE.

Section 1710(f)(2)(B) of title 38, United States Code, is amended by striking ''September 30, 2022'' and inserting ''September 30, 2024''.

SEC. 102. EXTENSION OF REQUIREMENT TO PROVIDE NURSING HOME CARE TO CERTAIN VETERANS WITH SERVICE-CONNECTED DISABILITIES.

Section 1710A(d) of title 38, United States Code, is amended by striking ''September 30, 2022'' and inserting ''September 30, 2024''.

SEC. 103. EXTENSION OF AUTHORITY TO CONTINUE DOD-VA HEALTH CARE SHARING INCENTIVE FUND.

Section 8111(d)(3) of title 38, United States Code, is amended by striking ''September 30, 2023'' and inserting ''September 30, 2026''.

SEC. 104. EXTENSION OF AUTHORITY FOR JOINT DEPARTMENT OF DEFENSE-DEPARTMENT OF VETERANS AFFAIRS MEDICAL FACILITY DEMONSTRATION FUND.

Section 1704(e) of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111–84; 123 Stat. 2573), as most recently amended by section 715 of the National Defense Authorization Act for Fiscal Year 2022 (Public Law 117–81; 135 Stat. 1787), is amended by striking ''September 30, 2023'' and inserting ''September 30, 2024''.

SEC. 105. EXTENSION OF TEMPORARY EXPANSION OF PAYMENTS AND ALLOWANCES FOR BENEFICIARY TRAVEL IN CONNECTION WITH VETERANS RECEIVING CARE FROM VET CENTERS.

Section 104(a) of the Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012 (Public Law 112–154; 126 Stat. 1169), as most recently amended by section 3 of the Department of Veterans Affairs Expiring Authorities Act of 2021 (Public Law 117–42; 135 Stat. 342), is amended by striking ''September 30, 2022'' and inserting ''September 30, 2023''.

TITLE II—EXTENSIONS OF AUTHORITIES RELATING TO BENEFITS

SEC. 201. EXTENSION OF AUTHORITY TO TRANSPORT INDIVIDUALS TO AND FROM DEPARTMENT OF VETERANS AFFAIRS FACILITIES.

Section 111A(a)(2) of title 38, United States Code, is amended by striking ''September 30, 2022'' and inserting ''September 30, 2024''.

SEC. 202. EXTENSION OF AUTHORITY TO MAINTAIN REGIONAL OFFICE IN THE REPUBLIC OF THE PHILIPPINES.

Section 315(b) of title 38, United States Code, is amended by striking ''September 30, 2022'' and inserting ''September 30, 2024''.

SEC. 203. EXTENSION OF AUTHORITY FOR REPORT ON EQUITABLE RELIEF PROVIDED DUE TO ADMINISTRATIVE ERROR.

Section 503(c) of title 38, United States Code, is amended by striking ''December 31, 2022'' and inserting ''December 31, 2024''.

SEC. 204. EXTENSION OF AUTHORITY TO PROVIDE ASSISTANCE FOR SPECIALLY ADAPTED HOUSING FOR DISABLED VETERANS RESIDING TEMPORARILY IN HOUSING OWNED BY A FAMILY MEMBER.

Section 2102A(e) of title 38, United States Code, is amended by striking ''December 31, 2022'' and inserting ''December 31, 2024''.

SEC. 205. EXTENSION OF SPECIALLY ADAPTED HOUSING ASSISTIVE TECHNOLOGY GRANT PROGRAM.

Section 2108(g) of title 38, United States Code, is amended by striking ''September 30, 2022'' and inserting ''September 30, 2024''.

TITLE III—EXTENSIONS OF AUTHORITIES RELATING TO HOMELESS VETERANS

SEC. 301. EXTENSION OF AUTHORIZATION OF APPROPRIATIONS FOR HOMELESS VETERANS REINTEGRATION PROGRAMS.

Section 2021(e)(1)(F) of title 38, United States Code, is amended by striking ''2022'' and inserting ''2024''.

SEC. 302. EXTENSION OF AUTHORIZATION OF APPROPRIATIONS FOR HOMELESS WOMEN VETERANS AND HOMELESS VETERANS WITH CHILDREN REINTEGRATION GRANT PROGRAM.

Section 2021A(f)(1) of title 38, United States Code, is amended by striking ''2022'' and inserting ''2024''.

SEC. 303. EXTENSION OF AUTHORITY FOR TREATMENT AND REHABILITATION FOR SERIOUSLY MENTALLY ILL AND HOMELESS VETERANS.

(a) GENERAL TREATMENT.—Section 2031(b) of title 38, United States Code, is amended by striking ''September 30, 2022'' and inserting ''September 30, 2024''.

(b) ADDITIONAL SERVICES AT CERTAIN LOCATIONS.—Section 2033(d) of such title is amended by striking ''September 30, 2022'' and inserting ''September 30, 2024''.

SEC. 304. EXTENSION OF FUNDING FOR FINANCIAL ASSISTANCE FOR SUPPORTIVE SERVICES FOR VERY LOW-INCOME VETERAN FAMILIES IN PERMANENT HOUSING.

Section 2044(e)(1)(H) of title 38, United States Code, is amended by striking ''and 2022'' and inserting ''through 2024''.

SEC. 305. EXTENSION OF FUNDING FOR GRANT PROGRAM FOR HOMELESS VETERANS WITH SPECIAL NEEDS.

Section 2061(d)(1) of title 38, United States Code, is amended by striking ''2022'' and inserting ''2024''.

SEC. 306. EXTENSION OF AUTHORITY FOR THE ADVISORY COMMITTEE ON HOMELESS VETERANS.

Section 2066(d) of title 38, United States Code, is amended by striking ''September 30, 2022'' and inserting ''September 30, 2026''.

TITLE IV—EXTENSIONS OF OTHER AUTHORITIES

SEC. 401. EXTENSION OF AUTHORIZATION OF APPROPRIATIONS FOR MONTHLY ASSISTANCE ALLOWANCE UNDER THE OFFICE OF NATIONAL VETERANS SPORTS PROGRAMS AND SPECIAL EVENTS.

Section 322(d)(4) of title 38, United States Code, is amended by striking ''2022'' and inserting ''2026''.

SEC. 402. EXTENSION AND AUTHORIZATION OF APPROPRIATIONS FOR ADAPTIVE SPORTS PROGRAMS FOR DISABLED VETERANS AND MEMBERS OF THE ARMED FORCES.

(a) AUTHORIZATION OF APPROPRIATIONS.—Subsection (g)(1)(B) of section 521A of title 38, United States Code, is amended by striking ''and 2022'' and inserting ''through 2026''.

(b) EXTENSION.—Subsection (l) of such section is amended by striking ''2022'' and inserting ''2026''.

(c) TECHNICAL CORRECTION.—Subsection (g)(1)(A) of such section is amended by striking ''. for each of fiscal years 2010 through 2020''.

SEC. 403. EXTENSION OF ADVISORY COMMITTEE ON MINORITY VETERANS.

Section 544(e) of title 38, United States Code, is amended by striking ''September 30, 2022'' and inserting ''September 30, 2026''.

SEC. 404. EXTENSION OF VETERANS' ADVISORY COMMITTEE ON EDUCATION.

Section 3692(c) of title 38, United States Code, is amended by striking ''December 31, 2022'' and inserting ''December 31, 2026''.

SEC. 405. EXTENSION OF AUTHORITY FOR TRANSFER OF REAL PROPERTY.

Section 8118(a)(5) of title 38, United States Code, is amended by striking ''September 30, 2022'' and inserting ''September 30, 2024''.

DIVISION F—FDA USER FEE REAUTHORIZATION ACT OF 2022

SECTION 1. SHORT TITLE.

This division may be cited as the ''FDA User Fee Reauthorization Act of 2022''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this division is as follows:

DIVISION F—FDA USER FEE REAUTHORIZATION ACT OF 2022

Sec. 1. Short title.
Sec. 2. Table of contents.

TITLE I—FEES RELATING TO DRUGS

Sec. 1001. Short title; finding.
Sec. 1002. Definitions.
Sec. 1003. Authority to assess and use drug fees.
Sec. 1004. Reauthorization; reporting requirements.
Sec. 1005. Sunset dates.
Sec. 1006. Effective date.
Sec. 1007. Savings clause.

TITLE II—FEES RELATING TO DEVICES

Sec. 2001. Short title; finding.
Sec. 2002. Definitions.
Sec. 2003. Authority to assess and use device fees.
Sec. 2004. Reauthorization; reporting requirements.
Sec. 2005. Conformity assessment pilot program.
Sec. 2006. Reauthorization of third-party review program.
Sec. 2007. Sunset dates.
Sec. 2008. Effective date.
Sec. 2009. Savings clause.

TITLE III—FEES RELATING TO GENERIC DRUGS

Sec. 3001. Short title; finding.
Sec. 3002. Authority to assess and use human generic drug fees.
Sec. 3003. Reauthorization; reporting requirements.
Sec. 3004. Sunset dates.
Sec. 3005. Effective date.
Sec. 3006. Savings clause.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

Sec. 4001. Short title; finding.
Sec. 4002. Definitions.
Sec. 4003. Authority to assess and use biosimilar biological product fees.
Sec. 4004. Reauthorization; reporting requirements.
Sec. 4005. Sunset dates.
Sec. 4006. Effective date.
Sec. 4007. Savings clause.

TITLE V—REAUTHORIZATION OF OTHER PROVISIONS

Sec. 5001. Reauthorization of the best pharmaceuticals for children program.
Sec. 5002. Reauthorization of the humanitarian device exemption incentive.
Sec. 5003. Reauthorization of the pediatric device consortia program.
Sec. 5004. Reauthorization of provision pertaining to drugs containing single enantiomers.

Sec. 5005. Reauthorization of the critical path public-private partnership.
Sec. 5006. Reauthorization of orphan drug grants.
Sec. 5007. Reauthorization of certain device inspections.
Sec. 5008. Reauthorization of reporting requirements related to pending generic drug applications and priority review applications.

TITLE I—FEES RELATING TO DRUGS

SEC. 1001. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Prescription Drug User Fee Amendments of 2022''.

(b) FINDING.—Congress finds that the fees authorized by the amendments made by this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 1002. DEFINITIONS.

(a) HUMAN DRUG APPLICATION.—Section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) is amended, in the matter following subparagraph (B), by striking ''an allergenic extract product, or'' and inserting ''does not include an application with respect to an allergenic extract product licensed before October 1, 2022, does not include an application with respect to a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022, does not include an application with respect to''.

(b) PRESCRIPTION DRUG PRODUCT.—Section 735(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(3)) is amended—

(1) by redesignating subparagraphs (A), (B), and (C) as clauses (i), (ii), and (iii), respectively;

(2) by striking ''(3) The term'' and inserting ''(3)(A) The term'';

(3) by striking ''Such term does not include whole blood'' and inserting the following:

''(B) Such term does not include whole blood'';

(4) by striking ''an allergenic extract product,'' and inserting ''an allergenic extract product licensed before October 1, 2022, a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022,'' ; and

(5) by adding at the end the following:

''(C)(i) If a written request to place a product in the discontinued section of either of the lists referenced in subparagraph (A)(iii) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is, or will be, withdrawn from sale, then for purposes of assessing the prescription drug program fee under section 736(a)(2), the Secretary shall consider such product to have been included in the discontinued section on the later of—

''(I) the date such request was received; or

''(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

''(ii) For purposes of this subparagraph, a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.''.

(c) SKIN-TEST DIAGNOSTIC PRODUCT.—Section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) is amended by adding at the end the following:

''(12) The term 'skin-test diagnostic product'—

''(A) means a product—

''(i) for prick, scratch, intradermal, or subcutaneous administration;

''(ii) expected to produce a limited, local reaction at the site of administration (if positive), rather than a systemic effect;

''(iii) not intended to be a preventive or therapeutic intervention; and

''(iv) intended to detect an immediate- or delayed-type skin hypersensitivity reaction to aid in the diagnosis of—

''(I) an allergy to an antimicrobial agent;

''(II) an allergy that is not to an antimicrobial agent, if the diagnostic product was authorized for marketing prior to October 1, 2022; or

''(III) infection with fungal or mycobacterial pathogens; and

''(B) includes positive and negative controls required to interpret the results of a product described in subparagraph (A).''.

SEC. 1003. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—

(1) HUMAN DRUG APPLICATION FEE.—Section 736(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is amended—

(A) in the matter preceding paragraph (1), by striking ''fiscal year 2018'' and inserting ''fiscal year 2023'';

(B) in paragraph (1)(A), by striking ''(c)(5)'' each place it appears and inserting ''(c)(6)'';

(C) in paragraph (1)(C), by inserting ''prior to approval'' after ''or was withdrawn''; and

(D) in paragraph (1), by adding at the end the following:

''(H) EXCEPTION FOR SKIN-TEST DIAGNOSTIC PRODUCTS.—A human drug application for a skin-test diagnostic product shall not be subject to a fee under subparagraph (A).''.

(2) PRESCRIPTION DRUG PROGRAM FEE.—Section 736(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(2)) is amended—

(A) in subparagraph (A)—

(i) by striking ''Except as provided in subparagraphs (B) and (C)'' and inserting the following:

''(i) PAYMENT OF FEES.—Except as provided in subparagraphs (B) and (C)'';

(ii) by striking ''subsection (c)(5)'' and inserting ''subsection (c)(6)''; and

(iii) by adding at the end the following:

''(ii) SPECIAL RULE FOR PREVIOUSLY DISCONTINUED DRUG PRODUCTS.—If a drug product that is identified in a human drug application approved as of October 1 of a fiscal year is not a prescription drug product as of that date because the drug product is in the discontinued section of a list referenced in section 735(3)(A)(iii), and on any subsequent day during such fiscal year the drug product is a prescription drug product, then except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application with respect to such product, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(6) for such prescription drug product. Such fee shall be due on the last business day of such fiscal year and shall be paid only once for each such product for a fiscal year in which the fee is payable.''; and

(B) by amending subparagraph (B) to read as follows:

''(B) EXCEPTION FOR CERTAIN PRESCRIPTION DRUG PRODUCTS.—A prescription drug program fee shall not be assessed for a prescription drug product under subparagraph (A) if such product is—

''(i) a large volume parenteral product (a sterile aqueous drug product packaged in a single-dose container with a volume greater than or equal to 100 mL, not including powders for reconstitution or pharmacy bulk packages) identified on the list compiled under section 505(j)(7);

''(ii) pharmaceutically equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulation)) to another product on the list of products compiled under section 505(j)(7) (not including the discontinued section of such list); or

''(iii) a skin-test diagnostic product.''.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—Paragraph (1) of section 736(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)) is amended to read as follows:

''(1) IN GENERAL.—For each of the fiscal years 2023 through 2027, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

''(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

''(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

''(C) the dollar amount equal to the strategic hiring and retention adjustment for the fiscal year (as determined under subsection (c)(2));

''(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

''(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

''(F) the dollar amount equal to the additional direct cost adjustment for the fiscal year (as determined under subsection (c)(5)); and

''(G) additional dollar amounts for each fiscal year as follows:

''(i) $65,773,693 for fiscal year 2023.

''(ii) $25,097,671 for fiscal year 2024.

''(iii) $14,154,169 for fiscal year 2025.

''(iv) $4,864,860 for fiscal year 2026.

''(v) $1,314,620 for fiscal year 2027.''.

(2) ANNUAL BASE REVENUE.—Paragraph (3) of section 736(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)) is amended to read as follows:

''(3) ANNUAL BASE REVENUE.—For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

''(A) for fiscal year 2023, $1,151,522,958; and

''(B) for fiscal years 2024 through 2027, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, not including any adjustments made under subsection (c)(4) or (c)(5).''.

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

(1) INFLATION ADJUSTMENT.—Section 736(c)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)(1)(B)(ii)) is amended by striking ''Washington-Baltimore, DC–MD–VA–WV'' and inserting ''Washington-Arlington-Alexandria, DC–VA–MD–WV''.

(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—Section 736(c) of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended—

(A) by redesignating paragraphs (2) through (6) as paragraphs (3) through (7), respectively; and

(B) by inserting after paragraph (1) the following:

''(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by the following amounts:

''(A) For fiscal year 2023, $9,000,000.

''(B) For each of fiscal years 2024 through 2027, $4,000,000.''.

(3) CAPACITY PLANNING ADJUSTMENT.—Paragraph (3), as redesignated, of section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended to read as follows:

''(3) CAPACITY PLANNING ADJUSTMENT.—

''(A) IN GENERAL.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted in accordance with paragraphs (1) and (2), such revenue shall be adjusted further for such fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for the process for the review of human drug applications.

''(B) METHODOLOGY.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled 'Prescription Drug User Fee Rates for Fiscal Year 2021' published in the Federal Register on August 3, 2020 (85 Fed. Reg. 46651). The workload categories used in applying such methodology in forecasting shall include only the activities described in that notice and, as feasible, additional activities that are directly related to the direct review of applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved prescription drug products. Subject to the exceptions in the preceding sentence, the Secretary shall not include as workload categories in applying such methodology in forecasting any non-core review activities, including those activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021.

''(C) LIMITATION.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(1)(A) (the annual base revenue for the fiscal year), (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year), and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment for the fiscal year).

''(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under paragraph (6) of the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.''.

(4) OPERATING RESERVE ADJUSTMENT.—Paragraph (4), as redesignated, of section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended—

(A) by amending subparagraph (A) to read as follows:

''(A) INCREASE.—For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for operating reserves of carryover user fees for the process for the review of human drug applications for each fiscal year in at least the following amounts:

''(i) For fiscal year 2023, at least 8 weeks of operating reserves.

''(ii) For fiscal year 2024, at least 9 weeks of operating reserves.

''(iii) For fiscal year 2025 and subsequent fiscal years, at least 10 weeks of operating reserves.''; and

(B) in subparagraph (C), by striking ''paragraph (5)'' and inserting ''paragraph (6)''.

(5) ADDITIONAL DIRECT COST ADJUSTMENT.—Paragraph (5), as redesignated, of section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended to read as follows:

''(5) ADDITIONAL DIRECT COST ADJUSTMENT.—

''(A) INCREASE.—The Secretary shall, in addition to adjustments under paragraphs (1), (2), (3), and (4), further increase the fee revenue and fees—

''(i) for fiscal year 2023, by $44,386,150; and

''(ii) for each of fiscal years 2024 through 2027, by the amount set forth in clauses (i) through (iv) of subparagraph (B), as applicable, multiplied by the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such Index for 2021.

''(B) APPLICABLE AMOUNTS.—The amounts referred to in subparagraph (A)(ii) are the following:

''(i) For fiscal year 2024, $60,967,993.

''(ii) For fiscal year 2025, $35,799,314.

''(iii) For fiscal year 2026, $35,799, 314.

''(iv) For fiscal year 2027, $35,799,314.''.

(6) ANNUAL FEE SETTING.—Paragraph (6), as redesignated, of section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended by striking ''September 30, 2017'' and inserting ''September 30, 2022''.

(d) CREDITING AND AVAILABILITY OF FEES.—Section 736(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(3)) is amended by striking ''fiscal years 2018 through 2022'' and inserting ''fiscal years 2023 through 2027''.

(e) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING FEES.—Section 736(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(i)) is amended to read as follows:

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING FEES.—To qualify for consideration for a waiver or reduction under subsection (d), an exemption under subsection (k), or the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall—

''(1) not later than 180 days after such fee is due, submit to the Secretary a written request justifying such waiver, reduction, exemption, or return; and

''(2) include in the request any legal authorities under which the request is made.''.

(f) ORPHAN DRUGS.—Section 736(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(k)) is amended—

(1) in paragraph (1)(B), by striking ''during the previous year'' and inserting ''as determined under paragraph (2)''; and

(2) by amending paragraph (2) to read as follows:

''(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that the applicant's gross annual revenues did not exceed $50,000,000 for the last calendar year ending prior to the fiscal year for which the exemption is requested. Such certification shall be supported by—

''(A) tax returns submitted to the United States Internal Revenue Service; or

''(B) as necessary, other appropriate financial information.''.

SEC. 1004. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) is amended—

(1) in subsection (a)(1), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

(2) by striking ''Prescription Drug User Fee Amendments of 2017'' each place it appears and inserting ''Prescription Drug User Fee Amendments of 2022'';

(3) in subsection (a)(3)(A), by striking ''Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter'' and inserting ''Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this part'';

(4) in subsection (a)(4), by striking ''Beginning with fiscal year 2020, the'' and inserting ''The'';

(5) in subsection (b), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

(6) in subsection (c), by striking ''Beginning with fiscal year 2018, for'' and inserting ''For''; and

(7) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''fiscal year 2022'' and inserting ''fiscal year 2027''; and

(B) in paragraph (5), by striking ''January 15, 2022'' and inserting ''January 15, 2027''.

SEC. 1005. SUNSET DATES.

(a) AUTHORIZATION.—Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g; 379h) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2022, subsections (a) and (b) of section 104 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 1006. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.) shall be assessed for all human drug applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 1007. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE II—FEES RELATING TO DEVICES

SEC. 2001. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Medical Device User Fee Amendments of 2022''.

(b) FINDING.—Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 2002. DEFINITIONS.

Section 737 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i) is amended—

(1) in paragraph (9)—

(A) in the matter preceding subparagraph (A), by striking ''and premarket notification submissions'' and inserting ''premarket notification submissions, and de novo classification requests'';

(B) in subparagraph (D), by striking ''and submissions'' and inserting ''submissions, and de novo classification requests'';

(C) in subparagraph (F), by striking ''and premarket notification submissions'' and inserting ''premarket notification submissions, and de novo classification requests'';

(D) in each of subparagraphs (G) and (H), by striking ''or submissions'' and inserting ''submissions, or requests''; and

(E) in subparagraph (K), by striking ''or premarket notification submissions'' and inserting ''premarket notification submissions, or de novo classification requests''; and

(2) in paragraph (11), by striking ''2016'' and inserting ''2021''.

SEC. 2003. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is amended—

(1) in paragraph (1), by striking ''fiscal year 2018'' and inserting ''fiscal year 2023''; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''October 1, 2017'' and inserting ''October 1, 2022'';

(ii) in clause (iii), by striking ''75 percent'' and inserting ''80 percent''; and

(iii) in clause (viii), by striking ''3.4 percent'' and inserting ''4.5 percent'';

(B) in subparagraph (B)(iii), by striking ''or premarket notification submission'' and inserting ''premarket notification submission, or de novo classification request''; and

(C) in subparagraph (C), by striking ''or periodic reporting concerning a class III device'' and inserting ''periodic reporting concerning a class III device, or de novo classification request''.

(b) FEE AMOUNTS.—Section 738(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is amended—

(1) in paragraph (1), by striking ''2018 through 2022'' and inserting ''2023 through 2027'';

(2) by amending paragraph (2) to read as follows:

''(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

''Fee Type	Fiscal Year 2023	Fiscal Year 2024	Fiscal Year 2025	Fiscal Year 2026	Fiscal Year 2027
Premarket Application	$425,000	$435,000	$445,000	$455,000	$470,000
Establishment Registration	$6,250	$6,875	$7,100	$7,575	$8,465''; and

(3) by amending paragraph (3) to read as follows:

''(3) TOTAL REVENUE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

''(A) $312,606,000 for fiscal year 2023.

''(B) $335,750,000 for fiscal year 2024.

''(C) $350,746,400 for fiscal year 2025.

''(D) $366,486,300 for fiscal year 2026.

''(E) $418,343,000 for fiscal year 2027.''.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section 738(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(c)) is amended—

(1) in paragraph (1), by striking ''2017'' and inserting ''2022'';

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''2018'' and inserting ''2023'';

(B) in subparagraph (B)—

(i) in the matter preceding clause (i), by striking ''fiscal year 2018'' and inserting ''fiscal year 2023''; and

(ii) in clause (ii), by striking ''fiscal year 2016'' and inserting ''fiscal year 2022'';

(C) in subparagraph (C), by striking ''Washington-Baltimore, DC–MD–VA–WV'' and inserting ''Washington-Arlington-Alexandria, DC–VA–MD–WV''; and

(D) in subparagraph (D), in the matter preceding clause (i), by striking ''fiscal years 2018 through 2022'' and inserting ''fiscal years 2023 through 2027'';

(3) in paragraph (3), by striking ''2018 through 2022'' and inserting ''2023 through 2027'';

(4) by redesignating paragraphs (4) and (5) as paragraphs (7) and (8), respectively; and

(5) by inserting after paragraph (3) the following:

''(4) PERFORMANCE IMPROVEMENT ADJUSTMENT.—

''(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2) and (3), the base establishment registration fee amounts for such fiscal year shall be increased to reflect changes in the resource needs of the Secretary due to improved review performance goals for the process for the review of device applications identified in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022, as the Secretary determines necessary to achieve an increase in total fee collections for such fiscal year equal to the following amounts, as applicable:

''(i) For fiscal year 2025, the product of—

''(I) the amount determined under subparagraph (B)(i)(I); and

''(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

''(ii) For fiscal year 2026, the product of—

''(I) the sum of the amounts determined under subparagraphs (B)(i)(II), (B)(ii)(I), and (B)(iii)(I); and

''(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

''(iii) For fiscal year 2027, the product of—

''(I) the sum of the amounts determined under subparagraphs (B)(i)(III), (B)(ii)(II), and (B)(iii)(II); and

''(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

''(B) AMOUNTS.—

''(i) PRESUBMISSION AMOUNT.—For purposes of subparagraph (A), with respect to the Presubmission Written Feedback goal, the amounts determined under this subparagraph are as follows:

''(I) For fiscal year 2025, $15,396,600 if such goal for fiscal year 2023 is met.

''(II) For fiscal year 2026:

''(aa) $15,396,600 if such goal for fiscal year 2023 is met and such goal for fiscal year 2024 is not met.

''(bb) $36,792,200 if such goal for fiscal year 2024 is met.

''(III) For fiscal year 2027:

''(aa) $15,396,600 if such goal for fiscal year 2023 is met and such goal for each of fiscal years 2024 and 2025 is not met.

''(bb) $36,792,200 if such goal for fiscal year 2024 is met and such goal for fiscal year 2025 is not met.

''(cc) $40,572,600 if such goal for fiscal year 2025 is met.

''(ii) DE NOVO CLASSIFICATION REQUEST AMOUNT.—For purposes of subparagraph (A), with respect to the De Novo Decision goal, the amounts determined under this subparagraph are as follows:

''(I) For fiscal year 2026, $6,323,500 if such goal for fiscal year 2023 is met.

''(II) For fiscal year 2027:

''(aa) $6,323,500 if such goal for fiscal year 2023 is met and such goal for fiscal year 2024 is not met.

''(bb) $11,765,400 if such goal for fiscal year 2024 is met.

''(iii) PREMARKET NOTIFICATION AND PREMARKET APPROVAL AMOUNT.—For purposes of subparagraph (A), with respect to the 510(k) decision goal, 510(k) Shared Outcome Total Time to Decision goal, PMA decision goal, and PMA Shared Outcome Total Time to Decision goal, the amounts determined under this subparagraph are as follows:

''(I) For fiscal year 2026, $1,020,000 if the 4 goals for fiscal year 2023 are met.

''(II) For fiscal year 2027:

''(aa) $1,020,000 if the 4 goals for fiscal year 2023 are met and one or more of the 4 goals for fiscal year 2024 are not met.

''(bb) $3,906,000 if the 4 goals for fiscal year 2024 are met.

''(C) PERFORMANCE CALCULATION.—For purposes of this paragraph, performance of the following goals shall be determined as specified in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 and based on data available, as follows:

''(i) The performance of the Presubmission Written Feedback goal shall be based on data available as of—

''(I) for fiscal year 2023, March 31, 2024;

''(II) for fiscal year 2024, March 31, 2025; and

''(III) for fiscal year 2025, March 31, 2026.

''(ii) The performance of the De Novo Decision goal, 510(k) decision goal, 510(k) Shared Outcome Total Time to Decision goal, PMA decision goal, and PMA Shared Outcome Total Time to Decision goal shall be based on data available as of—

''(I) for fiscal year 2023, March 31, 2025; and

''(II) for fiscal year 2024, March 31, 2026.

''(D) GOALS DEFINED.—For purposes of this paragraph, the terms 'Presubmission Written Feedback goal', 'De Novo Decision goal', '510(k) decision goal', '510(k) Shared Outcome Total Time to Decision goal', 'PMA decision goal', and 'PMA Shared Outcome Total Time to Decision goal' refer to the goals identified by the same names in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022.

''(5) HIRING ADJUSTMENT.—

''(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2), (3), and (4), if applicable, if the number of hires to support the process for the review of device applications falls below the thresholds specified in subparagraph (B) for the applicable fiscal years, the base establishment registration fee amounts shall be decreased as the Secretary determines necessary to achieve a reduction in total fee collections equal to the hiring adjustment amount under subparagraph (C).

''(B) THRESHOLDS.—The thresholds specified in this subparagraph are as follows:

''(i) For fiscal year 2025, the threshold is 123 hires for fiscal year 2023.

''(ii) For fiscal year 2026, the threshold is 38 hires for fiscal year 2024.

''(iii) For fiscal year 2027, the threshold is—

''(I) 22 hires for fiscal year 2025 if the base establishment registration fees are not increased by the amount determined under paragraph (4)(A)(i); or

''(II) 75 hires for fiscal year 2025 if such fees are so increased.

''(C) HIRING ADJUSTMENT AMOUNT.—The hiring adjustment amount for fiscal year 2025 and each subsequent fiscal year is the product of—

''(i) the number of hires by which the hiring goal specified in subparagraph (D) for the fiscal year before the prior fiscal year was not met;

''(ii) $72,877; and

''(iii) the applicable inflation adjustment under paragraph (2)(B) for the fiscal year for which the hiring goal was not met.

''(D) HIRING GOALS.—The hiring goals for each of fiscal years 2023 through 2025 are as follows:

''(i) For fiscal year 2023, 144 hires.

''(ii) For fiscal year 2024, 42 hires.

''(iii) For fiscal year 2025:

''(I) 24 hires if the base establishment registration fees are not increased by the amount determined under paragraph (4)(A)(i).

''(II) 83 hires if the base establishment registration fees are increased by the amount determined under paragraph (4)(A)(i).

''(E) NUMBER OF HIRES.—For purposes of this paragraph, the number of hires for a fiscal year shall be determined by the Secretary as set forth in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022.

''(6) OPERATING RESERVE ADJUSTMENT.—

''(A) IN GENERAL.—For each of fiscal years 2023 through 2027, after the adjustments under paragraphs (2), (3), (4), and (5), if applicable, if the Secretary has operating reserves of carryover user fees for the process for the review of device applications in excess of the designated amount in subparagraph (B), the Secretary shall decrease the base establishment registration fee amounts to provide for not more than such designated amount of operating reserves.

''(B) DESIGNATED AMOUNT.—Subject to subparagraph (C), for each fiscal year, the designated amount in this subparagraph is equal to the sum of—

''(i) 13 weeks of operating reserves of carryover user fees; and

''(ii) 1 month of operating reserves maintained pursuant to paragraph (8).

''(C) EXCLUDED AMOUNT.—For the period of fiscal years 2023 through 2026, a total amount equal to $118,000,000 shall not be considered part of the designated amount under subparagraph (B) and shall not be subject to the decrease under subparagraph (A).''.

(d) CONDITIONS.—Section 738(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(g)) is amended—

(1) in paragraph (1)(A), by striking ''$320,825,000'' and inserting ''$398,566,000''; and

(2) in paragraph (2), by inserting ''de novo classification requests,'' after ''class III device,''.

(e) CREDITING AND AVAILABILITY OF FEES.—Section 738(h)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h)(3)) is amended to read as follows:

''(3) AUTHORIZATION OF APPROPRIATIONS.—

''(A) IN GENERAL.—For each of fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equal to the revenue amount determined under subparagraph (B), less the amount of reductions determined under subparagraph (C).

''(B) REVENUE AMOUNT.—For purposes of this paragraph, the revenue amount for each fiscal year is the sum of—

''(i) the total revenue amount under subsection (b)(3) for the fiscal year, as adjusted under paragraphs (2) and (3) of subsection (c); and

''(ii) the performance improvement adjustment amount for the fiscal year under subsection (c)(4), if applicable.

''(C) AMOUNT OF REDUCTIONS.—For purposes of this paragraph, the amount of reductions for each fiscal year is the sum of—

''(i) the hiring adjustment amount for the fiscal year under subsection (c)(5), if applicable; and

''(ii) the operating reserve adjustment amount for the fiscal year under subsection (c)(6), if applicable.''.

SEC. 2004. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORTS.—Section 738A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)) is amended—

(1) by striking ''fiscal year 2018'' each place it appears and inserting ''fiscal year 2023'';

(2) by striking ''Medical Device User Fee Amendments of 2017'' each place it appears and inserting ''Medical Device User Fee Amendments of 2022'';

(3) in paragraph (1)—

(A) in subparagraph (A), by redesignating the second clause (iv) (relating to analysis) as clause (v); and

(B) in subparagraph (A)(iv), by striking ''fiscal year 2020'' and inserting ''fiscal year 2023''; and

(4) in paragraph (4), by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

(b) REAUTHORIZATION.—Section 738A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(b)) is amended—

(1) in paragraph (1), by striking ''2022'' and inserting ''2027''; and

(2) in paragraph (5), by striking ''2022'' and inserting ''2027''.

SEC. 2005. CONFORMITY ASSESSMENT PILOT PROGRAM.

Section 514(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(d)) is amended to read as follows:

''(d) ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT.—

''(1) IN GENERAL.—The Secretary shall establish a program under which—

''(A) testing laboratories meeting criteria specified in guidance by the Secretary may be accredited, by accreditation bodies meeting criteria specified in guidance by the Secretary, to conduct testing to support the assessment of the conformity of a device to certain standards recognized under this section; and

''(B) subject to paragraph (2), results from tests conducted to support the assessment of conformity of devices as described in subparagraph (A) conducted by testing laboratories accredited pursuant to this subsection shall be accepted by the Secretary for purposes of demonstrating such conformity unless the Secretary finds that certain results of such tests should not be so accepted.

''(2) SECRETARIAL REVIEW OF ACCREDITED LABORATORY RESULTS.—The Secretary may—

''(A) review the results of tests conducted by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such results or of the processes of accredited bodies or testing laboratories;

''(B) following such review, take additional measures under this Act, as the Secretary determines appropriate, such as—

''(i) suspension or withdrawal of accreditation of a testing laboratory or recognition of an accreditation body under paragraph (1)(A); or

''(ii) requesting additional information with respect to a device; and

''(C) if the Secretary becomes aware of information materially bearing on the safety or effectiveness of a device for which an assessment of conformity was supported by testing conducted by a testing laboratory accredited under this subsection, take such additional measures under this Act, as the Secretary determines appropriate, such as—

''(i) suspension or withdrawal of accreditation of a testing laboratory or recognition of an accreditation body under paragraph (1)(A); or

''(ii) requesting additional information with regard to such device.

''(3) REPORT.—The Secretary shall make available on the internet website of the Food and Drug Administration an annual report on the progress of the program under this subsection.''.

SEC. 2006. REAUTHORIZATION OF THIRD-PARTY REVIEW PROGRAM.

Section 523(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m(c)) is amended by striking ''October 1'' and inserting ''December 17''.

SEC. 2007. SUNSET DATES.

(a) AUTHORIZATION.—Sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i; 379j) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 738A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1) shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISIONS.—Effective October 1, 2022, subsections (a) and (b) of section 210 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 2008. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.) shall be assessed for all submissions listed in section 738(a)(2)(A) of such Act received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 2009. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this

title, shall continue to be in effect with respect to the submissions listed in section 738(a)(2)(A) of such Act (as defined in such part as of such day) that on or after October 1, 2017, but before October 1, 2022, were received by the Food and Drug Administration with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 3001. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Generic Drug User Fee Amendments of 2022''.

(b) FINDING.—Congress finds that the fees authorized by the amendments made by this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41 et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 3002. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

(a) TYPES OF FEES.—Section 744B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(a)) is amended—

(1) in the matter preceding paragraph (1), by striking ''2018'' and inserting ''2023'';

(2) in paragraph (2)(C), by striking ''2018 through 2022'' and inserting ''2023 through 2027'';

(3) in paragraph (3)(B), by striking ''2018 through 2022'' and inserting ''2023 through 2027'';

(4) in paragraph (4)(D), by striking ''2018 through 2022'' and inserting ''2023 through 2027''; and

(5) in paragraph (5)(D), by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

(b) FEE REVENUE AMOUNTS.—Section 744B(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(b)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in the heading, by striking ''2018'' and inserting ''2023'';

(ii) by striking ''2018'' and inserting ''2023''; and

(iii) by striking ''$493,600,000'' and inserting ''$582,500,000''; and

(B) by amending subparagraph (B) to read as follows:

''(B) FISCAL YEARS 2024 THROUGH 2027.—

''(i) IN GENERAL.—For each of the fiscal years 2024 through 2027, fees under paragraphs (2) through (5) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to the base revenue amount for the fiscal year under clause (ii), as adjusted pursuant to subsection (c).

''(ii) BASE REVENUE AMOUNT.—The base revenue amount for a fiscal year referred to in clause (i) is equal to the total revenue amount established under this paragraph for the previous fiscal year, not including any adjustments made for such previous fiscal year under subsection (c)(3).''; and

(2) in paragraph (2)—

(A) in subparagraph (C), by striking ''one-third the amount'' and inserting ''twenty-four percent'';

(B) in subparagraph (D), by striking ''Seven percent'' and inserting ''Six percent''; and

(C) in subparagraph (E)(i), by striking ''Thirty-five percent'' and inserting ''Thirty-six percent''.

(c) ADJUSTMENTS.—Section 744B(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(c)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A)—

(i) by striking ''2019'' and inserting ''2024''; and

(ii) by striking ''to equal the product of the total revenues established in such notice for the prior fiscal year multiplied'' and inserting ''to equal the base revenue amount for the fiscal year (as specified in subsection (b)(1)(B)(ii)) multiplied''; and

(B) in subparagraph (C), by striking ''Washington-Baltimore, DC–MD–VA–WV'' and inserting ''Washington-Arlington-Alexandria, DC–VA–MD–WV''; and

(2) by striking paragraph (2) and inserting the following:

''(2) CAPACITY PLANNING ADJUSTMENT.—

''(A) IN GENERAL.—Beginning with fiscal year 2024, the Secretary shall, in addition to the adjustment under paragraph (1), further increase the fee revenue and fees under this section for a fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for human generic drug activities.

''(B) CAPACITY PLANNING METHODOLOGY.—The Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

''(i) be derived from the methodology and recommendations made in the report titled 'Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations' announced in the Federal Register on August 3, 2020 (85 Fed. Reg. 46658); and

''(ii) incorporate approaches and attributes determined appropriate by the Secretary, including approaches and attributes made in such report, except that in incorporating such approaches and attributes the workload categories used in forecasting resources shall only be the workload categories specified in section VIII.B.2.e. of the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022.

''(C) LIMITATIONS.—

''(i) IN GENERAL.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsection (b)(1)(B)(ii) (the base revenue amount for the fiscal year) and paragraph (1) (the dollar amount of the inflation adjustment for the fiscal year).

''(ii) ADDITIONAL LIMITATION.—An adjustment under this paragraph shall not exceed 3 percent of the sum described in clause (i) for the fiscal year, except that such limitation shall be 4 percent if—

''(I) for purposes of a fiscal year 2024 adjustment, the Secretary determines that during the period from April 1, 2021, through March 31, 2023—

''(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,000; or

''(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as that term is defined in section XI of the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022);

''(II) for purposes of a fiscal year 2025 adjustment, the Secretary determines that during the period from April 1, 2022, through March 31, 2024—

''(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

''(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined);

''(III) for purposes of a fiscal year 2026 adjustment, the Secretary determines that during the period from April 1, 2023, through March 31, 2025—

''(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

''(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined); and

''(IV) for purposes of a fiscal year 2027 adjustment, the Secretary determines that during the period from April 1, 2024, through March 31, 2026—

''(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

''(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined).

''(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice referred to in subsection (a) the fee revenue and fees resulting from the adjustment and the methodology under this paragraph.

''(3) OPERATING RESERVE ADJUSTMENT.—

''(A) IN GENERAL.—For fiscal year 2024 and each subsequent fiscal year, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees under this section for such fiscal year if such an adjustment is necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in subparagraph (B) with respect to that fiscal year.

''(B) NUMBER OF WEEKS.—The number of weeks specified in this subparagraph is—

''(i) 8 weeks for fiscal year 2024;

''(ii) 9 weeks for fiscal year 2025; and

''(iii) 10 weeks for each of fiscal year 2026 and 2027.

''(C) DECREASE.—If the Secretary has carryover balances for human generic drug activities in excess of 12 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 12 weeks of such operating reserves.

''(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under subsection (a) publishing the fee revenue and fees for the fiscal year involved.''.

(d) ANNUAL FEE SETTING.—Section 744B(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(d)(1)) is amended—

(1) in the paragraph heading, by striking ''2018 THROUGH 2022'' and inserting ''2023 THROUGH 2027''; and

(2) by striking ''more than 60 days before the first day of each of fiscal years 2018 through 2022'' and inserting ''later than 60 days before the first day of each of fiscal years 2023 through 2027''.

(e) EFFECT OF FAILURE TO PAY FEES.—The heading of paragraph (3) of section 744B(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(g)) is amended by striking ''AND PRIOR APPROVAL SUPPLEMENT FEE''.

(f) CREDITING AND AVAILABILITY OF FEES.—Section 744B(i)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(i)(3)) is amended by striking ''fiscal years 2018 through 2022'' and inserting ''fiscal years 2023 through 2027''.

SEC. 3003. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43) is amended—

(1) in subsection (a)(1), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

(2) by striking ''Generic Drug User Fee Amendments of 2017'' each place it appears and inserting ''Generic Drug User Fee Amendments of 2022'';

(3) in subsection (a)(2), by striking ''Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter'' and inserting ''Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this part'';

(4) in subsection (a)(3), by striking ''Beginning with fiscal year 2020, the'' and inserting ''The'';

(5) in subsection (b), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

(6) in subsection (c), by striking ''Beginning with fiscal year 2018, for'' and inserting ''For''; and

(7) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''fiscal year 2022'' and inserting ''fiscal year 2027''; and

(B) in paragraph (5), by striking ''January 15, 2022'' and inserting ''January 15, 2027''.

SEC. 3004. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744A and 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41; 379j–42) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43) shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2022, subsections (a) and (b) of section 305 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 3005. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41 et seq.) shall be assessed for all abbreviated new drug applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 3006. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41 et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to abbreviated new drug applications (as defined in such part as of such day) that were received by the Food and Drug Administration within the meaning of section 505(j)(5)(A) of such Act (21 U.S.C. 355(j)(5)(A)), prior approval supplements that were submitted, and drug master files for Type II active pharmaceutical ingredients that were first referenced on or after October 1, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 4001. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Biosimilar User Fee Amendments of 2022''.

(b) FINDING.—Congress finds that the fees authorized by the amendments made by this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 4002. DEFINITIONS.

(a) ADJUSTMENT FACTOR.—Section 744G(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(1)) is amended to read as follows:

''(1) The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items) for September of the preceding fiscal year divided by such Index for September 2011.''.

(b) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—Section 744G(4)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(4)(B)(iii)) is amended—

(1) by striking subclause (II) (relating to an allergenic extract product); and

(2) by redesignating subclauses (III) and (IV) as subclauses (II) and (III), respectively.

SEC. 4003. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—The matter preceding paragraph (1) in section 744H(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is amended by striking ''fiscal year 2018'' and inserting ''fiscal year 2023''.

(2) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—Clauses (iv)(I) and (v)(II) of section 744H(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(A)) are each amended by striking ''5 days'' and inserting ''7 days''.

(3) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—Section 744H(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(B)) is amended—

(A) in clause (i), by inserting before the period at the end the following: '', except that, in the case that such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee'';

(B) in clause (iii)—

(i) in subclause (I), by striking ''or'' at the end;

(ii) in subclause (II), by striking the period at the end and inserting ''; or''; and

(iii) by adding at the end the following:

''(III) been administratively removed from the biosimilar biological product development program for the product under subparagraph (E)(v).''; and

(C) in clause (iv), by striking ''is accepted for filing on or after October 1 of such fiscal year'' and inserting ''is subsequently accepted for filing''.

(4) REACTIVATION FEE.—Section 744H(a)(1)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(D)) is amended to read as follows:

''(D) REACTIVATION FEE.—

''(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C), or who has been administratively removed from such program for a product under subparagraph (E)(v), shall, if the person seeks to resume participation in such program, pay all annual biosimilar biological product development fees previously assessed for such product and still owed and a fee (referred to in this section as 'reactivation fee') by the earlier of the following:

''(I) Not later than 7 days after the Secretary grants a request by such person for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued or the date of administrative removal, as applicable).

''(II) Upon the date of submission (after the date on which such participation was discontinued or the date of administrative removal, as applicable) by such person of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

''(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B), except that, in the case that such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee.''.

(5) EFFECT OF FAILURE TO PAY FEES.—Section 744H(a)(1)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(E)) is amended by adding at the end the following:

''(v) ADMINISTRATIVE REMOVAL FROM THE BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM.—If a person has failed to pay an annual biosimilar biological product development fee for a product as required under subparagraph (B) for a period of 2 consecutive fiscal years, the Secretary may administratively remove such person from the biosimilar biological product development program for the product. At least 30 days prior to administratively removing a person from the biosimilar biological product development program for a product under this clause, the Secretary shall provide written notice to such person of the intended administrative removal.''.

(6) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—Section 744H(a)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(2)(D)) is amended by inserting after ''or was withdrawn'' the following: ''prior to approval''.

(7) BIOSIMILAR BIOLOGICAL PRODUCT PROGRAM FEE.—Section 744H(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(3)) is amended—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''and'' at the end;

(ii) by redesignating clause (ii) as clause (iii); and

(iii) by inserting after clause (i) the following:

''(ii) may be dispensed only under prescription pursuant to section 503(b); and''; and

(B) by adding at the end the following:

''(E) MOVEMENT TO DISCONTINUED LIST.—

''(i) DATE OF INCLUSION.—If a written request to place a product on the list referenced in subparagraph (A) of discontinued biosimilar biological products is submitted to the Secretary on behalf of an applicant,

and the request identifies the date the product is, or will be, withdrawn from sale, then for purposes of assessing the biosimilar biological product program fee, the Secretary shall consider such product to have been included on such list on the later of—

''(I) the date such request was received; or

''(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

''(ii) TREATMENT AS WITHDRAWN FROM SALE.—For purposes of clause (i), a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.

''(iii) SPECIAL RULE FOR PRODUCTS REMOVED FROM DISCONTINUED LIST.—If a biosimilar biological product that is identified in a biosimilar biological product application approved as of October 1 of a fiscal year appears, as of October 1 of such fiscal year, on the list referenced in subparagraph (A) of discontinued biosimilar biological products, and on any subsequent day during such fiscal year the biosimilar biological product does not appear on such list, except as provided in subparagraph (D), each person who is named as the applicant in a biosimilar biological product application with respect to such product shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for such biosimilar biological product. Notwithstanding subparagraph (B), such fee shall be due on the last business day of such fiscal year and shall be paid only once for each such product for each fiscal year.''.

(8) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—Section 744H(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is amended by striking paragraph (4).

(b) FEE REVENUE AMOUNTS.—Subsection (b) of section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) is amended—

(1) by striking paragraph (1);

(2) by redesignating paragraphs (2) through (4) as paragraphs (1) through (3), respectively;

(3) by amending paragraph (1) (as so redesignated) to read as follows:

''(1) IN GENERAL.—For each of the fiscal years 2023 through 2027, fees under subsection (a) shall, except as provided in subsection (c), be established to generate a total revenue amount equal to the sum of—

''(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

''(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

''(C) the dollar amount equal to the strategic hiring and retention adjustment (as determined under subsection (c)(2));

''(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

''(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

''(F) for fiscal year 2023 an additional amount of $4,428,886; and

''(G) for fiscal year 2024 an additional amount of $320,569.'';

(4) in paragraph (2) (as so redesignated)—

(A) in the paragraph heading, by striking ''; LIMITATIONS ON FEE AMOUNTS'';

(B) by striking subparagraph (B); and

(C) by redesignating subparagraphs (C) and (D) as subparagraphs (B) and (C), respectively; and

(5) by amending paragraph (3) (as so redesignated) to read as follows:

''(3) ANNUAL BASE REVENUE.—For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

''(A) for fiscal year 2023, $43,376,922; and

''(B) for fiscal years 2024 through 2027, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, excluding any adjustments to such revenue amount under subsection (c)(4).''.

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section 744H(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(c)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''subsection (b)(2)(B)'' and inserting ''subsection (b)(1)(B)''; and

(ii) in clause (i), by striking ''subsection (b)'' and inserting ''subsection (b)(1)(A)''; and

(B) in subparagraph (B)(ii), by striking ''Washington-Baltimore, DC–MD–VA–WV'' and inserting ''Washington-Arlington-Alexandria, DC–VA–MD–WV'';

(2) by striking paragraphs (2) through (4) and inserting the following:

''(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue under subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by $150,000.

''(3) CAPACITY PLANNING ADJUSTMENT.—

''(A) IN GENERAL.—For each fiscal year, the Secretary shall, in addition to the adjustments under paragraphs (1) and (2), further adjust the fee revenue and fees under this section for a fiscal year to reflect changes in the resource capacity needs of the Secretary for the process for the review of biosimilar biological product applications.

''(B) METHODOLOGY.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled 'Biosimilar User Fee Rates for Fiscal Year 2021' published in the Federal Register on August 4, 2020 (85 Fed. Reg. 47220). The workload categories used in applying such methodology in forecasting shall include only the activities described in that notice and, as feasible, additional activities that are directly related to the direct review of biosimilar biological product applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved biosimilar biological products. Subject to the exceptions in the preceding sentence, the Secretary shall not include as workload categories in applying such methodology in forecasting any non-core review activities, including those activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021.

''(C) LIMITATIONS.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(1)(A) (the annual base revenue for the fiscal year), (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year), and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment).

''(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under paragraph (5) the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

''(4) OPERATING RESERVE ADJUSTMENT.—

''(A) INCREASE.—For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications.

''(B) DECREASE.—

''(i) FISCAL YEAR 2023.—For fiscal year 2023, if the Secretary has carryover balances for such process in excess of 33 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 33 weeks of such operating reserves.

''(ii) FISCAL YEAR 2024.—For fiscal year 2024, if the Secretary has carryover balances for such process in excess of 27 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 27 weeks of such operating reserves.

''(iii) FISCAL YEAR 2025 AND SUBSEQUENT FISCAL YEARS.—For fiscal year 2025 and subsequent fiscal years, if the Secretary has carryover balances for such process in excess of 21 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 21 weeks of such operating reserves.

''(C) FEDERAL REGISTER NOTICE.—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5)(B) establishing fee revenue and fees for the fiscal year involved.''; and

(3) in paragraph (5), in the matter preceding subparagraph (A), by striking ''2018'' and inserting ''2023''.

(d) CREDITING AND AVAILABILITY OF FEES.—Subsection (f)(3) of section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(f)(3)) is amended by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

(e) WRITTEN REQUESTS FOR WAIVERS AND RETURNS; DISPUTES CONCERNING FEES.—Section 744H(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(h)) is amended to read as follows:

''(h) WRITTEN REQUESTS FOR WAIVERS AND RETURNS; DISPUTES CONCERNING FEES.—To qualify for consideration for a waiver under subsection (d), or for the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall submit to the Secretary a written request justifying such waiver or return and, except as otherwise specified in this section, such written request shall be submitted to the Secretary not later than 180 days after such fee is due. A request submitted under this paragraph shall include any legal authorities under which the request is made.''.

SEC. 4004. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 744I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53) is amended—

(1) in subsection (a)(1), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

(2) by striking ''Biosimilar User Fee Amendments of 2017'' each place it appears and inserting ''Biosimilar User Fee Amendments of 2022'';

(3) in subsection (a)(2), by striking ''Beginning with fiscal year 2018, the'' and inserting ''The'';

(4) in subsection (a)(3)(A), by striking ''Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end

of each quarter of each fiscal year thereafter'' and inserting ''Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this part'';

(5) in subsection (b), by striking ''Not later than 120 days after the end of fiscal year 2018 and each subsequent fiscal year for which fees are collected under this part'' and inserting ''Not later than 120 days after the end of each fiscal year for which fees are collected under this part'';

(6) in subsection (c), by striking ''Beginning with fiscal year 2018, and for'' and inserting ''For''; and

(7) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''fiscal year 2022'' and inserting ''fiscal year 2027''; and

(B) in paragraph (3), by striking ''January 15, 2022'' and inserting ''January 15, 2027''.

SEC. 4005. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744G and 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51, 379j–52) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 744I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53) shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2022, subsections (a) and (b) of section 405 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 4006. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be assessed for all biosimilar biological product applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 4007. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to biosimilar biological product applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE V—REAUTHORIZATION OF OTHER PROVISIONS

SEC. 5001. REAUTHORIZATION OF THE BEST PHARMACEUTICALS FOR CHILDREN PROGRAM.

Section 409I(d)(1) of the Public Health Service Act (42 U.S.C. 284m(d)(1)) is amended by striking ''$25,000,000 for each of fiscal years 2018 through 2022'' and inserting ''$5,273,973 for the period beginning on October 1, 2022 and ending on December 16, 2022''.

SEC. 5002. REAUTHORIZATION OF THE HUMANITARIAN DEVICE EXEMPTION INCENTIVE.

Section 520(m)(6)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by striking ''October 1'' and inserting ''December 17''.

SEC. 5003. REAUTHORIZATION OF THE PEDIATRIC DEVICE CONSORTIA PROGRAM.

Section 305(e) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85; 42 U.S.C. 282 note) is amended by striking ''$5,250,000 for each of fiscal years 2018 through 2022'' and inserting ''$1,107,534 for the period beginning on October 1, 2022, and ending on December 16, 2022''.

SEC. 5004. REAUTHORIZATION OF PROVISION PERTAINING TO DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505(u)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by striking ''October 1'' and inserting ''December 17''.

SEC. 5005. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIP.

Section 566(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5(f)) is amended by striking ''$6,000,000 for each of fiscal years 2018 through 2022'' and inserting ''$1,265,753 for the period beginning on October 1, 2022 and ending on December 16, 2022''.

SEC. 5006. REAUTHORIZATION OF ORPHAN DRUG GRANTS.

Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended by striking ''$30,000,000 for each of fiscal years 2018 through 2022'' and inserting ''$6,328,767 for the period beginning on October 1, 2022, and ending on December 16, 2022''.

SEC. 5007. REAUTHORIZATION OF CERTAIN DEVICE INSPECTIONS.

Section 704(g)(11) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by striking ''October 1'' and inserting ''December 17''.

SEC. 5008. REAUTHORIZATION OF REPORTING REQUIREMENTS RELATED TO PENDING GENERIC DRUG APPLICATIONS AND PRIORITY REVIEW APPLICATIONS.

Section 807 of the FDA Reauthorization Act of 2017 (Public Law 115–52) is amended, in the matter preceding paragraph (1), by striking ''October 1'' and inserting ''December 16''.

DIVISION G—HERMIT'S PEAK/CALF CANYON FIRE ASSISTANCE ACT

SEC. 101. SHORT TITLE.

This division may be cited as the ''Hermit's Peak/Calf Canyon Fire Assistance Act''.

SEC. 102. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) on April 6, 2022, the Forest Service initiated the Las Dispensas-Gallinas prescribed burn on Federal land in the Santa Fe National Forest in San Miguel County, New Mexico, when erratic winds were prevalent in the area that was also suffering from severe drought after many years of insufficient precipitation;

(2) on April 6, 2022, the prescribed burn, which became known as the ''Hermit's Peak Fire'', exceeded the containment capabilities of the Forest Service, was declared a wildfire, and spread to other Federal and non-Federal land;

(3) on April 19, 2022, the Calf Canyon Fire, also in San Miguel County, New Mexico, began burning on Federal land and was later identified as the result of a pile burn in January 2022 that remained dormant under the surface before reemerging;

(4) on April 27, 2022, the Hermit's Peak Fire and the Calf Canyon Fire merged, and both fires were reported as the Hermit's Peak Fire or the Hermit's Peak/Calf Canyon Fire, which shall be referred to hereafter as the Hermit's Peak/Calf Canyon Fire;

(5) by May 2, 2022, the fire had grown in size and caused evacuations in multiple villages and communities in San Miguel County and Mora County, including in the San Miguel county jail, the State's psychiatric hospital, the United World College, and New Mexico Highlands University;

(6) on May 4, 2022, the President issued a major disaster declaration for the counties of Colfax, Mora, and San Miguel, New Mexico;

(7) on May 20, 2022, U.S. Forest Service Chief Randy Moore ordered a 90-day review of prescribed burn policies to reduce the risk of wildfires and ensure the safety of the communities involved;

(8) the U.S. Forest Service has assumed responsibility for the Hermit's Peak/Calf Canyon Fire;

(9) the fire resulted in the loss of Federal, State, local, Tribal, and private property; and

(10) the United States should compensate the victims of the Hermit's Peak/Calf Canyon Fire.

(b) PURPOSES.—The purposes of this Act are—

(1) to compensate victims of the Hermit's Peak/Calf Canyon Fire, for injuries resulting from the fire; and

(2) to provide for the expeditious consideration and settlement of claims for those injuries.

SEC. 103. DEFINITIONS.

In this Act:

(1) ADMINISTRATOR.—The term ''Administrator'' means—

(A) the Administrator of the Federal Emergency Management Agency; or

(B) if a Manager is appointed under section 104(a)(3), the Manager.

(2) HERMIT'S PEAK/CALF CANYON FIRE.—The term ''Hermit's Peak/Calf Canyon Fire'' means—

(A) the fire resulting from the initiation by the Forest Service of a prescribed burn in the Santa Fe National Forest in San Miguel County, New Mexico, on April 6, 2022;

(B) the pile burn holdover resulting from the prescribed burn by the Forest Service, which reemerged on April 19, 2022; and

(C) the merger of the two fires described in subparagraphs (A) and (B), reported as the Hermit's Peak Fire or the Hermit's Peak Fire/Calf Canyon Fire.

(3) INDIAN TRIBE.—The term ''Indian Tribe'' means the recognized governing body of any Indian or Alaska Native Tribe, band, nation, pueblo, village, community, component band, or component reservation individually identified (including parenthetically) in the list published most recently as of the date of enactment of this Act pursuant to section 104 of the Federally Recognized Indian Tribe List Act of 1994 (25 U.S.C. 5131).

(4) INJURED PERSON.—The term ''injured person'' means—

(A) an individual, regardless of the citizenship or alien status of the individual; or

(B) an Indian Tribe, corporation, Tribal corporation, partnership, company, association, county, township, city, State, school district, or other non-Federal entity (including a legal representative) that suffered injury resulting from the Hermit's Peak/Calf Canyon Fire.

(5) INJURY.—The term ''injury'' has the same meaning as the term ''injury or loss of property, or personal injury or death'' as used in section 1346(b)(1) of title 28, United States Code.

(6) MANAGER.—The term ''Manager'' means an Independent Claims Manager appointed under section 104(a)(3).

(7) OFFICE.—The term ''Office'' means the Office of Hermit's Peak/Calf Canyon Fire Claims established by section 104(a)(2).

(8) TRIBAL ENTITY.—The term ''Tribal entity'' includes any Indian Tribe, tribal organization, Indian-controlled organization serving Indians, Native Hawaiian organization, or Alaska Native entity, as such terms are defined or used in section 166 of the Workforce Innovation and Opportunity Act (29 U.S.C. 3221).

SEC. 104. COMPENSATION FOR VICTIMS OF HERMIT'S PEAK/CALF CANYON FIRE.

(a) IN GENERAL.—

(1) COMPENSATION.—Each injured person shall be eligible to receive from the United States compensation for injury suffered by the injured person as a result of the Hermit's Peak/Calf Canyon Fire, subject to the availability of appropriations and subject to the Administrator making the determinations required under subsection (d).

(2) OFFICE OF HERMIT'S PEAK/CALF CANYON FIRE CLAIMS.—

(A) IN GENERAL.—There is established within the Federal Emergency Management Agency an Office of Hermit's Peak/Calf Canyon Fire Claims.

(B) PURPOSE.—The Office shall receive, process, and pay claims in accordance with this Act.

(C) FUNDING.—The Office—

(i) shall be funded from funds made available to the Administrator for carrying out this section;

(ii) may appoint and fix the compensation of such temporary personnel as may be necessary, without regard to the provisions of title 5, United States Code, governing appointments in competitive service; and

(iii) may reimburse other Federal agencies for claims processing support and assistance.

(3) OPTION TO APPOINT INDEPENDENT CLAIMS MANAGER.—The Administrator may appoint an Independent Claims Manager to—

(A) head the Office; and

(B) assume the duties of the Administrator under this Act.

(4) DETAIL.—Upon the request of the Administrator, the head of any Federal department or agency may detail, on a reimbursable basis, any of the personnel of that department or agency to the Federal Emergency Management Agency to assist the Agency in carrying out the duties under this Act.

(b) SUBMISSION OF CLAIMS.—Not later than 2 years after the date on which regulations are first promulgated under subsection (f), an injured person may submit to the Administrator a written claim for 1 or more injuries suffered by the injured person in accordance with such requirements as the Administrator determines to be appropriate.

(c) INVESTIGATION OF CLAIMS.—

(1) IN GENERAL.—In accordance with subsection (d), the Administrator shall, on behalf of the United States, investigate, consider, ascertain, adjust, determine, grant, deny, or settle any claim for money damages asserted under subsection (b).

(2) APPLICABILITY OF STATE LAW.—Except as otherwise provided in this Act, the laws of the State of New Mexico shall apply to the calculation of damages under subsection (d)(4).

(3) EXTENT OF DAMAGES.—Any payment under this Act—

(A) shall be limited to actual compensatory damages measured by injuries suffered; and

(B) shall not include—

(i) interest before settlement or payment of a claim; or

(ii) punitive damages.

(d) PAYMENT OF CLAIMS.—

(1) DETERMINATION AND PAYMENT OF AMOUNT.—

(A) IN GENERAL.—

(i) PAYMENT.—Not later than 180 days after the date on which a claim is submitted under this Act, the Administrator shall determine and fix the amount, if any, to be paid for the claim.

(ii) PRIORITY.—The Administrator, to the maximum extent practicable, shall pay subrogation claims submitted under this Act only after paying claims submitted by injured parties that are not insurance companies seeking payment as subrogees.

(B) PARAMETERS OF DETERMINATION.—In determining and settling a claim under this Act, the Administrator shall determine only—

(i) whether the claimant is an injured person;

(ii) whether the injury that is the subject of the claim resulted from the Hermit's Peak/Calf Canyon Fire;

(iii) whether the person or persons are otherwise eligible to receive any amount determined under clause (iv); and

(iv) whether sufficient funds are available for payment and, if so, the amount, if any, to be allowed and paid under this Act.

(C) INSURANCE AND OTHER BENEFITS.—

(i) IN GENERAL.—In determining the amount of, and paying, a claim under this Act, to prevent recovery by a claimant in excess of actual compensatory damages, the Administrator shall reduce the amount to be paid for the claim by an amount that is equal to the total of insurance benefits (excluding life insurance benefits) or other payments or settlements of any nature that were paid, or will be paid, with respect to the claim.

(ii) GOVERNMENT LOANS.—This subparagraph shall not apply to the receipt by a claimant of any government loan that is required to be repaid by the claimant.

(2) PARTIAL PAYMENT.—

(A) IN GENERAL.—At the request of a claimant, the Administrator may make 1 or more advance or partial payments, subject to the determination required under paragraph (1)(B), before the final settlement of a claim, including final settlement on any portion or aspect of a claim that is determined to be severable.

(B) JUDICIAL DECISION.—If a claimant receives a partial payment on a claim under this Act, but further payment on the claim is subsequently denied by the Administrator, the claimant may—

(i) seek judicial review under subsection (i); and

(ii) keep any partial payment that the claimant received, unless the Administrator determines that the claimant—

(I) was not eligible to receive the compensation; or

(II) fraudulently procured the compensation.

(3) RIGHTS OF INSURER OR OTHER THIRD PARTY.—If an insurer or other third party pays any amount to a claimant to compensate for an injury described in subsection (a), the insurer or other third party shall be subrogated to any right that the claimant has to receive any payment under this Act or any other law.

(4) ALLOWABLE DAMAGES.—

(A) LOSS OF PROPERTY.—A claim that is paid for loss of property under this Act may include otherwise uncompensated damages resulting from the Hermit's Peak/Calf Canyon Fire for—

(i) an uninsured or underinsured property loss;

(ii) a decrease in the value of real property;

(iii) damage to physical infrastructure, including irrigation infrastructure such as acequia systems;

(iv) a cost resulting from lost subsistence from hunting, fishing, firewood gathering, timbering, grazing, or agricultural activities conducted on land damaged by the Hermit's Peak/Calf Canyon Fire;

(v) a cost of reforestation or revegetation on Tribal or non-Federal land, to the extent that the cost of reforestation or revegetation is not covered by any other Federal program; and

(vi) any other loss that the Administrator determines to be appropriate for inclusion as loss of property.

(B) BUSINESS LOSS.—A claim that is paid for injury under this Act may include damages resulting from the Hermit's Peak/Calf Canyon Fire for the following types of otherwise uncompensated business loss:

(i) Damage to tangible assets or inventory, including natural resources.

(ii) Business interruption losses.

(iii) Overhead costs.

(iv) Employee wages for work not performed.

(v) Loss of business net income.

(vi) Any other loss that the Administrator determines to be appropriate for inclusion as business loss.

(C) FINANCIAL LOSS.—A claim that is paid for injury under this Act may include damages resulting from the Hermit's Peak/Calf Canyon Fire for the following types of otherwise uncompensated financial loss:

(i) Increased mortgage interest costs.

(ii) An insurance deductible.

(iii) A temporary living or relocation expense.

(iv) Lost wages or personal income.

(v) Emergency staffing expenses.

(vi) Debris removal and other cleanup costs.

(vii) Costs of reasonable efforts, as determined by the Administrator, to reduce the risk of wildfire, flood, or other natural disaster in the counties impacted by the Hermit's Peak/Calf Canyon Fire to risk levels prevailing in those counties before the Hermit's Peak/Calf Canyon Fire, that are incurred not later than the date that is 3 years after the date on which the regulations under subsection (f) are first promulgated.

(viii) A premium for flood insurance that is required to be paid on or before May 31, 2024, if, as a result of the Hermit's Peak/Calf Canyon Fire, a person that was not required to purchase flood insurance before the Hermit's Peak/Calf Canyon Fire is required to purchase flood insurance.

(ix) A disaster assistance loan received from the Small Business Administration.

(x) Any other loss that the Administrator determines to be appropriate for inclusion as financial loss.

(e) ACCEPTANCE OF AWARD.—The acceptance by a claimant of any payment under this Act, except an advance or partial payment made under subsection (d)(2), shall—

(1) be final and conclusive on the claimant, with respect to all claims arising out of or relating to the same subject matter; and

(2) constitute a complete release of all claims against the United States (including any agency or employee of the United States) under chapter 171 of title 28, United States Code (commonly known as the ''Federal Tort Claims Act''), or any other Federal or State law, arising out of or relating to the same subject matter.

(f) REGULATIONS AND PUBLIC INFORMATION.—

(1) REGULATIONS.—Notwithstanding any other provision of law, not later than 45 days after the date of enactment of this Act, the Administrator shall promulgate and publish in the Federal Register interim final regulations for the processing and payment of claims under this Act.

(2) PUBLIC INFORMATION.—

(A) IN GENERAL.—At the time at which the Administrator promulgates regulations under paragraph (1), the Administrator shall publish, online and in print, in newspapers of general circulation in the State of New Mexico, a clear, concise, and easily understandable explanation, in English and Spanish, of—

(i) the rights conferred under this Act; and

(ii) the procedural and other requirements of the regulations promulgated under paragraph (1).

(B) DISSEMINATION THROUGH OTHER MEDIA.—The Administrator shall disseminate the explanation published under subparagraph (A)

through websites, blogs, social media, brochures, pamphlets, radio, television, and other media that the Administrator determines are likely to reach prospective claimants.

(g) CONSULTATION.—In administering this Act, the Administrator shall consult with the Secretary of the Interior, the Secretary of Energy, the Secretary of Agriculture, the Administrator of the Small Business Administration, other Federal agencies, and State, local, and Tribal authorities, as determined to be necessary by the Administrator, to—

(1) ensure the efficient administration of the claims process; and

(2) provide for local concerns.

(h) ELECTION OF REMEDY.—

(1) IN GENERAL.—An injured person may elect to seek compensation from the United States for 1 or more injuries resulting from the Hermit's Peak/Calf Canyon Fire by—

(A) submitting a claim under this Act;

(B) filing a claim or bringing a civil action under chapter 171 of title 28, United States Code (commonly known as the ''Federal Tort Claims Act''); or

(C) bringing an authorized civil action under any other provision of law.

(2) EFFECT OF ELECTION.—In accordance with subsection (e), an election by an injured person to seek compensation in any manner described in paragraph (1) shall be final and conclusive on the claimant with respect to all injuries resulting from the Hermit's Peak/Calf Canyon Fire that are suffered by the claimant upon acceptance of an award.

(3) ARBITRATION.—

(A) IN GENERAL.—Not later than 45 days after the date of enactment of this Act, the Administrator shall establish by regulation procedures under which a dispute regarding a claim submitted under this Act may be settled by arbitration.

(B) ARBITRATION AS REMEDY.—On establishment of arbitration procedures under subparagraph (A), an injured person that submits a disputed claim under this Act may elect to settle the claim through arbitration.

(C) BINDING EFFECT.—An election by an injured person to settle a claim through arbitration under this paragraph shall—

(i) be binding; and

(ii) preclude any exercise by the injured person of the right to judicial review of a claim described in subsection (i).

(4) NO EFFECT ON ENTITLEMENTS.—The value of compensation that may be provided under this Act shall not be considered income or resources for any purpose under any Federal, State, or local laws, including laws relating to taxation, welfare, and public assistance programs, and no State or political subdivision thereof shall decrease any assistance otherwise provided to an injured person because of the receipt of benefits under this Act.

(i) JUDICIAL REVIEW.—

(1) IN GENERAL.—Any claimant aggrieved by a final decision of the Administrator under this Act may, not later than 60 days after the date on which the decision is issued, bring a civil action in the United States District Court for the District of New Mexico, to modify or set aside the decision, in whole or in part.

(2) RECORD.—The court shall hear a civil action under paragraph (1) on the record made before the Administrator.

(3) STANDARD.—The decision of the Administrator incorporating the findings of the Administrator shall be upheld if the decision is supported by substantial evidence on the record considered as a whole.

(j) ATTORNEY'S AND AGENT'S FEES.—

(1) IN GENERAL.—No attorney or agent, acting alone or in combination with any other attorney or agent, shall charge, demand, receive, or collect, for services rendered in connection with a claim submitted under this Act, fees in excess of the limitations established under section 2678 of title 28, United States Code.

(2) VIOLATION.—An attorney or agent who violates paragraph (1) shall be fined not more than $10,000.

(k) WAIVER OF REQUIREMENT FOR MATCHING FUNDS.—

(1) STATE AND LOCAL PROJECT.—

(A) IN GENERAL.—Notwithstanding any other provision of law, a State or local project that is determined by the Administrator to be carried out in response to the Hermit's Peak/Calf Canyon Fire under any Federal program that applies to an area affected by the Hermit's Peak/Calf Canyon Fire shall not be subject to any requirement for State or local matching funds to pay the cost of the project under the Federal program.

(B) FEDERAL SHARE.—The Federal share of the costs of a project described in subparagraph (A) shall be 100 percent.

(2) OTHER NEEDS PROGRAM ASSISTANCE.—Notwithstanding section 408(g)(2) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5174(g)(2)), for any emergency or major disaster declared by the President under that Act for the Hermit's Peak/Calf Canyon Fire, the Federal share of assistance provided under that section shall be 100 percent.

(3) AGRICULTURAL PROGRAM ASSISTANCE.—

(A) IN GENERAL.—Notwithstanding any other provision of law, a State, local, or individual project that is determined by the Secretary of Agriculture to be carried out in response to the Hermit's Peak/Calf Canyon Fire under any Federal program that applies to an area affected by the Hermit's Peak/Calf Canyon Fire shall not be subject to any requirement for State, local, or individual matching funds to pay the cost of the project under the Federal program.

(B) FEDERAL SHARE.—The Federal share of the costs of a project described in subparagraph (A) shall be 100 percent.

(l) APPLICABILITY OF DEBT COLLECTION REQUIREMENTS.—Section 3711(a) of title 31, United States Code, shall not apply to any payment under this Act, unless—

(1) there is evidence of civil or criminal fraud, misrepresentation, presentation of a false claim; or

(2) a claimant was not eligible under subsection (d)(2) of this Act to any partial payment.

(m) INDIAN COMPENSATION.—Notwithstanding any other provision of law, in the case of an Indian Tribe, a Tribal entity, or a member of an Indian Tribe that submits a claim under this Act—

(1) the Bureau of Indian Affairs shall have no authority over, or any trust obligation regarding, any aspect of the submission of, or any payment received for, the claim;

(2) the Indian Tribe, Tribal entity, or member of an Indian Tribe shall be entitled to proceed under this Act in the same manner and to the same extent as any other injured person; and

(3) except with respect to land damaged by the Hermit's Peak/Calf Canyon Fire that is the subject of the claim, the Bureau of Indian Affairs shall have no responsibility to restore land damaged by the Hermit's Peak/Calf Canyon Fire.

(n) REPORT.—Not later than 1 year after the date of promulgation of regulations under subsection (f)(1), and annually thereafter, the Administrator shall submit to Congress a report that describes the claims submitted under this Act during the year preceding the date of submission of the report, including, for each claim—

(1) the amount claimed;

(2) a brief description of the nature of the claim; and

(3) the status or disposition of the claim, including the amount of any payment under this Act.

(o) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this Act.

SA 5746. Mr. CORNYN (for himself and Mr. CARPER) submitted an amendment intended to be proposed to amendment SA 5499 submitted by Mr. REED (for himself and Mr. INHOFE) and intended to be proposed to the bill H.R. 7900, to authorize appropriations for fiscal year 2023 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table; as follows:

At the end of subtitle F of title XII, add the following:

SEC. 1276. STRATEGY TO ENHANCE COOPERATION WITH CANADA AND MEXICO WITH RESPECT TO THE RESILIENCY OF NORTH AMERICAN SUPPLY CHAINS.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the United States Trade Representative, in consultation with the Secretary of State, the Secretary of Commerce, the Commissioner of U.S. Customs and Border Protection, and the heads of other relevant agencies, shall submit to the appropriate congressional committees a strategy for how the United States will work with the governments of Canada and Mexico to improve the resiliency of North American supply chains, including by reducing overdependence on, and concentration of critical supply chains in, countries that are foreign adversaries of the United States.

(b) ELEMENTS.—The strategy required by subsection (a) shall—

(1) include a summary of initiatives carried out with counterparts in Canada and Mexico to enhance cooperation between the United States, Canada, and Mexico with respect to supply chain resiliency, including through the USMCA (as defined in section 3 of the United States-Mexico-Canada Agreement Implementation Act (19 U.S.C. 4502));

(2) identify critical sectors for which cooperation with Canada and Mexico can strengthen the resiliency of supply chains; and

(3) identify challenges to improving the resiliency of supply chains.

(c) CONSULTATIONS.—Not later than one year after the date of enactment of this Act, the United States Trade Representative shall consult with the appropriate congressional committees regarding the development and implementation of the strategy required by subsection (a).

(d) APPROPRIATE CONGRESSIONAL COMMITTEES DEFINED.—In this section, the term ''appropriate congressional committees'' means the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives.

AUTHORITY FOR COMMITTEES TO MEET

Mr. MURPHY. Mr. President, I have two requests for committees to meet during today's session of the Senate. They have the approval of the Majority and Minority Leaders.