

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

H.R. 6833

An act 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.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by Mr. SCHUMER

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Continuing Appropria-
5 tions and Ukraine Supplemental Appropriations Act,
6 2023”.

7 **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**1 SEC. 3. REFERENCES.**

2 Except as expressly provided otherwise, any reference
3 to “this Act” contained in any division of this Act shall
4 be treated as referring only to the provisions of that divi-
5 sion.

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

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

1 **DIVISION A—CONTINUING**
2 **APPROPRIATIONS ACT, 2023**

3 The following sums are hereby appropriated, out of
4 any money in the Treasury not otherwise appropriated,
5 and out of applicable corporate or other revenues, receipts,
6 and funds, for the several departments, agencies, corpora-
7 tions, and other organizational units of Government for
8 fiscal year 2023, and for other purposes, namely:

9 SEC. 101. Such amounts as may be necessary, at a
10 rate for operations as provided in the applicable appro-
11 priations Acts for fiscal year 2022 and under the authority
12 and conditions provided in such Acts, for continuing
13 projects or activities (including the costs of direct loans
14 and loan guarantees) that are not otherwise specifically
15 provided for in this Act, that were conducted in fiscal year
16 2022, and for which appropriations, funds, or other au-
17 thority were made available in the following appropriations
18 Acts:

19 (1) The Agriculture, Rural Development, Food
20 and Drug Administration, and Related Agencies Ap-
21 propriations Act, 2022 (division A of Public Law
22 117–103), except section 783, and except that sec-
23 tion 785 shall be applied by substituting
24 “\$125,000,000” for “\$250,000,000”.

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

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

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

9 (5) The Financial Services and General Govern-
10 ment Appropriations Act, 2022 (division E of Public
11 Law 117–103), except the matter under the heading
12 “Postal Regulatory Commission” in title V.

13 (6) The Department of Homeland Security Ap-
14 propriations Act, 2022 (division F of Public Law
15 117–103), except sections 544 and 545, and includ-
16 ing title II of division O of Public Law 117–103.

17 (7) The Department of the Interior, Environ-
18 ment, and Related Agencies Appropriations Act,
19 2022 (division G of Public Law 117–103).

20 (8) The Departments of Labor, Health and
21 Human Services, and Education, and Related Agen-
22 cies Appropriations Act, 2022 (division H of Public
23 Law 117–103), and section 162 of division A of
24 Public Law 117–43.

1 (9) The Legislative Branch Appropriations Act,
2 2022 (division I of Public Law 117–103), and sec-
3 tion 6 in the matter preceding division A of Public
4 Law 117–103.

5 (10) The Military Construction, Veterans Af-
6 fairs, and Related Agencies Appropriations Act,
7 2022 (division J of Public Law 117–103).

8 (11) The Department of State, Foreign Oper-
9 ations, and Related Programs Appropriations Act,
10 2022 (division K of Public Law 117–103), except
11 the first proviso of section 7069(e).

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

15 SEC. 102. (a) No appropriation or funds made avail-
16 able or authority granted pursuant to section 101 for the
17 Department of Defense shall be used for:

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

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

22 (3) the initiation, resumption, or continuation
23 of any project, activity, operation, or organization
24 (defined as any project, subproject, activity, budget
25 activity, program element, and subprogram within a

1 program element, and for any investment items de-
2 fined as a P-1 line item in a budget activity within
3 an appropriation account and an R-1 line item that
4 includes a program element and subprogram element
5 within an appropriation account) for which appro-
6 priations, funds, or other authority were not avail-
7 able during fiscal year 2022.

8 (b) No appropriation or funds made available or au-
9 thority granted pursuant to section 101 for the Depart-
10 ment of Defense shall be used to initiate multi-year pro-
11 curements utilizing advance procurement funding for eco-
12 nomic order quantity procurement unless specifically ap-
13 propriated later.

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

17 SEC. 104. Except as otherwise provided in section
18 102, no appropriation or funds made available or author-
19 ity granted pursuant to section 101 shall be used to ini-
20 tiate or resume any project or activity for which appro-
21 priations, funds, or other authority were not available dur-
22 ing fiscal year 2022.

23 SEC. 105. Appropriations made and authority grant-
24 ed pursuant to this Act shall cover all obligations or ex-
25 penditures incurred for any project or activity during the

1 period for which funds or authority for such project or
2 activity are available under this Act.

3 SEC. 106. Unless otherwise provided for in this Act
4 or in the applicable appropriations Act for fiscal year
5 2023, appropriations and funds made available and au-
6 thority granted pursuant to this Act shall be available
7 until whichever of the following first occurs:

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

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

13 (3) December 16, 2022.

14 SEC. 107. Expenditures made pursuant to this Act
15 shall be charged to the applicable appropriation, fund, or
16 authorization whenever a bill in which such applicable ap-
17 propriation, fund, or authorization is contained is enacted
18 into law.

19 SEC. 108. Appropriations made and funds made
20 available by or authority granted pursuant to this Act may
21 be used without regard to the time limitations for submis-
22 sion and approval of apportionments set forth in section
23 1513 of title 31, United States Code, but nothing in this
24 Act may be construed to waive any other provision of law
25 governing the apportionment of funds.

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

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

15 SEC. 111. (a) For entitlements and other mandatory
16 payments whose budget authority was provided in appro-
17 priations Acts for fiscal year 2022, and for activities under
18 the Food and Nutrition Act of 2008, activities shall be
19 continued at the rate to maintain program levels under
20 current law, under the authority and conditions provided
21 in the applicable appropriations Act for fiscal year 2022,
22 to be continued through the date specified in section
23 106(3).

24 (b) Notwithstanding section 106, obligations for man-
25 datory payments due on or about the first day of any

1 month that begins after October 2022 but not later than
2 30 days after the date specified in section 106(3) may con-
3 tinue to be made, and funds shall be available for such
4 payments.

5 SEC. 112. Amounts made available under section 101
6 for civilian personnel compensation and benefits in each
7 department and agency may be apportioned up to the rate
8 for operations necessary to avoid furloughs within such de-
9 partment or agency, consistent with the applicable appro-
10 priations Act for fiscal year 2022, except that such author-
11 ity provided under this section shall not be used until after
12 the department or agency has taken all necessary actions
13 to reduce or defer non-personnel-related administrative ex-
14 penses.

15 SEC. 113. Funds appropriated by this Act may be
16 obligated and expended notwithstanding section 10 of
17 Public Law 91-672 (22 U.S.C. 2412), section 15 of the
18 State Department Basic Authorities Act of 1956 (22
19 U.S.C. 2680), section 313 of the Foreign Relations Au-
20 thorization Act, Fiscal Years 1994 and 1995 (22 U.S.C.
21 6212), and section 504(a)(1) of the National Security Act
22 of 1947 (50 U.S.C. 3094(a)(1)).

23 SEC. 114. Each amount incorporated by reference in
24 this Act that was previously designated by the Congress
25 as an emergency requirement pursuant to sections

1 4001(a)(1) and 4001(b) of S. Con. Res. 14 (117th Con-
2 gress), the concurrent resolution on the budget for fiscal
3 year 2022, or as being for disaster relief pursuant to sec-
4 tion 4005(f) of such concurrent resolution, is designated
5 as being an emergency requirement pursuant to section
6 4001(a)(1) of such concurrent resolution and section 1(e)
7 of H. Res. 1151 (117th Congress), as engrossed in the
8 House of Representatives on June 8, 2022, or as being
9 for disaster relief pursuant to section 1(f) of such House
10 resolution, respectively.

11 SEC. 115. (a) Rescissions or cancellations of discre-
12 tionary budget authority that continue pursuant to section
13 101 in Treasury Appropriations Fund Symbols (TAFS)—

14 (1) to which other appropriations are not pro-
15 vided by this Act, but for which there is a current
16 applicable TAFS that does receive an appropriation
17 in this Act; or

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

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

1 (b) Rescissions or cancellations described in sub-
2 section (a) shall continue in an amount equal to the lesser
3 of—

4 (1) the amount specified for rescission or can-
5 cellation in the applicable appropriations Act ref-
6 erenced in section 101 of this Act; or

7 (2) the amount of balances available, as of Oc-
8 tober 1, 2022, from the funds specified for rescission
9 or cancellation in the applicable appropriations Act
10 referenced in section 101 of this Act.

11 (c) No later than November 21, 2022, the Director
12 of the Office of Management and Budget shall provide to
13 the Committees on Appropriations of the House of Rep-
14 resentatives and the Senate a comprehensive list of the
15 rescissions or cancellations that will continue pursuant to
16 section 101: *Provided*, That the information in such com-
17 prehensive list shall be periodically updated to reflect any
18 subsequent changes in the amount of balances available,
19 as of October 1, 2022, from the funds specified for rescis-
20 sion or cancellation in the applicable appropriations Act
21 referenced in section 101, and such updates shall be trans-
22 mitted to the Committees on Appropriations of the House
23 of Representatives and the Senate upon request.

24 SEC. 116. Amounts made available by section 101 for
25 “Farm Service Agency—Agricultural Credit Insurance

1 Fund Program Account” may be apportioned up to the
2 rate for operations necessary to accommodate approved
3 applications for direct and guaranteed farm ownership
4 loans, as authorized by 7 U.S.C. 1922 et seq.

5 SEC. 117. Amounts made available by section 101 to
6 the Department of Agriculture for “Rural Business—Co-
7 operative Service—Rural Microentrepreneur Assistance
8 Program” may be used for the costs of loans, including
9 the cost of modifying such loans, as defined in section 502
10 of the Congressional Budget Act of 1974, under the same
11 terms and conditions as authorized by section 379E of the
12 Consolidated Farm and Rural Development Act (7 U.S.C.
13 2008s).

14 SEC. 118. Section 260 of the Agricultural Marketing
15 Act of 1946 (7 U.S.C. 1636i) and section 942 of the Live-
16 stock Mandatory Reporting Act of 1999 (7 U.S.C. 1635
17 note; Public Law 106–78) shall be applied by substituting
18 the date specified in section 106(3) of this Act for “Sep-
19 tember 30, 2022”.

20 SEC. 119. Amounts made available by section 101 to
21 the Department of Commerce for “Economic Development
22 Administration—Salaries and Expenses” may be appor-
23 tioned up to the rate for operations necessary to maintain
24 agency operations.

1 SEC. 120. Amounts made available by section 101 for
2 “Department of Commerce—National Telecommuni-
3 cations and Information Administration—Salaries and
4 Expenses” may be apportioned up to the rate for oper-
5 ations necessary to ensure continued oversight of public
6 safety communications programs.

7 SEC. 121. In addition to amounts otherwise provided
8 by section 101, for “Department of Justice—Federal Bu-
9 reau of Investigation—Salaries and Expenses”, there is
10 appropriated \$15,300,000, for an additional amount for
11 fiscal year 2023, to remain available until September 30,
12 2023, for investigative activities associated with Afghan
13 resettlement operations: *Provided*, That such amount is
14 designated by the Congress as being for an emergency re-
15 quirement pursuant to section 4001(a)(1) of S. Con. Res.
16 14 (117th Congress), the concurrent resolution on the
17 budget for fiscal year 2022, and section 1(e) of H. Res.
18 1151 (117th Congress), as engrossed in the House of Rep-
19 resentatives on June 8, 2022.

20 SEC. 122. (a) Notwithstanding sections 101 and 106,
21 through September 30, 2023, the Secretary of Defense
22 may transfer up to \$3,000,000,000 from unobligated bal-
23 ances from amounts made available under the heading
24 “Department of Defense—Operation and Maintenance—
25 Overseas Humanitarian, Disaster, and Civic Aid” in divi-

1 sion C of Public Law 117–43 and division B of Public
2 Law 117–70 to any appropriation account under the head-
3 ings “Department of State and Related Agency—Depart-
4 ment of State—Administration of Foreign Affairs”, “Bi-
5 lateral Economic Assistance—Department of State—Mi-
6 gration and Refugee Assistance”, and “Bilateral Eco-
7 nomic Assistance—Department of State—United States
8 Emergency Refugee and Migration Assistance Fund” for
9 support of Operation Allies Welcome or any successor op-
10 eration: *Provided*, That upon transfer, such funds shall be
11 merged with the appropriation to which such funds are
12 transferred except that such funds may be made available
13 for such purposes notwithstanding any requirement or
14 limitation applicable to the appropriation to which trans-
15 ferred, including sections 2(c)(1) and 2(c)(2) of the Migra-
16 tion and Refugee Assistance Act of 1962 with respect to
17 the United States Emergency Refugee and Migration As-
18 sistance Fund and in sections 4(a) and 4(b) of the State
19 Department Basic Authorities Act of 1956 with respect
20 to funds transferred to the Emergencies in the Diplomatic
21 and Consular Service account: *Provided further*, That sec-
22 tion 2215 of title 10, United States Code, shall not apply
23 to a transfer of funds under this subsection: *Provided fur-*
24 *ther*, That the exercise of the authority of this subsection
25 shall be subject to prior consultation with, and the regular

1 notification procedures of, the Committees on Appropria-
2 tions of the House of Representatives and the Senate: *Pro-*
3 *vided further*, That any funds transferred pursuant to this
4 subsection that were previously designated by the Con-
5 gress as an emergency requirement pursuant to the con-
6 current resolution on the budget are designated by the
7 Congress as being for an emergency requirement pursuant
8 to section 4001(a)(1) of S. Con. Res. 14 (117th Con-
9 gress), the concurrent resolution on the budget for fiscal
10 year 2022, and section 1(e) of H. Res. 1151 (117th Con-
11 gress), as engrossed in the House of Representatives on
12 June 8, 2022.

13 (b) Not later than November 1, 2022 and prior to
14 any transfer of funds pursuant to subsection (a), the Di-
15 rector of the Office of Management and Budget shall pro-
16 vide to the Committees on Appropriations of the House
17 of Representatives and the Senate a written report on Op-
18 eration Allies Welcome or any successor operation: *Pro-*
19 *vided*, That such report shall describe the number and sta-
20 tus of Afghans residing at Department of Defense and De-
21 partment of State-managed facilities and any anticipated
22 future arrivals at such facilities; the strategy and plan,
23 including timeline, for adjudicating and relocating all Af-
24 ghans residing at Department of Defense or overseas civil-
25 ian facilities and for the transition of operations and re-

1 sponsibilities under Operation Allies Welcome or any suc-
2 cessor operation from the Department of Defense to the
3 Department of State during fiscal year 2023; the activities
4 and responsibilities assigned to each Federal agency in-
5 volved in such strategy and plan; and a spend plan, con-
6 taining an estimate of the costs, including additional con-
7 struction and security costs, to be incurred by each such
8 agency for carrying out such strategy and plan, and the
9 sources of funds: *Provided further*, That prior to the initial
10 obligation of funds transferred to the Department of State
11 pursuant to subsection (a), the Secretary of State shall
12 submit a report to such Committees detailing the roles and
13 responsibilities of Department of State bureaus and offices
14 in Operation Allies Welcome or any successor operation.

15 SEC. 123. During the period covered by this Act, sec-
16 tion 714(b)(2)(B) of title 10, United States Code, shall
17 be applied by substituting “three years” for “two years”.

18 SEC. 124. (a) Of the remaining unobligated balances,
19 as of September 30, 2022, from amounts provided under
20 the heading “Afghanistan Security Forces Fund” in title
21 IX of division C of Public Law 116–260, \$100,000,000
22 is hereby permanently rescinded, and in addition to
23 amounts otherwise provided by section 101, an amount of
24 additional new budget authority equivalent to the amount
25 rescinded pursuant to this subsection is hereby appro-

1 priated on September 30, 2022, for an additional amount
2 for fiscal year 2022, to remain available until September
3 30, 2025, for the same purposes and under the same au-
4 thorities provided under such heading in Public Law 116–
5 260, in addition to other funds as may be available for
6 such purposes.

7 (b)(1) Subject to paragraph (2), this section shall be-
8 come effective immediately upon enactment of this Act.

9 (2) If this Act is enacted after September 30,
10 2022, this section shall be applied as if it were in
11 effect on September 30, 2022.

12 SEC. 125. In addition to amounts otherwise provided
13 by section 101, for “Corps of Engineers—Civil—Con-
14 struction”, there is appropriated \$20,000,000, for an ad-
15 ditional amount for fiscal year 2023, to remain available
16 until expended, for necessary expenses related to water
17 and wastewater infrastructure under section 219 of the
18 Water Resources Development Act of 1992 (106 Stat.
19 4835): *Provided*, That such amount is designated by the
20 Congress as being for an emergency requirement pursuant
21 to section 4001(a)(1) of S. Con. Res. 14 (117th Con-
22 gress), the concurrent resolution on the budget for fiscal
23 year 2022, and section 1(e) of H. Res. 1151 (117th Con-
24 gress), as engrossed in the House of Representatives on
25 June 8, 2022.

1 SEC. 126. (a) During the period covered by this Act,
2 title I of Public Law 108–361 (the Calfed Bay-Delta Au-
3 thorization Act) (118 Stat. 1681), as amended by section
4 204 of division D of Public Law 117–103, shall be applied
5 by substituting “2023” for “2022” each place it appears.

6 (b) During the period covered by this Act, section
7 103(f)(4)(A) of title I of Public Law 108–361 (the Calfed
8 Bay-Delta Authorization Act) (118 Stat. 1696) shall be
9 applied by substituting “\$25,650,000” for
10 “\$25,000,000”.

11 SEC. 127. (a) During the period covered by this Act,
12 section 9106(g)(2) of Public Law 111–11 (Omnibus Pub-
13 lic Land Management Act of 2009) shall be applied by
14 substituting “2023” for “2022”.

15 (b) During the period covered by this Act, section
16 104(c) of the Reclamation States Emergency Drought Re-
17 lief Act of 1991 (43 U.S.C. 2214(c)) shall be applied by
18 substituting “2023” for “2022”.

19 (c) During the period covered by this Act, section 301
20 of the Reclamation States Emergency Drought Relief Act
21 of 1991 (43 U.S.C. 2241) shall be applied by substituting
22 “2023” for “2022”.

23 SEC. 128. In addition to amounts otherwise provided
24 by section 101, amounts are provided for “Department of
25 the Treasury—Alcohol and Tobacco Tax and Trade Bu-

1 reau—Salaries and Expenses” at a rate for operations of
2 \$14,929,000, for an additional amount to administer the
3 Craft Beverage Modernization Act import claims program,
4 as required by the Taxpayer Certainty and Disaster Tax
5 Relief Act of 2020, and such amounts may be apportioned
6 up to the rate for operations necessary to establish and
7 implement a new import claims program.

8 SEC. 129. Notwithstanding section 101, title II of di-
9 vision E of Public Law 117–103 shall be applied by adding
10 the following new heading and appropriation language
11 under the heading “Executive Office of the President and
12 Funds Appropriated to the President”:

13 “OFFICE OF THE NATIONAL CYBER DIRECTOR

14 “SALARIES AND EXPENSES

15 “For necessary expenses of the Office of the National
16 Cyber Director, as authorized by section 1752 of the Wil-
17 liam M. (Mac) Thornberry National Defense Authoriza-
18 tion Act for Fiscal Year 2021 (Public Law 116–283),
19 \$21,000,000, of which not to exceed \$5,000 shall be avail-
20 able for official reception and representation expenses.”.

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

1 SEC. 131. In addition to amounts otherwise provided
2 by section 101, for “The Judiciary—Courts of Appeals,
3 District Courts, and Other Judicial Services—Court Secu-
4 rity”, there is appropriated \$112,500,000, for an addi-
5 tional amount for fiscal year 2023, to remain available
6 until expended, for security improvements at United
7 States courthouses and Federal court facilities: *Provided*,
8 That not later than 90 days after the date of enactment
9 of this Act, and every 90 days thereafter until all funds
10 provided by this section have been expended, the Director
11 of the Administrative Office of the United States Courts
12 shall provide, in an appropriate format, quarterly reports
13 on the obligations and expenditures of the funds provided
14 under this section to the Committees on Appropriations
15 of the House of Representatives and the Senate: *Provided*
16 *further*, That such amount is designated by the Congress
17 as being for an emergency requirement pursuant to sec-
18 tion 4001(a)(1) of S. Con. Res. 14 (117th Congress), the
19 concurrent resolution on the budget for fiscal year 2022,
20 and section 1(e) of H. Res. 1151 (117th Congress), as
21 engrossed in the House of Representatives on June 8,
22 2022.

23 SEC. 132. Notwithstanding any other provision of
24 this Act, except section 106, the District of Columbia may
25 expend local funds made available under the heading “Dis-

1 triet of Columbia—District of Columbia Funds” for such
2 programs and activities under the District of Columbia
3 Appropriations Act, 2022 (title IV of division E of Public
4 Law 117–103) at the rate set forth in the Fiscal Year
5 2023 Local Budget Act of 2022 (D.C. Act 24–486), as
6 modified as of the date of enactment of this Act.

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

22 SEC. 134. Amounts made available by section 101 for
23 “Small Business Administration—Business Loans Pro-
24 gram Account” may be apportioned up to the rate for op-
25 erations necessary to accommodate increased demand for

1 commitments for general business loans authorized under
2 paragraphs (1) through (35) of section 7(a) of the Small
3 Business Act (15 U.S.C. 636(a)), for guarantees of trust
4 certificates authorized by section 5(g) of the Small Busi-
5 ness Act (15 U.S.C. 634(g)), for commitments to guar-
6 antee loans under section 503 of the Small Business In-
7 vestment Act of 1958 (15 U.S.C. 697), and for commit-
8 ments to guarantee loans for debentures under section
9 303(b) of the Small Business Investment Act of 1958 (15
10 U.S.C. 683(b)).

11 SEC. 135. Amounts made available by section 101 to
12 the Department of Homeland Security under the heading
13 “Federal Emergency Management Agency—Disaster Re-
14 lief Fund” may be apportioned up to the rate for oper-
15 ations necessary to carry out response and recovery activi-
16 ties under the Robert T. Stafford Disaster Relief and
17 Emergency Assistance Act (42 U.S.C. 5121 et seq.).

18 SEC. 136. Notwithstanding sections 101, 104, and
19 106, to carry out the Hermit’s Peak/Calf Canyon Fire As-
20 sistance Act, there is appropriated \$2,500,000,000, to re-
21 main available until expended, to the Department of
22 Homeland Security for “Federal Emergency Management
23 Agency—Hermit’s Peak/Calf Canyon Fire Assistance Ac-
24 count”, which shall be derived by transfer from amounts
25 made available under the heading “Federal Emergency

1 Management Agency—Disaster Relief Fund” in title VI
2 of division B of the Coronavirus Aid, Relief, and Economic
3 Security Act (Public Law 116–136), of which \$1,000,000
4 shall be transferred to “Office of the Inspector General—
5 Operations and Support” for oversight of activities au-
6 thorized by the Hermit’s Peak/Calf Canyon Fire Assist-
7 ance Act: *Provided*, That no amounts may be derived from
8 amounts made available for major disasters declared pur-
9 suant to the Robert T. Stafford Disaster Relief and Emer-
10 gency Assistance Act (42 U.S.C. 5121 et seq.): *Provided*
11 *further*, That amounts provided by this section shall be
12 subject to the same authorities and conditions as if such
13 amounts were provided by title III of the Department of
14 Homeland Security Appropriations Act, 2022 (division F
15 of Public Law 117–103): *Provided further*, That not later
16 than 90 days after the date of enactment of this Act, and
17 every 90 days thereafter until all funds provided by this
18 section have been expended, the Administrator of the Fed-
19 eral Emergency Management Agency shall provide, in an
20 appropriate format, quarterly reports to the Committees
21 on Appropriations of the Senate and the House of Rep-
22 resentatives on the obligations and expenditures of the
23 funds made available by this section: *Provided further*,
24 That amounts transferred by this section that were pre-
25 viously designated by the Congress as an emergency re-

1 quirement pursuant to the Balanced Budget and Emer-
2 gency Deficit Control Act of 1985 or a concurrent resolu-
3 tion on the budget are designated as an emergency re-
4 quirement pursuant to section 4001(a)(1) of S. Con. Res.
5 14 (117th Congress), the concurrent resolution on the
6 budget for fiscal year 2022, and section 1(e) of H. Res.
7 1151 (117th Congress), as engrossed in the House of Rep-
8 resentatives on June 8, 2022.

9 SEC. 137. Section 708(b)(13) of the Homeland Secu-
10 rity Act of 2002 (6 U.S.C. 348(b)(13)) shall be applied
11 by substituting the date specified in section 106(3) of this
12 Act for “September 30, 2022”.

13 SEC. 138. During the period covered by this Act, sec-
14 tion 822(a) of the Homeland Security Act of 2002 (6
15 U.S.C. 383(a)) shall be applied by substituting “2023”
16 for “2022”.

17 SEC. 139. (a) Sections 1309(a) and 1319 of the Na-
18 tional Flood Insurance Act of 1968 (42 U.S.C. 4016(a)
19 and 4026) shall be applied by substituting the date speci-
20 fied in section 106(3) of this Act for “September 30,
21 2022”.

22 (b)(1) Subject to paragraph (2), this section shall be-
23 come effective immediately upon enactment of this Act.

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

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

8 SEC. 141. Section 210G(i) of the Homeland Security
9 Act of 2002 (6 U.S.C. 124n(i)) shall be applied by sub-
10 stituting the date specified in section 106(3) of this Act
11 for “the date that is 4 years after the date of enactment
12 of this section”.

13 SEC. 142. Amounts made available by section 101 for
14 “Department of the Interior—National Park Service—
15 National Recreation and Preservation” for heritage part-
16 nership programs may be used to provide financial assist-
17 ance to any national heritage area, national heritage cor-
18 ridor, cultural heritage corridor, national heritage partner-
19 ship, national heritage route, national heritage canalway,
20 and battlefields national historic district established as of
21 September 1, 2022, notwithstanding any statutory sunset
22 provision terminating the Secretary’s authority to provide
23 assistance to any such area and notwithstanding any limi-
24 tation on amounts authorized to be appropriated with re-
25 spect to any such area.

1 SEC. 143. Amounts made available by section 101 to
2 the Department of the Interior under the heading “Work-
3 ing Capital Fund” may be apportioned up to the rate for
4 operations necessary to implement enterprise cybersecu-
5 rity safeguards.

6 SEC. 144. (a) In addition to amounts otherwise pro-
7 vided by section 101, amounts are provided for “Depart-
8 ment of Health and Human Services—Indian Health
9 Service—Indian Health Services” at a rate for operations
10 of \$16,721,000, for an additional amount for costs of
11 staffing and operating facilities that were opened, ren-
12 ovated, or expanded in fiscal years 2022 and 2023, and
13 such amounts may be apportioned up to the rate for oper-
14 ations necessary to staff and operate such facilities.

15 (b) In addition to amounts otherwise provided by sec-
16 tion 101, amounts are provided for “Department of
17 Health and Human Services—Indian Health Service—In-
18 dian Health Facilities” at a rate for operations of
19 \$1,201,000, for an additional amount for costs of staffing
20 and operating facilities that were opened, renovated, or ex-
21 panded in fiscal years 2022 and 2023, and such amounts
22 may be apportioned up to the rate for operations necessary
23 to staff and operate such facilities.

24 SEC. 145. In addition to amounts otherwise provided
25 by section 101, for “Department of Health and Human

1 Services—Substance Abuse and Mental Health Services
2 Administration—Mental Health”, there is appropriated
3 \$62,000,000, for an additional amount for fiscal year
4 2023, to remain available until September 30, 2023, for
5 carrying out 988 Suicide Lifeline activities and behavioral
6 health crisis services.

7 SEC. 146. In addition to amounts otherwise provided
8 by section 101, for “Department of Health and Human
9 Services—Administration for Children and Families—
10 Low Income Home Energy Assistance”, there is appro-
11 priated \$1,000,000,000, for an additional amount for fis-
12 cal year 2023, to remain available until September 30,
13 2023, for making payments under subsection (b) of sec-
14 tion 2602 of the Low-Income Home Energy Assistance
15 Act of 1981 (42 U.S.C. 8621 et seq.): *Provided*, That of
16 the funds made available by this section, \$500,000,000
17 shall be allocated as though the total appropriation for
18 such payments for fiscal year 2023 was less than
19 \$1,975,000,000: *Provided further*, That such amount is
20 designated by the Congress as being for an emergency re-
21 quirement pursuant to section 4001(a)(1) of S. Con. Res.
22 14 (117th Congress), the concurrent resolution on the
23 budget for fiscal year 2022, and section 1(e) of H. Res.
24 1151 (117th Congress), as engrossed in the House of Rep-
25 resentatives on June 8, 2022.

1 SEC. 147. In addition to amounts otherwise provided
2 by section 101, for “Department of Health and Human
3 Services—Administration for Children and Families—
4 Refugee and Entrant Assistance”, there is appropriated
5 \$1,775,000,000, for an additional amount for fiscal year
6 2023, to remain available until September 30, 2025, to
7 carry out section 462 of the Homeland Security Act of
8 2002 and section 235 of the William Wilberforce Traf-
9 ficking Victims Protection Reauthorization Act of 2008,
10 and for refugee and entrant assistance activities author-
11 ized by section 414 of the Immigration and Nationality
12 Act and section 501 of the Refugee Education Assistance
13 Act of 1980: *Provided*, That such amount is designated
14 by the Congress as being for an emergency requirement
15 pursuant to section 4001(a)(1) of S. Con. Res. 14 (117th
16 Congress), the concurrent resolution on the budget for fis-
17 cal year 2022, and section 1(e) of H. Res. 1151 (117th
18 Congress), as engrossed in the House of Representatives
19 on June 8, 2022.

20 SEC. 148. Notwithstanding section 101, the first
21 paragraph under the heading “Social Security Administra-
22 tion—Limitation on Administrative Expenses” in title IV
23 of division H of Public Law 117–103 shall be applied by
24 substituting “\$13,602,945,000” for “\$13,202,945,000”.

1 SEC. 149. (a) During the period covered by this Act,
2 subsection (a)(1)(A) of section 2502 of the Afghanistan
3 Supplemental Appropriations Act, 2022 (division C of
4 Public Law 117–43) shall be applied by substituting the
5 date specified in section 106(3) for “September 30,
6 2022”.

7 (b) The amount provided by this section is designated
8 as an emergency requirement pursuant to section
9 4001(a)(1) of S. Con. Res. 14 (117th Congress), the con-
10 current resolution on the budget for fiscal year 2022, and
11 section 1(e) of H. Res. 1151 (117th Congress), as en-
12 grossed in the House of Representatives on June 8, 2022.

13 SEC. 150. Activities authorized by part A of title IV
14 (other than under section 403(c) or 418) and section
15 1108(b) of the Social Security Act shall continue through
16 the date specified in section 106(3), in the manner author-
17 ized for fiscal year 2022, and out of any money in the
18 Treasury of the United States not otherwise appropriated,
19 there are hereby appropriated such sums as may be nec-
20 essary for such purpose.

21 SEC. 151. Notwithstanding section 101, section 126
22 of division J of Public Law 117–103 shall be applied dur-
23 ing the period covered by this Act by substituting “fiscal
24 year 2017 and fiscal year 2018” for “fiscal year 2017”.

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

3 (1) “Department of State and Related Agen-
4 cy—Department of State—Administration of For-
5 eign Affairs—Diplomatic Programs” at a rate for
6 operations of \$9,228,789,000;

7 (2) “Bilateral Economic Assistance—Funds
8 Appropriated to the President—International Dis-
9 aster Assistance” at a rate for operations of
10 \$4,555,460,000;

11 (3) “Bilateral Economic Assistance—Funds
12 Appropriated to the President—Transition Initia-
13 tives” at a rate for operations of \$100,000,000;

14 (4) “Bilateral Economic Assistance—Funds
15 Appropriated to the President—Assistance for Eu-
16 rope, Eurasia and Central Asia” at a rate for oper-
17 ations of \$850,000,000;

18 (5) “Bilateral Economic Assistance—Depart-
19 ment of State—Migration and Refugee Assistance”
20 at a rate for operations of \$3,562,188,000;

21 (6) “International Security Assistance—De-
22 partment of State—International Narcotics Control
23 and Law Enforcement” at a rate for operations of
24 \$1,421,004,000; and

1 (7) “International Security Assistance—Funds
2 Appropriated to the President—Foreign Military Fi-
3 nancing Program” at a rate for operations of
4 \$6,190,424,000.

5 SEC. 153. During the period covered by this Act, sec-
6 tion 579 of the Multifamily Assisted Housing Reform and
7 Affordability Act of 1997 (42 U.S.C. 1437f note) shall be
8 applied by substituting “2023” for “2022” each place it
9 appears.

10 SEC. 154. Amounts made available by section 101 to
11 the Department of Housing and Urban Development for
12 “Public and Indian Housing—Native Hawaiian Housing
13 Loan Guarantee Fund Program Account” may be appor-
14 tioned up to the rate for operations necessary to accommo-
15 date demand for commitments to guarantee loans as au-
16 thorized by section 184A of the Housing and Community
17 Development Act of 1992 (12 U.S.C. 1715z–13b).

18 SEC. 155. In addition to amounts otherwise provided
19 by section 101, for “Department of Housing and Urban
20 Development—Community Planning and Development—
21 Community Development Fund”, there is appropriated
22 \$2,000,000,000, for an additional amount for fiscal year
23 2023, to remain available until expended, for the same
24 purposes and under the same terms and conditions as
25 funds appropriated under such heading in title VIII of the

1 Disaster Relief Supplemental Appropriations Act, 2022
2 (division B of Public Law 117–43), except that such
3 amounts shall be for major disasters that occurred in 2021
4 or 2022 and the fourth, twentieth, and twenty-first pro-
5 visos under such heading in such Act shall not apply: *Pro-*
6 *vided*, That amounts made available under this section
7 and under such heading in such Act may be used by a
8 grantee to assist utilities as part of a disaster-related eligi-
9 ble activity under section 105(a) of the Housing and Com-
10 munity Development Act of 1974 (42 U.S.C. 5305(a)):
11 *Provided further*, That such amount is designated by the
12 Congress as being for an emergency requirement pursuant
13 to section 4001(a)(1) of S. Con. Res. 14 (117th Con-
14 gress), the concurrent resolution on the budget for fiscal
15 year 2022, and section 1(e) of H. Res. 1151 (117th Con-
16 gress), as engrossed in the House of Representatives on
17 June 8, 2022.

18 SEC. 156. Notwithstanding section 106 of this Act,
19 at any time during fiscal year 2023, the Secretary of
20 Housing and Urban Development may transfer up to
21 \$1,300,000 in unobligated balances from amounts made
22 available in prior Acts under the heading “Housing Pro-
23 grams—Project-Based Rental Assistance” to Treasury
24 Appropriation Fund Symbol 86 X 0148 for the liquidation
25 of obligations incurred in fiscal year 2018 in connection

1 with the continued provision of interest reduction pay-
2 ments authorized under section 236 of the National Hous-
3 ing Act (12 U.S.C. 1715z-1).

4 SEC. 157. (a) The remaining unobligated balances,
5 as of September 30, 2022, from amounts made available
6 for “Department of Transportation—Office of the Sec-
7 retary—National Infrastructure Investments” in title I of
8 division H of the Further Consolidated Appropriations
9 Act, 2020 (Public Law 116-94) are hereby permanently
10 rescinded, and in addition to amounts otherwise provided
11 by section 101, an amount of additional new budget au-
12 thority equivalent to the amount rescinded pursuant to
13 this subsection is hereby appropriated on September 30,
14 2022, for an additional amount for fiscal year 2022, to
15 remain available until September 30, 2023, and shall be
16 available, without additional competition, for completing
17 the funding of awards made pursuant to the fiscal year
18 2020 national infrastructure investments program, in ad-
19 dition to other funds as may be available for such pur-
20 poses.

21 (b) The remaining unobligated balances, as of Sep-
22 tember 30, 2022, from amounts made available to the De-
23 partment of Transportation in section 105 of division L
24 of the Consolidated Appropriations Act, 2021 (Public Law
25 116-260) are hereby permanently rescinded, and in addi-

1 tion to amounts otherwise provided by section 101, an
2 amount of additional new budget authority equivalent to
3 the amount rescinded pursuant to this subsection is here-
4 by appropriated on September 30, 2022, for an additional
5 amount for fiscal year 2022, to remain available until Sep-
6 tember 30, 2023, and shall be available, without additional
7 competition, for completing the funding of awards made
8 pursuant to the fiscal year 2019 national infrastructure
9 investments program, in addition to other funds as may
10 be available for such purposes.

11 (c)(1) Subject to paragraph (2), this section shall be-
12 come effective immediately upon enactment of this Act.

13 (2) If this Act is enacted after September 30,
14 2022, this section shall be applied as if it were in
15 effect on September 30, 2022.

16 This division may be cited as the “Continuing Appro-
17 priations Act, 2023”.

1 **DIVISION B—UKRAINE SUPPLEMENTAL**
2 **APPROPRIATIONS ACT, 2023**

3 The following sums are appropriated, out of any
4 money in the Treasury not otherwise appropriated, for the
5 fiscal year ending September 30, 2023, and for other pur-
6 poses, namely:

7 **TITLE I**

8 **DEPARTMENT OF DEFENSE**

9 **MILITARY PERSONNEL**

10 **MILITARY PERSONNEL, ARMY**

11 For an additional amount for “Military Personnel,
12 Army”, \$110,107,000, to remain available until Sep-
13 tember 30, 2023, to respond to the situation in Ukraine
14 and for related expenses.

15 **MILITARY PERSONNEL, NAVY**

16 For an additional amount for “Military Personnel,
17 Navy”, \$462,000, to remain available until September 30,
18 2023, to respond to the situation in Ukraine and for re-
19 lated expenses.

20 **MILITARY PERSONNEL, MARINE CORPS**

21 For an additional amount for “Military Personnel,
22 Marine Corps”, \$600,000, to remain available until Sep-
23 tember 30, 2023, to respond to the situation in Ukraine
24 and for related expenses.

1 MILITARY PERSONNEL, AIR FORCE

2 For an additional amount for “Military Personnel,
3 Air Force”, \$11,582,000, to remain available until Sep-
4 tember 30, 2023, to respond to the situation in Ukraine
5 and for related expenses.

6 OPERATION AND MAINTENANCE

7 OPERATION AND MAINTENANCE, ARMY

8 For an additional amount for “Operation and Main-
9 tenance, Army”, \$654,696,000, to remain available until
10 September 30, 2023, to respond to the situation in
11 Ukraine and for related expenses.

12 OPERATION AND MAINTENANCE, NAVY

13 For an additional amount for “Operation and Main-
14 tenance, Navy”, \$433,035,000, to remain available until
15 September 30, 2023, to respond to the situation in
16 Ukraine and for related expenses.

17 OPERATION AND MAINTENANCE, MARINE CORPS

18 For an additional amount for “Operation and Main-
19 tenance, Marine Corps”, \$34,984,000, to remain available
20 until September 30, 2023, to respond to the situation in
21 Ukraine and for related expenses.

22 OPERATION AND MAINTENANCE, AIR FORCE

23 For an additional amount for “Operation and Main-
24 tenance, Air Force”, \$267,084,000, to remain available

1 until September 30, 2023, to respond to the situation in
2 Ukraine and for related expenses.

3 OPERATION AND MAINTENANCE, SPACE FORCE

4 For an additional amount for “Operation and Main-
5 tenance, Space Force”, \$1,771,000, to remain available
6 until September 30, 2023, to respond to the situation in
7 Ukraine and for related expenses.

8 OPERATION AND MAINTENANCE, DEFENSE-WIDE

9 (INCLUDING TRANSFER OF FUNDS)

10 For an additional amount for “Operation and Main-
11 tenance, Defense-Wide”, \$4,713,544,000, to remain avail-
12 able until September 30, 2023, to respond to the situation
13 in Ukraine and for related expenses: *Provided*, That of the
14 total amount provided under this heading in this Act,
15 \$3,000,000,000, to remain available until September 30,
16 2024, shall be for the Ukraine Security Assistance Initia-
17 tive: *Provided further*, That such funds for the Ukraine
18 Security Assistance Initiative shall be available to the Sec-
19 retary of Defense under the same terms and conditions
20 as are provided for in section 8139 of the Department of
21 Defense Appropriations Act, 2022 (division C of Public
22 Law 117–103): *Provided further*, That of the total amount
23 provided under this heading in this Act, up to
24 \$1,500,000,000, to remain available until September 30,
25 2024, may be transferred to accounts under the headings

1 “Operation and Maintenance” and “Procurement” for re-
2 placement of defense articles from the stocks of the De-
3 partment of Defense, and for reimbursement for defense
4 services of the Department of Defense and military edu-
5 cation and training, provided to the government of
6 Ukraine or to foreign countries that have provided support
7 to Ukraine at the request of the United States: *Provided*
8 *further*, That funds transferred pursuant to a transfer au-
9 thority provided under this heading in this Act shall be
10 merged with and available for the same purposes and for
11 the same time period as the appropriations to which the
12 funds are transferred: *Provided further*, That the Sec-
13 retary of Defense shall notify the congressional defense
14 committees of the details of such transfers not less than
15 15 days before any such transfer: *Provided further*, That
16 upon a determination that all or part of the funds trans-
17 ferred from this appropriation are not necessary for the
18 purposes provided herein, such amounts may be trans-
19 ferred back and merged with this appropriation: *Provided*
20 *further*, That the transfer authority provided under this
21 heading in this Act is in addition to any other transfer
22 authority provided by law.

1 30, 2025, to respond to the situation in Ukraine and for
2 related expenses.

3 OTHER PROCUREMENT, AIR FORCE

4 For an additional amount for “Other Procurement,
5 Air Force”, \$437,991,000, to remain available until Sep-
6 tember 30, 2025, to respond to the situation in Ukraine
7 and for other expenses.

8 PROCUREMENT, DEFENSE-WIDE

9 For an additional amount for “Procurement, De-
10 fense-Wide”, \$9,770,000, to remain available until Sep-
11 tember 30, 2025, to respond to the situation in Ukraine
12 and for related expenses.

13 RESEARCH, DEVELOPMENT, TEST AND
14 EVALUATION

15 RESEARCH, DEVELOPMENT, TEST AND EVALUATION,
16 ARMY

17 For an additional amount for “Research, Develop-
18 ment, Test and Evaluation, Army”, \$3,300,000, to remain
19 available until September 30, 2024, to respond to the situ-
20 ation in Ukraine and for related expenses.

21 RESEARCH, DEVELOPMENT, TEST AND EVALUATION,
22 NAVY

23 For an additional amount for “Research, Develop-
24 ment, Test and Evaluation, Navy”, \$2,077,000, to remain

1 available until September 30, 2024, to respond to the situ-
2 ation in Ukraine and for related expenses.

3 RESEARCH, DEVELOPMENT, TEST AND EVALUATION,
4 AIR FORCE

5 For an additional amount for “Research, Develop-
6 ment, Test and Evaluation, Air Force”, \$99,704,000, to
7 remain available until September 30, 2024, to respond to
8 the situation in Ukraine and for related expenses.

9 RESEARCH, DEVELOPMENT, TEST AND EVALUATION,
10 DEFENSE-WIDE

11 For an additional amount for “Research, Develop-
12 ment, Test and Evaluation, Defense-Wide”, \$31,230,000,
13 to remain available until September 30, 2024, to respond
14 to the situation in Ukraine and for related expenses.

15 OTHER DEPARTMENT OF DEFENSE PROGRAMS
16 OFFICE OF THE INSPECTOR GENERAL

17 For an additional amount for “Office of the Inspector
18 General”, \$2,000,000, to remain available until September
19 30, 2023, to carry out reviews of the activities of the De-
20 partment of Defense to execute funds appropriated in this
21 title, including assistance provided to Ukraine: *Provided,*
22 That the Inspector General of the Department of Defense
23 shall provide to the congressional defense committees a
24 briefing not later than 90 days after the date of enactment
25 of this Act.

1 RELATED AGENCIES

2 INTELLIGENCE COMMUNITY MANAGEMENT ACCOUNT

3 For an additional amount for “Intelligence Commu-
4 nity Management Account”, \$500,000, to remain available
5 until September 30, 2023, to respond to the situation in
6 Ukraine and for related expenses.

7 GENERAL PROVISIONS—THIS TITLE

8 SEC. 1101. Not later than 60 days after the date of
9 enactment of this Act, the Secretary of Defense, in coordi-
10 nation with the Secretary of State, shall submit a report
11 to the Committees on Appropriations, Armed Services,
12 and Foreign Affairs of the House of Representatives and
13 the Committees on Appropriations, Armed Services, and
14 Foreign Relations of the Senate on measures being taken
15 to account for United States defense articles designated
16 for Ukraine since the February 24, 2022, Russian inva-
17 sion of Ukraine, particularly measures with regard to such
18 articles that require enhanced end-use monitoring; meas-
19 ures to ensure that such articles reach their intended re-
20 cipients and are used for their intended purposes; and any
21 other measures to promote accountability for the use of
22 such articles: *Provided*, That such report shall include a
23 description of any occurrences of articles not reaching
24 their intended recipients or used for their intended pur-
25 poses and a description of any remedies taken: *Provided*

1 *further*, That such report shall be submitted in unclassified
2 form, but may be accompanied by a classified annex.

3 SEC. 1102. Not later than 30 days after the date of
4 enactment of this Act, and every 30 days thereafter
5 through fiscal year 2023, the Secretary of Defense, in co-
6 ordination with the Secretary of State, shall provide a
7 written report to the Committees on Appropriations,
8 Armed Services, and Foreign Affairs of the House of Rep-
9 resentatives and the Committees on Appropriations,
10 Armed Services, and Foreign Relations of the Senate de-
11 scribing United States security assistance provided to
12 Ukraine since the February 24, 2022, Russian invasion
13 of Ukraine, including a comprehensive list of the defense
14 articles and services provided to Ukraine and the associ-
15 ated authority and funding used to provide such articles
16 and services: *Provided*, That such report shall be sub-
17 mitted in unclassified form, but may be accompanied by
18 a classified annex.

1 TITLE II
2 DEPARTMENT OF ENERGY
3 ATOMIC ENERGY DEFENSE ACTIVITIES
4 NATIONAL NUCLEAR SECURITY
5 ADMINISTRATION
6 DEFENSE NUCLEAR NONPROLIFERATION

7 For an additional amount for “Defense Nuclear Non-
8 proliferation”, \$35,000,000, to remain available until ex-
9 pended, to respond to the situation in Ukraine and for
10 related expenses.

11 TITLE III
12 BILATERAL ECONOMIC ASSISTANCE
13 FUNDS APPROPRIATED TO THE PRESIDENT
14 ECONOMIC SUPPORT FUND

15 For an additional amount for “Economic Support
16 Fund”, \$4,500,000,000, to remain available until Sep-
17 tember 30, 2024, for assistance for Ukraine: *Provided*,
18 That funds appropriated under this heading in this Act
19 may be made available notwithstanding any other provi-
20 sion of law that restricts assistance to foreign countries
21 and may be made available as contributions.

22 GENERAL PROVISIONS—THIS TITLE

23 SEC. 1301. During fiscal year 2023, section
24 506(a)(1) of the Foreign Assistance Act of 1961 (22

1 U.S.C. 2318(a)(1)) shall be applied by substituting
2 “\$3,700,000,000” for “\$100,000,000”.

3 SEC. 1302. (a) Funds appropriated by this title shall
4 be made available for direct financial support for the Gov-
5 ernment of Ukraine, including for Ukrainian first re-
6 sponders, and may be made available as a cash transfer
7 subject to the requirements of subsection (b): *Provided*,
8 That such funds shall be provided on a reimbursable basis
9 and matched by sources other than the United States Gov-
10 ernment, to the maximum extent practicable: *Provided fur-*
11 *ther*, That the Secretary of State or the Administrator of
12 the United States Agency for International Development,
13 as appropriate, shall ensure third-party monitoring of such
14 funds: *Provided further*, That at least 15 days prior to the
15 initial obligation of such funds, the Secretary of State, fol-
16 lowing consultation with the Administrator of the United
17 States Agency for International Development, shall certify
18 and report to the appropriate congressional committees
19 that mechanisms for monitoring and oversight of such
20 funds are in place and functioning and that the Govern-
21 ment of Ukraine has in place substantial safeguards to
22 prevent corruption and ensure accountability of such
23 funds: *Provided further*, That not less than 45 days after
24 the initial obligation of such funds, the Inspectors General
25 of the Department of State and the United States Agency

1 for International Development shall submit a report to the
2 appropriate congressional committees detailing and as-
3 sessing the mechanisms for monitoring and safeguards de-
4 scribed in the previous proviso.

5 (b) Funds made available to the Government of
6 Ukraine as a cash transfer under subsection (a) shall be
7 subject to a memorandum of understanding between the
8 Governments of the United States and Ukraine that de-
9 scribes how the funds proposed to be made available will
10 be used and the appropriate safeguards to ensure trans-
11 parency and accountability: *Provided*, That such assist-
12 ance shall be maintained in a separate, auditable account
13 and may not be comingled with any other funds.

14 (c) The Secretary of State or the Administrator of
15 the United States Agency for International Development,
16 as appropriate, shall report to the appropriate congres-
17 sional committees on the uses of funds provided for direct
18 financial support to the Government of Ukraine pursuant
19 to subsection (a) not later than 45 days after the date
20 of enactment of this Act and every 45 days thereafter until
21 all such funds have been expended: *Provided*, That such
22 report shall include a detailed description of the use of
23 such funds, including categories and amounts, the in-
24 tended results and the results achieved, a summary of
25 other donor contributions, and a description of the efforts

1 undertaken by the Secretary and Administrator to in-
2 crease other donor contributions for direct financial sup-
3 port: *Provided further*, That such report shall also include
4 the metrics established to measure such results.

5 (d) Funds made available for the purposes of sub-
6 section (a) shall be subject to the regular notification pro-
7 cedures of the Committees on Appropriations of the House
8 of Representatives and the Senate.

9 TITLE IV

10 GENERAL PROVISIONS—THIS ACT

11 SEC. 1401. Each amount appropriated or made avail-
12 able by this Act is in addition to amounts otherwise appro-
13 priated for the fiscal year involved.

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

17 SEC. 1403. Unless otherwise provided for by this Act,
18 the additional amounts appropriated by this Act to appro-
19 priations accounts shall be available under the authorities
20 and conditions applicable to such appropriations accounts
21 for fiscal year 2023.

22 SEC. 1404. Each amount provided by this division is
23 designated by the Congress as being for an emergency re-
24 quirement pursuant to section 4001(a)(1) of S. Con. Res.
25 14 (117th Congress), the concurrent resolution on the

1 budget for fiscal year 2022, and section 1(e) of H. Res.
2 1151 (117th Congress), as engrossed in the House of Rep-
3 resentatives on June 8, 2022.

4 This division may be cited as the “Ukraine Supple-
5 mental Appropriations Act, 2023”.

1 **DIVISION C—OTHER MATTERS**
2 **TITLE I—EXTENSIONS, TECH-**
3 **NICAL CORRECTIONS, AND**
4 **OTHER MATTERS**

5 **SEC. 101. EXTENSION OF FCC AUCTION AUTHORITY.**

6 Section 309(j)(11) of the Communications Act of
7 1934 (47 U.S.C. 309(j)(11)) is amended by striking “Sep-
8 tember 30, 2022” and inserting “December 16, 2022”.

9 **SEC. 102. EXTENSION OF AUTHORIZATION FOR SPECIAL AS-**
10 **SESSMENT FOR DOMESTIC TRAFFICKING VIC-**
11 **TIMS’ FUND.**

12 Section 3014(a) of title 18, United States Code, is
13 amended, in the matter preceding paragraph (1), by strik-
14 ing “September 30, 2022” and inserting “December 16,
15 2022”.

16 **SEC. 103. UNITED STATES PAROLE COMMISSION EXTEN-**
17 **SION.**

18 (a) **SHORT TITLE.**—This section may be cited as the
19 “United States Parole Commission Extension Act of
20 2022”.

21 (b) **AMENDMENT OF SENTENCING REFORM ACT OF**
22 1984.—For purposes of section 235(b) of the Sentencing
23 Reform Act of 1984 (18 U.S.C. 3551 note; Public Law
24 98–473; 98 Stat. 2032), as such section relates to chapter
25 311 of title 18, United States Code, and the United States

1 Parole Commission, each reference in such section to “35
2 years” or “35-year period” shall be deemed a reference
3 to “35 years and 46 days” or “35-year and 46-day pe-
4 riod”, respectively.

5 **SEC. 104. EXTENSION OF COMMODITY FUTURES TRADING**
6 **COMMISSION CUSTOMER PROTECTION FUND**
7 **EXPENSES ACCOUNT.**

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

11 **TITLE II—BUDGETARY EFFECTS**

12 **SEC. 201. BUDGETARY EFFECTS.**

13 (a) **STATUTORY PAYGO SCORECARDS.**—The budg-
14 etary effects of this division and each succeeding division
15 shall not be entered on either PAYGO scorecard main-
16 tained pursuant to section 4(d) of the Statutory Pay-As-
17 You-Go Act of 2010.

18 (b) **SENATE PAYGO SCORECARDS.**—The budgetary
19 effects of this division and each succeeding division shall
20 not be entered on any PAYGO scorecard maintained for
21 purposes of section 4106 of H. Con. Res. 71 (115th Con-
22 gress).

23 (c) **CLASSIFICATION OF BUDGETARY EFFECTS.**—
24 Notwithstanding Rule 3 of the Budget Scorekeeping
25 Guidelines set forth in the joint explanatory statement of

1 the committee of conference accompanying Conference Re-
2 port 105–217 and section 250(c)(8) of the Balanced
3 Budget and Emergency Deficit Control Act of 1985, the
4 budgetary effects of this division and each succeeding divi-
5 sion shall not be estimated—

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

7 (2) for purposes of an allocation to the Com-
8 mittee on Appropriations pursuant to section 302(a)
9 of the Congressional Budget Act of 1974; and

10 (3) for purposes of paragraph (4)(C) of section
11 3 of the Statutory Pay-As-You-Go Act of 2010 as
12 being included in an appropriation Act.

1 **DIVISION D—HEALTH AND**
2 **HUMAN SERVICES EXTENSIONS**
3 **TITLE I—MEDICARE AND**
4 **MEDICAID**

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

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

10 (1) in subparagraph (B), in the matter pre-
11 ceding clause (i), by striking “in fiscal year 2023
12 and subsequent fiscal years” and inserting “during
13 the portion of fiscal year 2023 beginning on Decem-
14 ber 17, 2022, and ending on September 30, 2023,
15 and in fiscal year 2024 and subsequent fiscal years”;

16 (2) in subparagraph (C)(i)—

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

19 (i) by inserting “or portion of a fiscal
20 year” after “for a fiscal year”; and

21 (ii) by inserting “and the portion of
22 fiscal year 2023 beginning on October 1,
23 2022, and ending on December 16, 2022”
24 after “through 2022”;

1 (B) in subclause (III), by inserting “and
2 the portion of fiscal year 2023 beginning on Oc-
3 tober 1, 2022, and ending on December 16,
4 2022” after “through 2022”; and

5 (C) in subclause (IV), by striking “fiscal
6 year 2023” and inserting “the portion of fiscal
7 year 2023 beginning on December 17, 2022,
8 and ending on September 30, 2023, and fiscal
9 year 2024”; and

10 (3) in subparagraph (D)—

11 (A) in the matter preceding clause (i), by
12 inserting “or during the portion of fiscal year
13 2023 beginning on October 1, 2022, and ending
14 on December 16, 2022” after “through 2022”;
15 and

16 (B) in clause (ii), by inserting “and the
17 portion of fiscal year 2023 beginning on Octo-
18 ber 1, 2022, and ending on December 16,
19 2022” after “through 2022”.

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

1 **SEC. 102. EXTENSION OF THE MEDICARE-DEPENDENT HOS-**
2 **PITAL (MDH) PROGRAM.**

3 (a) IN GENERAL.—Section 1886(d)(5)(G) of the So-
4 cial Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amend-
5 ed—

6 (1) in clause (i), by striking “October 1, 2022”
7 and inserting “December 17, 2022”; and

8 (2) in clause (ii)(II), by striking “October 1,
9 2022” and inserting “December 17, 2022”.

10 (b) CONFORMING AMENDMENTS.—

11 (1) EXTENSION OF TARGET AMOUNT.—Section
12 1886(b)(3)(D) of the Social Security Act (42 U.S.C.
13 1395ww(b)(3)(D)) is amended—

14 (A) in the matter preceding clause (i), by
15 striking “October 1, 2022” and inserting “De-
16 cember 17, 2022”; and

17 (B) in clause (iv), by inserting “and the
18 portion of fiscal year 2023 beginning on Octo-
19 ber 1, 2022, and ending on December 16,
20 2022,” after “through fiscal year 2022”.

21 (2) PERMITTING HOSPITALS TO DECLINE RE-
22 CLASSIFICATION.—Section 13501(e)(2) of the Omni-
23 bus Budget Reconciliation Act of 1993 (42 U.S.C.
24 1395ww note) is amended by striking “or fiscal year
25 2000 through fiscal year 2022,” and inserting “fis-
26 cal year 2000 through fiscal year 2022, or the por-

1 tion of fiscal year 2023 beginning on October 1,
2 2022, and ending on December 16, 2022”.

3 **SEC. 103. EXTENSION OF INCREASED FMAPS FOR THE TER-**
4 **RITORIES.**

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

9 **SEC. 104. REDUCTION OF MEDICARE IMPROVEMENT FUND.**

10 Section 1898(b)(1) of the Social Security Act (42
11 U.S.C. 1395iii(b)(1)) is amended by striking
12 “\$7,500,000,000” and inserting “\$7,308,000,000”.

13 **TITLE II—HUMAN SERVICES**

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

16 Activities authorized by section 511 of the Social Se-
17 curity Act shall continue through December 16, 2022, in
18 the manner authorized for fiscal year 2022, and out of
19 any money in the Treasury of the United States not other-
20 wise appropriated, there is hereby appropriated for such
21 purpose an amount equal to the pro rata portion of the
22 amount appropriated for such activities for fiscal year
23 2022.

1 **SEC. 202. EXTENSION OF CHILD AND FAMILY SERVICES**
2 **PROGRAMS.**

3 Activities authorized by part B of title IV of the So-
4 cial Security Act shall continue through December 16,
5 2022, in the manner authorized for fiscal year 2022, and
6 out of any money in the Treasury of the United States
7 not otherwise appropriated, there are hereby appropriated
8 such sums as may be necessary for such purpose.

9 **TITLE III—PUBLIC HEALTH**

10 **SEC. 301. EXTENSION OF THE PROGRAM TO DEEM CERTAIN**
11 **HEALTH PROFESSIONAL VOLUNTEERS EM-**
12 **PLOYEES OF THE PUBLIC HEALTH SERVICE**
13 **UNDER CERTAIN CIRCUMSTANCES.**

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

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

19 (1) in subsection (g)(1)(H)(iv), by striking
20 “this section.” and inserting “this section.”;

21 (2) in subsection (k)(3), by inserting “gov-
22 erning board members,” after “officers,”;

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

25 (4) in subsection (q)(5)(A), by striking “and
26 paragraph (6)”.

1 **SEC. 302. EXTENSION OF AUTHORIZATION FOR A COMMIS-**
2 **SIONED OFFICER OF THE PUBLIC HEALTH**
3 **SERVICE TO ACCUMULATE EXCESS ANNUAL**
4 **LEAVE.**

5 For purposes of annual leave accumulated in fiscal
6 year 2022, the authority provided in section 2106 of divi-
7 sion C of Public Law 116–159 (42 U.S.C. 210–1 note)
8 shall apply to such leave by substituting “2022” for
9 “2020” in subsections (a) and (d)(2).

10 **TITLE IV—INDIAN HEALTH**

11 **SEC. 401. EXTENSION OF MORATORIUM.**

12 Section 424(a) of title IV of division G of Public Law
13 113–76 is amended by striking “October 1, 2019” and
14 inserting “December 16, 2022”.

1 **DIVISION E—VETERANS AFFAIRS**
2 **EXTENSIONS**
3 **TITLE I—EXTENSIONS OF AU-**
4 **THORITIES RELATING TO**
5 **HEALTH CARE**

6 **SEC. 101. EXTENSION OF AUTHORITY FOR COLLECTION OF**
7 **COPAYMENTS FOR HOSPITAL CARE AND**
8 **NURSING HOME CARE.**

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

12 **SEC. 102. EXTENSION OF REQUIREMENT TO PROVIDE**
13 **NURSING HOME CARE TO CERTAIN VET-**
14 **ERANS WITH SERVICE-CONNECTED DISABIL-**
15 **ITIES.**

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

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

21 Section 8111(d)(3) of title 38, United States Code,
22 is amended by striking “September 30, 2023” and insert-
23 ing “September 30, 2026”.

1 **SEC. 104. EXTENSION OF AUTHORITY FOR JOINT DEPART-**
2 **MENT OF DEFENSE-DEPARTMENT OF VET-**
3 **ERANS AFFAIRS MEDICAL FACILITY DEM-**
4 **ONSTRATION FUND.**

5 Section 1704(e) of the National Defense Authoriza-
6 tion Act for Fiscal Year 2010 (Public Law 111–84; 123
7 Stat. 2573), as most recently amended by section 715 of
8 the National Defense Authorization Act for Fiscal Year
9 2022 (Public Law 117–81; 135 Stat. 1787), is amended
10 by striking “September 30, 2023” and inserting “Sep-
11 tember 30, 2024”.

12 **SEC. 105. EXTENSION OF TEMPORARY EXPANSION OF PAY-**
13 **MENTS AND ALLOWANCES FOR BENEFICIARY**
14 **TRAVEL IN CONNECTION WITH VETERANS**
15 **RECEIVING CARE FROM VET CENTERS.**

16 Section 104(a) of the Honoring America’s Veterans
17 and Caring for Camp Lejeune Families Act of 2012 (Pub-
18 lic Law 112–154; 126 Stat. 1169), as most recently
19 amended by section 3 of the Department of Veterans Af-
20 fairs Expiring Authorities Act of 2021 (Public Law 117–
21 42; 135 Stat. 342), is amended by striking “September
22 30, 2022” and inserting “September 30, 2023”.

1 **TITLE II—EXTENSIONS OF AU-**
2 **THORITIES RELATING TO**
3 **BENEFITS**

4 **SEC. 201. EXTENSION OF AUTHORITY TO TRANSPORT INDI-**
5 **VIDUALS TO AND FROM DEPARTMENT OF**
6 **VETERANS AFFAIRS FACILITIES.**

7 Section 111A(a)(2) of title 38, United States Code,
8 is amended by striking “September 30, 2022” and insert-
9 ing “September 30, 2024”.

10 **SEC. 202. EXTENSION OF AUTHORITY TO MAINTAIN RE-**
11 **GIONAL OFFICE IN THE REPUBLIC OF THE**
12 **PHILIPPINES.**

13 Section 315(b) of title 38, United States Code, is
14 amended by striking “September 30, 2022” and inserting
15 “September 30, 2024”.

16 **SEC. 203. EXTENSION OF AUTHORITY FOR REPORT ON EQ-**
17 **UITABLE RELIEF PROVIDED DUE TO ADMIN-**
18 **ISTRATIVE ERROR.**

19 Section 503(c) of title 38, United States Code, is
20 amended by striking “December 31, 2022” and inserting
21 “December 31, 2024”.

1 **SEC. 204. EXTENSION OF AUTHORITY TO PROVIDE ASSIST-**
2 **ANCE FOR SPECIALLY ADAPTED HOUSING**
3 **FOR DISABLED VETERANS RESIDING TEMPO-**
4 **RARILY IN HOUSING OWNED BY A FAMILY**
5 **MEMBER.**

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

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

11 Section 2108(g) of title 38, United States Code, is
12 amended by striking “September 30, 2022” and inserting
13 “September 30, 2024”.

14 **TITLE III—EXTENSIONS OF AU-**
15 **THORITIES RELATING TO**
16 **HOMELESS VETERANS**

17 **SEC. 301. EXTENSION OF AUTHORIZATION OF APPROPRIA-**
18 **TIONS FOR HOMELESS VETERANS RE-**
19 **INTEGRATION PROGRAMS.**

20 Section 2021(e)(1)(F) of title 38, United States
21 Code, is amended by striking “2022” and inserting
22 “2024”.

1 **SEC. 302. EXTENSION OF AUTHORIZATION OF APPROPRIA-**
2 **TIONS FOR HOMELESS WOMEN VETERANS**
3 **AND HOMELESS VETERANS WITH CHILDREN**
4 **REINTEGRATION GRANT PROGRAM.**

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

7 **SEC. 303. EXTENSION OF AUTHORITY FOR TREATMENT AND**
8 **REHABILITATION FOR SERIOUSLY MENTALLY**
9 **ILL AND HOMELESS VETERANS.**

10 (a) GENERAL TREATMENT.—Section 2031(b) of title
11 38, United States Code, is amended by striking “Sep-
12 tember 30, 2022” and inserting “September 30, 2024”.

13 (b) ADDITIONAL SERVICES AT CERTAIN LOCA-
14 TIONS.—Section 2033(d) of such title is amended by strik-
15 ing “September 30, 2022” and inserting “September 30,
16 2024”.

17 **SEC. 304. EXTENSION OF FUNDING FOR FINANCIAL ASSIST-**
18 **ANCE FOR SUPPORTIVE SERVICES FOR VERY**
19 **LOW-INCOME VETERAN FAMILIES IN PERMA-**
20 **NENT HOUSING.**

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

1 **SEC. 305. EXTENSION OF FUNDING FOR GRANT PROGRAM**
2 **FOR HOMELESS VETERANS WITH SPECIAL**
3 **NEEDS.**

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

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

8 Section 2066(d) of title 38, United States Code, is
9 amended by striking “September 30, 2022” and inserting
10 “September 30, 2026”.

11 **TITLE IV—EXTENSIONS OF**
12 **OTHER AUTHORITIES**

13 **SEC. 401. EXTENSION OF AUTHORIZATION OF APPROPRIA-**
14 **TIONS FOR MONTHLY ASSISTANCE ALLOW-**
15 **ANCE UNDER THE OFFICE OF NATIONAL VET-**
16 **ERANS SPORTS PROGRAMS AND SPECIAL**
17 **EVENTS.**

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

20 **SEC. 402. EXTENSION AND AUTHORIZATION OF APPROPRIA-**
21 **TIONS FOR ADAPTIVE SPORTS PROGRAMS**
22 **FOR DISABLED VETERANS AND MEMBERS OF**
23 **THE ARMED FORCES.**

24 (a) AUTHORIZATION OF APPROPRIATIONS.—Sub-
25 section (g)(1)(B) of section 521A of title 38, United

1 States Code, is amended by striking “and 2022” and in-
2 serting “through 2026”.

3 (b) **EXTENSION.**—Subsection (l) of such section is
4 amended by striking “2022” and inserting “2026”.

5 (c) **TECHNICAL CORRECTION.**—Subsection (g)(1)(A)
6 of such section is amended by striking “. for each of fiscal
7 years 2010 through 2020”.

8 **SEC. 403. EXTENSION OF ADVISORY COMMITTEE ON MI-**
9 **NORITY VETERANS.**

10 Section 544(e) of title 38, United States Code, is
11 amended by striking “September 30, 2022” and inserting
12 “September 30, 2026”.

13 **SEC. 404. EXTENSION OF VETERANS’ ADVISORY COM-**
14 **MITTEE ON EDUCATION.**

15 Section 3692(e) of title 38, United States Code, is
16 amended by striking “December 31, 2022” and inserting
17 “December 31, 2026”.

18 **SEC. 405. EXTENSION OF AUTHORITY FOR TRANSFER OF**
19 **REAL PROPERTY.**

20 Section 8118(a)(5) of title 38, United States Code,
21 is amended by striking “September 30, 2022” and insert-
22 ing “September 30, 2024”.

1 **DIVISION F—FDA USER FEE**
 2 **REAUTHORIZATION ACT OF 2022**

3 **SECTION 1. SHORT TITLE.**

4 This division may be cited as the “FDA User Fee
 5 Reauthorization Act of 2022”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 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.

1 on Energy and Commerce of the House of Representa-
2 tives, as set forth in the Congressional Record.

3 **SEC. 1002. DEFINITIONS.**

4 (a) HUMAN DRUG APPLICATION.—Section 735(1) of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 379g(1)) is amended, in the matter following subpara-
7 graph (B), by striking “an allergenic extract product, or”
8 and inserting “does not include an application with respect
9 to an allergenic extract product licensed before October
10 1, 2022, does not include an application with respect to
11 a standardized allergenic extract product submitted pursu-
12 ant to a notification to the applicant from the Secretary
13 regarding the existence of a potency test that measures
14 the allergenic activity of an allergenic extract product li-
15 censed by the applicant before October 1, 2022, does not
16 include an application with respect to”.

17 (b) PRESCRIPTION DRUG PRODUCT.—Section 735(3)
18 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 379g(3)) is amended—

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

22 (2) by striking “(3) The term” and inserting
23 “(3)(A) The term”;

24 (3) by striking “Such term does not include
25 whole blood” and inserting the following:

1 “(B) Such term does not include whole blood”;

2 (4) by striking “an allergenic extract product,”

3 and inserting “an allergenic extract product licensed

4 before October 1, 2022, a standardized allergenic ex-

5 tract product submitted pursuant to a notification to

6 the applicant from the Secretary regarding the exist-

7 ence of a potency test that measures the allergenic

8 activity of an allergenic extract product licensed by

9 the applicant before October 1, 2022,” ; and

10 (5) by adding at the end the following:

11 “(C)(i) If a written request to place a

12 product in the discontinued section of either of

13 the lists referenced in subparagraph (A)(iii) is

14 submitted to the Secretary on behalf of an ap-

15 plicant, and the request identifies the date the

16 product is, or will be, withdrawn from sale, then

17 for purposes of assessing the prescription drug

18 program fee under section 736(a)(2), the Sec-

19 retary shall consider such product to have been

20 included in the discontinued section on the later

21 of—

22 “(I) the date such request was re-

23 ceived; or

24 “(II) if the product will be withdrawn

25 from sale on a future date, such future

1 date when the product is withdrawn from
2 sale.

3 “(ii) For purposes of this subparagraph, a
4 product shall be considered withdrawn from
5 sale once the applicant has ceased its own dis-
6 tribution of the product, whether or not the ap-
7 plicant has ordered recall of all previously dis-
8 tributed lots of the product, except that a rou-
9 tine, temporary interruption in supply shall not
10 render a product withdrawn from sale.”.

11 (c) SKIN-TEST DIAGNOSTIC PRODUCT.—Section 735
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 379g) is amended by adding at the end the following:

14 “(12) The term ‘skin-test diagnostic product’—

15 “(A) means a product—

16 “(i) for prick, scratch, intradermal, or
17 subcutaneous administration;

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

21 “(iii) not intended to be a preventive
22 or therapeutic intervention; and

23 “(iv) intended to detect an immediate-
24 or delayed-type skin hypersensitivity reac-
25 tion to aid in the diagnosis of—

1 “(I) an allergy to an anti-
2 microbial agent;

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

7 “(III) infection with fungal or
8 mycobacterial pathogens; and

9 “(B) includes positive and negative con-
10 trols required to interpret the results of a prod-
11 uct described in subparagraph (A).”.

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

13 (a) TYPES OF FEES.—

14 (1) HUMAN DRUG APPLICATION FEE.—Section
15 736(a) of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 379h(a)) is amended—

17 (A) in the matter preceding paragraph (1),
18 by striking “fiscal year 2018” and inserting
19 “fiscal year 2023”;

20 (B) in paragraph (1)(A), by striking
21 “(e)(5)” each place it appears and inserting
22 “(e)(6)”;

23 (C) in paragraph (1)(C), by inserting
24 “prior to approval” after “or was withdrawn”;
25 and

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

3 “(H) EXCEPTION FOR SKIN-TEST DIAG-
4 NOSTIC PRODUCTS.—A human drug application
5 for a skin-test diagnostic product shall not be
6 subject to a fee under subparagraph (A).”.

7 (2) PRESCRIPTION DRUG PROGRAM FEE.—Sec-
8 tion 736(a)(2) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 379h(a)(2)) is amended—

10 (A) in subparagraph (A)—

11 (i) by striking “Except as provided in
12 subparagraphs (B) and (C)” and inserting
13 the following:

14 “(i) PAYMENT OF FEES.—Except as
15 provided in subparagraphs (B) and (C)”;

16 (ii) by striking “subsection (c)(5)”
17 and inserting “subsection (c)(6)”; and

18 (iii) by adding at the end the fol-
19 lowing:

20 “(ii) SPECIAL RULE FOR PREVIOUSLY
21 DISCONTINUED DRUG PRODUCTS.—If a
22 drug product that is identified in a human
23 drug application approved as of October 1
24 of a fiscal year is not a prescription drug
25 product as of that date because the drug

1 product is in the discontinued section of a
2 list referenced in section 735(3)(A)(iii),
3 and on any subsequent day during such
4 fiscal year the drug product is a prescrip-
5 tion drug product, then except as provided
6 in subparagraphs (B) and (C), each person
7 who is named as the applicant in a human
8 drug application with respect to such prod-
9 uct, and who, after September 1, 1992,
10 had pending before the Secretary a human
11 drug application or supplement, shall pay
12 the annual prescription drug program fee
13 established for a fiscal year under sub-
14 section (c)(6) for such prescription drug
15 product. Such fee shall be due on the last
16 business day of such fiscal year and shall
17 be paid only once for each such product for
18 a fiscal year in which the fee is payable.”;
19 and

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

22 “(B) EXCEPTION FOR CERTAIN PRESCRIP-
23 TION DRUG PRODUCTS.—A prescription drug
24 program fee shall not be assessed for a pre-

1 description drug product under subparagraph (A)
2 if such product is—

3 “(i) a large volume parenteral product
4 (a sterile aqueous drug product packaged
5 in a single-dose container with a volume
6 greater than or equal to 100 mL, not in-
7 cluding powders for reconstitution or phar-
8 macy bulk packages) identified on the list
9 compiled under section 505(j)(7);

10 “(ii) pharmaceutically equivalent (as
11 defined in section 314.3 of title 21, Code
12 of Federal Regulations (or any successor
13 regulation)) to another product on the list
14 of products compiled under section
15 505(j)(7) (not including the discontinued
16 section of such list); or

17 “(iii) a skin-test diagnostic product.”.

18 (b) FEE REVENUE AMOUNTS.—

19 (1) IN GENERAL.—Paragraph (1) of section
20 736(b) of the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 379h(b)) is amended to read as follows:

22 “(1) IN GENERAL.—For each of the fiscal years
23 2023 through 2027, fees under subsection (a) shall,
24 except as provided in subsections (c), (d), (f), and
25 (g), be established to generate a total revenue

1 amount under such subsection that is equal to the
2 sum of—

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

5 “(B) the dollar amount equal to the infla-
6 tion adjustment for the fiscal year (as deter-
7 mined under subsection (c)(1));

8 “(C) the dollar amount equal to the stra-
9 tegic hiring and retention adjustment for the
10 fiscal year (as determined under subsection
11 (c)(2));

12 “(D) the dollar amount equal to the capac-
13 ity planning adjustment for the fiscal year (as
14 determined under subsection (c)(3));

15 “(E) the dollar amount equal to the oper-
16 ating reserve adjustment for the fiscal year, if
17 applicable (as determined under subsection
18 (c)(4));

19 “(F) the dollar amount equal to the addi-
20 tional direct cost adjustment for the fiscal year
21 (as determined under subsection (c)(5)); and

22 “(G) additional dollar amounts for each
23 fiscal year as follows:

24 “(i) \$65,773,693 for fiscal year 2023.

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

1 “(iii) \$14,154,169 for fiscal year
2 2025.

3 “(iv) \$4,864,860 for fiscal year 2026.

4 “(v) \$1,314,620 for fiscal year
5 2027.”.

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

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

13 “(A) for fiscal year 2023, \$1,151,522,958;
14 and

15 “(B) for fiscal years 2024 through 2027,
16 the dollar amount of the total revenue amount
17 established under paragraph (1) for the pre-
18 vious fiscal year, not including any adjustments
19 made under subsection (c)(4) or (c)(5).”.

20 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—

21 (1) INFLATION ADJUSTMENT.—Section
22 736(c)(1)(B)(ii) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 379h(c)(1)(B)(ii)) is
24 amended by striking “Washington-Baltimore, DC—

1 MD–VA–WV” and inserting “Washington–Arlington–
2 Alexandria, DC–VA–MD–WV”.

3 (2) STRATEGIC HIRING AND RETENTION AD-
4 JUSTMENT.—Section 736(c) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 379h(e)) is
6 amended—

7 (A) by redesignating paragraphs (2)
8 through (6) as paragraphs (3) through (7), re-
9 spectively; and

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

12 “(2) STRATEGIC HIRING AND RETENTION AD-
13 JUSTMENT.—For each fiscal year, after the annual
14 base revenue established in subsection (b)(1)(A) is
15 adjusted for inflation in accordance with paragraph
16 (1), the Secretary shall further increase the fee rev-
17 enue and fees by the following amounts:

18 “(A) For fiscal year 2023, \$9,000,000.

19 “(B) For each of fiscal years 2024 through
20 2027, \$4,000,000.”.

21 (3) CAPACITY PLANNING ADJUSTMENT.—Para-
22 graph (3), as redesignated, of section 736(c) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379h(e)) is amended to read as follows:

25 “(3) CAPACITY PLANNING ADJUSTMENT.—

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

10 “(B) METHODOLOGY.—For purposes of
11 this paragraph, the Secretary shall employ the
12 capacity planning methodology utilized by the
13 Secretary in setting fees for fiscal year 2021, as
14 described in the notice titled ‘Prescription Drug
15 User Fee Rates for Fiscal Year 2021’ published
16 in the Federal Register on August 3, 2020 (85
17 Fed. Reg. 46651). The workload categories
18 used in applying such methodology in fore-
19 casting shall include only the activities de-
20 scribed in that notice and, as feasible, addi-
21 tional activities that are directly related to the
22 direct review of applications and supplements,
23 including additional formal meeting types, the
24 direct review of postmarketing commitments
25 and requirements, the direct review of risk eval-

1 uation and mitigation strategies, and the direct
2 review of annual reports for approved prescrip-
3 tion drug products. Subject to the exceptions in
4 the preceding sentence, the Secretary shall not
5 include as workload categories in applying such
6 methodology in forecasting any non-core review
7 activities, including those activities that the
8 Secretary referenced for potential future use in
9 such notice but did not utilize in setting fees for
10 fiscal year 2021.

11 “(C) LIMITATION.—Under no cir-
12 cumstances shall an adjustment under this
13 paragraph result in fee revenue for a fiscal year
14 that is less than the sum of the amounts under
15 subsections (b)(1)(A) (the annual base revenue
16 for the fiscal year), (b)(1)(B) (the dollar
17 amount of the inflation adjustment for the fis-
18 cal year), and (b)(1)(C) (the dollar amount of
19 the strategic hiring and retention adjustment
20 for the fiscal year).

21 “(D) PUBLICATION IN FEDERAL REG-
22 ISTER.—The Secretary shall publish in the Fed-
23 eral Register notice under paragraph (6) of the
24 fee revenue and fees resulting from the adjust-

1 ment and the methodologies under this para-
2 graph.”.

3 (4) OPERATING RESERVE ADJUSTMENT.—Para-
4 graph (4), as redesignated, of section 736(e) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 379h(e)) is amended—

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

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

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

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

22 “(iii) For fiscal year 2025 and subse-
23 quent fiscal years, at least 10 weeks of op-
24 erating reserves.”; and

1 (B) in subparagraph (C), by striking
2 “paragraph (5)” and inserting “paragraph
3 (6)”.

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

8 “(5) ADDITIONAL DIRECT COST ADJUST-
9 MENT.—

10 “(A) INCREASE.—The Secretary shall, in
11 addition to adjustments under paragraphs (1),
12 (2), (3), and (4), further increase the fee rev-
13 enue and fees—

14 “(i) for fiscal year 2023, by
15 \$44,386,150; and

16 “(ii) for each of fiscal years 2024
17 through 2027, by the amount set forth in
18 clauses (i) through (iv) of subparagraph
19 (B), as applicable, multiplied by the Con-
20 sumer Price Index for urban consumers
21 (Washington-Arlington-Alexandria, DC-
22 VA-MD-WV; Not Seasonally Adjusted; All
23 Items; Annual Index) for the most recent
24 year of available data, divided by such
25 Index for 2021.

1 “(B) APPLICABLE AMOUNTS.—The
2 amounts referred to in subparagraph (A)(ii) are
3 the following:

4 “(i) For fiscal year 2024,
5 \$60,967,993.

6 “(ii) For fiscal year 2025,
7 \$35,799,314.

8 “(iii) For fiscal year 2026, \$35,799,
9 314.

10 “(iv) For fiscal year 2027,
11 \$35,799,314.”.

12 (6) ANNUAL FEE SETTING.—Paragraph (6), as
13 redesignated, of section 736(c) of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is
15 amended by striking “September 30, 2017” and in-
16 serting “September 30, 2022”.

17 (d) CREDITING AND AVAILABILITY OF FEES.—Sec-
18 tion 736(g)(3) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 379h(g)(3)) is amended by striking “fiscal
20 years 2018 through 2022” and inserting “fiscal years
21 2023 through 2027”.

22 (e) WRITTEN REQUESTS FOR WAIVERS, REDUC-
23 TIONS, EXEMPTIONS, AND RETURNS; DISPUTES CON-
24 CERNING FEES.—Section 736(i) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 379h(i)) is amended
2 to read as follows:

3 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-
4 TIONS, EXEMPTIONS, AND RETURNS; DISPUTES CON-
5 CERNING FEES.—To qualify for consideration for a waiver
6 or reduction under subsection (d), an exemption under
7 subsection (k), or the return of any fee paid under this
8 section, including if the fee is claimed to have been paid
9 in error, a person shall—

10 “(1) not later than 180 days after such fee is
11 due, submit to the Secretary a written request justi-
12 fying such waiver, reduction, exemption, or return;
13 and

14 “(2) include in the request any legal authorities
15 under which the request is made.”.

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

19 (1) in paragraph (1)(B), by striking “during
20 the previous year” and inserting “as determined
21 under paragraph (2)”; and

22 (2) by amending paragraph (2) to read as fol-
23 lows:

24 “(2) EVIDENCE OF QUALIFICATION.—An ex-
25 emption under paragraph (1) applies with respect to

1 a drug only if the applicant involved submits a cer-
2 tification that the applicant’s gross annual revenues
3 did not exceed \$50,000,000 for the last calendar
4 year ending prior to the fiscal year for which the ex-
5 emption is requested. Such certification shall be sup-
6 ported by—

7 “(A) tax returns submitted to the United
8 States Internal Revenue Service; or

9 “(B) as necessary, other appropriate finan-
10 cial information.”.

11 **SEC. 1004. REAUTHORIZATION; REPORTING REQUIRE-**
12 **MENTS.**

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

15 (1) in subsection (a)(1), by striking “Beginning
16 with fiscal year 2018, not” and inserting “Not”;

17 (2) by striking “Prescription Drug User Fee
18 Amendments of 2017” each place it appears and in-
19 serting “Prescription Drug User Fee Amendments
20 of 2022”;

21 (3) in subsection (a)(3)(A), by striking “Not
22 later than 30 calendar days after the end of the sec-
23 ond quarter of fiscal year 2018, and not later than
24 30 calendar days after the end of each quarter of
25 each fiscal year thereafter” and inserting “Not later

1 than 30 calendar days after the end of each quarter
2 of each fiscal year for which fees are collected under
3 this part”;

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

6 (5) in subsection (b), by striking “Beginning
7 with fiscal year 2018, not” and inserting “Not”;

8 (6) in subsection (c), by striking “Beginning
9 with fiscal year 2018, for” and inserting “For”; and

10 (7) in subsection (f)—

11 (A) in paragraph (1), in the matter pre-
12 ceding subparagraph (A), by striking “fiscal
13 year 2022” and inserting “fiscal year 2027”;
14 and

15 (B) in paragraph (5), by striking “January
16 15, 2022” and inserting “January 15, 2027”.

17 **SEC. 1005. SUNSET DATES.**

18 (a) **AUTHORIZATION.**—Sections 735 and 736 of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
20 379h) shall cease to be effective October 1, 2027.

21 (b) **REPORTING REQUIREMENTS.**—Section 736B of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 379h–2) shall cease to be effective January 31, 2028.

24 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-
25 ber 1, 2022, subsections (a) and (b) of section 104 of the

1 FDA Reauthorization Act of 2017 (Public Law 115–52)
2 are repealed.

3 **SEC. 1006. EFFECTIVE DATE.**

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

12 **SEC. 1007. SAVINGS CLAUSE.**

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

1 **TITLE II—FEES RELATING TO**
2 **DEVICES**

3 **SEC. 2001. SHORT TITLE; FINDING.**

4 (a) **SHORT TITLE.**—This title may be cited as the
5 “Medical Device User Fee Amendments of 2022”.

6 (b) **FINDING.**—Congress finds that the fees author-
7 ized under the amendments made by this title will be dedi-
8 cated toward expediting the process for the review of de-
9 vice applications and for assuring the safety and effective-
10 ness of devices, as set forth in the goals identified for pur-
11 poses of part 3 of subchapter C of chapter VII of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379i et
13 seq.), in the letters from the Secretary of Health and
14 Human Services to the Chairman of the Committee on
15 Health, Education, Labor, and Pensions of the Senate and
16 the Chairman of the Committee on Energy and Commerce
17 of the House of Representatives, as set forth in the Con-
18 gressional Record.

19 **SEC. 2002. DEFINITIONS.**

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

22 (1) in paragraph (9)—

23 (A) in the matter preceding subparagraph

24 (A), by striking “and premarket notification
25 submissions” and inserting “premarket notifica-

1 tion submissions, and de novo classification re-
2 quests”;

3 (B) in subparagraph (D), by striking “and
4 submissions” and inserting “submissions, and
5 de novo classification requests”;

6 (C) in subparagraph (F), by striking “and
7 premarket notification submissions” and insert-
8 ing “premarket notification submissions, and de
9 novo classification requests”;

10 (D) in each of subparagraphs (G) and (H),
11 by striking “or submissions” and inserting
12 “submissions, or requests”; and

13 (E) in subparagraph (K), by striking “or
14 premarket notification submissions” and insert-
15 ing “premarket notification submissions, or de
16 novo classification requests”; and

17 (2) in paragraph (11), by striking “2016” and
18 inserting “2021”.

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

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

23 (1) in paragraph (1), by striking “fiscal year
24 2018” and inserting “fiscal year 2023”; and

25 (2) in paragraph (2)—

1 (A) in subparagraph (A)—

2 (i) in the matter preceding clause (i),
3 by striking “October 1, 2017” and insert-
4 ing “October 1, 2022”;

5 (ii) in clause (iii), by striking “75 per-
6 cent” and inserting “80 percent”; and

7 (iii) in clause (viii), by striking “3.4
8 percent” and inserting “4.5 percent”;

9 (B) in subparagraph (B)(iii), by striking
10 “or premarket notification submission” and in-
11 serting “premarket notification submission, or
12 de novo classification request”; and

13 (C) in subparagraph (C), by striking “or
14 periodic reporting concerning a class III device”
15 and inserting “periodic reporting concerning a
16 class III device, or de novo classification re-
17 quest”.

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

21 (1) in paragraph (1), by striking “2018
22 through 2022” and inserting “2023 through 2027”;

23 (2) by amending paragraph (2) to read as fol-
24 lows:

1 “(2) BASE FEE AMOUNTS SPECIFIED.—For
 2 purposes of paragraph (1), the base fee amounts
 3 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

4 (3) by amending paragraph (3) to read as fol-
 5 lows:

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

- 9 “(A) \$312,606,000 for fiscal year 2023.
- 10 “(B) \$335,750,000 for fiscal year 2024.
- 11 “(C) \$350,746,400 for fiscal year 2025.
- 12 “(D) \$366,486,300 for fiscal year 2026.
- 13 “(E) \$418,343,000 for fiscal year 2027.”.

14 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
 15 738(c) of the Federal Food, Drug, and Cosmetic Act (21
 16 U.S.C. 379j(c)) is amended—

17 (1) in paragraph (1), by striking “2017” and
 18 inserting “2022”;

19 (2) in paragraph (2)—

20 (A) in subparagraph (A), by striking
 21 “2018” and inserting “2023”;

22 (B) in subparagraph (B)—

1 (i) in the matter preceding clause (i),
2 by striking “fiscal year 2018” and insert-
3 ing “fiscal year 2023”; and

4 (ii) in clause (ii), by striking “fiscal
5 year 2016” and inserting “fiscal year
6 2022”;

7 (C) in subparagraph (C), by striking
8 “Washington-Baltimore, DC–MD–VA–WV”
9 and inserting “Washington-Arlington-Alexan-
10 dria, DC–VA–MD–WV”; and

11 (D) in subparagraph (D), in the matter
12 preceding clause (i), by striking “fiscal years
13 2018 through 2022” and inserting “fiscal years
14 2023 through 2027”;

15 (3) in paragraph (3), by striking “2018
16 through 2022” and inserting “2023 through 2027”;

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

19 (5) by inserting after paragraph (3) the fol-
20 lowing:

21 “(4) PERFORMANCE IMPROVEMENT ADJUST-
22 MENT.—

23 “(A) IN GENERAL.—For each of fiscal
24 years 2025 through 2027, after the adjust-
25 ments under paragraphs (2) and (3), the base

1 establishment registration fee amounts for such
2 fiscal year shall be increased to reflect changes
3 in the resource needs of the Secretary due to
4 improved review performance goals for the proc-
5 ess for the review of device applications identi-
6 fied in the letters described in section 2001(b)
7 of the Medical Device User Fee Amendments of
8 2022, as the Secretary determines necessary to
9 achieve an increase in total fee collections for
10 such fiscal year equal to the following amounts,
11 as applicable:

12 “(i) For fiscal year 2025, the product
13 of—

14 “(I) the amount determined
15 under subparagraph (B)(i)(I); and

16 “(II) the applicable inflation ad-
17 justment under paragraph (2)(B) for
18 such fiscal year.

19 “(ii) For fiscal year 2026, the product
20 of—

21 “(I) the sum of the amounts de-
22 termined under subparagraphs
23 (B)(i)(II), (B)(ii)(I), and (B)(iii)(I);
24 and

1 “(II) the applicable inflation ad-
2 justment under paragraph (2)(B) for
3 such fiscal year.

4 “(iii) For fiscal year 2027, the prod-
5 uct of—

6 “(I) the sum of the amounts de-
7 termined under subparagraphs
8 (B)(i)(III), (B)(ii)(II), and
9 (B)(iii)(II); and

10 “(II) the applicable inflation ad-
11 justment under paragraph (2)(B) for
12 such fiscal year.

13 “(B) AMOUNTS.—

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

19 “(I) For fiscal year 2025,
20 \$15,396,600 if such goal for fiscal
21 year 2023 is met.

22 “(II) For fiscal year 2026:

23 “(aa) \$15,396,600 if such
24 goal for fiscal year 2023 is met

1 and such goal for fiscal year
2 2024 is not met.

3 “(bb) \$36,792,200 if such
4 goal for fiscal year 2024 is met.

5 “(III) For fiscal year 2027:

6 “(aa) \$15,396,600 if such
7 goal for fiscal year 2023 is met
8 and such goal for each of fiscal
9 years 2024 and 2025 is not met.

10 “(bb) \$36,792,200 if such
11 goal for fiscal year 2024 is met
12 and such goal for fiscal year
13 2025 is not met.

14 “(cc) \$40,572,600 if such
15 goal for fiscal year 2025 is met.

16 “(ii) DE NOVO CLASSIFICATION RE-
17 QUEST AMOUNT.—For purposes of sub-
18 paragraph (A), with respect to the De
19 Novo Decision goal, the amounts deter-
20 mined under this subparagraph are as fol-
21 lows:

22 “(I) For fiscal year 2026,
23 \$6,323,500 if such goal for fiscal year
24 2023 is met.

25 “(II) For fiscal year 2027:

1 “(aa) \$6,323,500 if such
2 goal for fiscal year 2023 is met
3 and such goal for fiscal year
4 2024 is not met.

5 “(bb) \$11,765,400 if such
6 goal for fiscal year 2024 is met.

7 “(iii) PREMARKET NOTIFICATION AND
8 PREMARKET APPROVAL AMOUNT.—For
9 purposes of subparagraph (A), with respect
10 to the 510(k) decision goal, 510(k) Shared
11 Outcome Total Time to Decision goal,
12 PMA decision goal, and PMA Shared Out-
13 come Total Time to Decision goal, the
14 amounts determined under this subpara-
15 graph are as follows:

16 “(I) For fiscal year 2026,
17 \$1,020,000 if the 4 goals for fiscal
18 year 2023 are met.

19 “(II) For fiscal year 2027:

20 “(aa) \$1,020,000 if the 4
21 goals for fiscal year 2023 are met
22 and one or more of the 4 goals
23 for fiscal year 2024 are not met.

1 “(bb) \$3,906,000 if the 4
2 goals for fiscal year 2024 are
3 met.

4 “(C) PERFORMANCE CALCULATION.—For
5 purposes of this paragraph, performance of the
6 following goals shall be determined as specified
7 in the letters described in section 2001(b) of
8 the Medical Device User Fee Amendments of
9 2022 and based on data available, as follows:

10 “(i) The performance of the Pre-
11 submission Written Feedback goal shall be
12 based on data available as of—

13 “(I) for fiscal year 2023, March
14 31, 2024;

15 “(II) for fiscal year 2024, March
16 31, 2025; and

17 “(III) for fiscal year 2025,
18 March 31, 2026.

19 “(ii) The performance of the De Novo
20 Decision goal, 510(k) decision goal, 510(k)
21 Shared Outcome Total Time to Decision
22 goal, PMA decision goal, and PMA Shared
23 Outcome Total Time to Decision goal shall
24 be based on data available as of—

1 “(I) for fiscal year 2023, March
2 31, 2025; and

3 “(II) for fiscal year 2024, March
4 31, 2026.

5 “(D) GOALS DEFINED.—For purposes of
6 this paragraph, the terms ‘Presubmission Writ-
7 ten Feedback goal’, ‘De Novo Decision goal’,
8 ‘510(k) decision goal’, ‘510(k) Shared Outcome
9 Total Time to Decision goal’, ‘PMA decision
10 goal’, and ‘PMA Shared Outcome Total Time
11 to Decision goal’ refer to the goals identified by
12 the same names in the letters described in sec-
13 tion 2001(b) of the Medical Device User Fee
14 Amendments of 2022.

15 “(5) HIRING ADJUSTMENT.—

16 “(A) IN GENERAL.—For each of fiscal
17 years 2025 through 2027, after the adjust-
18 ments under paragraphs (2), (3), and (4), if ap-
19 plicable, if the number of hires to support the
20 process for the review of device applications
21 falls below the thresholds specified in subpara-
22 graph (B) for the applicable fiscal years, the
23 base establishment registration fee amounts
24 shall be decreased as the Secretary determines
25 necessary to achieve a reduction in total fee col-

1 lections equal to the hiring adjustment amount
2 under subparagraph (C).

3 “(B) THRESHOLDS.—The thresholds speci-
4 fied in this subparagraph are as follows:

5 “(i) For fiscal year 2025, the thresh-
6 old is 123 hires for fiscal year 2023.

7 “(ii) For fiscal year 2026, the thresh-
8 old is 38 hires for fiscal year 2024.

9 “(iii) For fiscal year 2027, the thresh-
10 old is—

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

16 “(II) 75 hires for fiscal year
17 2025 if such fees are so increased.

18 “(C) HIRING ADJUSTMENT AMOUNT.—The
19 hiring adjustment amount for fiscal year 2025
20 and each subsequent fiscal year is the product
21 of—

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

1 “(ii) \$72,877; and

2 “(iii) the applicable inflation adjust-
3 ment under paragraph (2)(B) for the fiscal
4 year for which the hiring goal was not met.

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

8 “(i) For fiscal year 2023, 144 hires.

9 “(ii) For fiscal year 2024, 42 hires.

10 “(iii) For fiscal year 2025:

11 “(I) 24 hires if the base estab-
12 lishment registration fees are not in-
13 creased by the amount determined
14 under paragraph (4)(A)(i).

15 “(II) 83 hires if the base estab-
16 lishment registration fees are in-
17 creased by the amount determined
18 under paragraph (4)(A)(i).

19 “(E) NUMBER OF HIRES.—For purposes
20 of this paragraph, the number of hires for a fis-
21 cal year shall be determined by the Secretary as
22 set forth in the letters described in section
23 2001(b) of the Medical Device User Fee
24 Amendments of 2022.

25 “(6) OPERATING RESERVE ADJUSTMENT.—

1 “(A) IN GENERAL.—For each of fiscal
2 years 2023 through 2027, after the adjust-
3 ments under paragraphs (2), (3), (4), and (5),
4 if applicable, if the Secretary has operating re-
5 serves of carryover user fees for the process for
6 the review of device applications in excess of the
7 designated amount in subparagraph (B), the
8 Secretary shall decrease the base establishment
9 registration fee amounts to provide for not
10 more than such designated amount of operating
11 reserves.

12 “(B) DESIGNATED AMOUNT.—Subject to
13 subparagraph (C), for each fiscal year, the des-
14 ignated amount in this subparagraph is equal
15 to the sum of—

16 “(i) 13 weeks of operating reserves of
17 carryover user fees; and

18 “(ii) 1 month of operating reserves
19 maintained pursuant to paragraph (8).

20 “(C) EXCLUDED AMOUNT.—For the period
21 of fiscal years 2023 through 2026, a total
22 amount equal to \$118,000,000 shall not be con-
23 sidered part of the designated amount under
24 subparagraph (B) and shall not be subject to
25 the decrease under subparagraph (A).”.

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

4 (1) in paragraph (1)(A), by striking
5 “\$320,825,000” and inserting “\$398,566,000”; and

6 (2) in paragraph (2), by inserting “de novo
7 classification requests,” after “class III device,”.

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

11 “(3) AUTHORIZATION OF APPROPRIATIONS.—

12 “(A) IN GENERAL.—For each of fiscal
13 years 2023 through 2027, there is authorized to
14 be appropriated for fees under this section an
15 amount equal to the revenue amount deter-
16 mined under subparagraph (B), less the
17 amount of reductions determined under sub-
18 paragraph (C).

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

22 “(i) the total revenue amount under
23 subsection (b)(3) for the fiscal year, as ad-
24 justed under paragraphs (2) and (3) of
25 subsection (c); and

1 “(ii) the performance improvement
2 adjustment amount for the fiscal year
3 under subsection (c)(4), if applicable.

4 “(C) AMOUNT OF REDUCTIONS.—For pur-
5 poses of this paragraph, the amount of reduc-
6 tions for each fiscal year is the sum of—

7 “(i) the hiring adjustment amount for
8 the fiscal year under subsection (c)(5), if
9 applicable; and

10 “(ii) the operating reserve adjustment
11 amount for the fiscal year under sub-
12 section (c)(6), if applicable.”.

13 **SEC. 2004. REAUTHORIZATION; REPORTING REQUIRE-**
14 **MENTS.**

15 (a) PERFORMANCE REPORTS.—Section 738A(a) of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 379j–1(a)) is amended—

18 (1) by striking “fiscal year 2018” each place it
19 appears and inserting “fiscal year 2023”;

20 (2) by striking “Medical Device User Fee
21 Amendments of 2017” each place it appears and in-
22 serting “Medical Device User Fee Amendments of
23 2022”;

24 (3) in paragraph (1)—

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

4 (B) in subparagraph (A)(iv), by striking
5 “fiscal year 2020” and inserting “fiscal year
6 2023”; and

7 (4) in paragraph (4), by striking “2018
8 through 2022” and inserting “2023 through 2027”.

9 (b) REAUTHORIZATION.—Section 738A(b) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
11 1(b)) is amended—

12 (1) in paragraph (1), by striking “2022” and
13 inserting “2027”; and

14 (2) in paragraph (5), by striking “2022” and
15 inserting “2027”.

16 **SEC. 2005. CONFORMITY ASSESSMENT PILOT PROGRAM.**

17 Section 514(d) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 360d(d)) is amended to read as fol-
19 lows:

20 “(d) ACCREDITATION SCHEME FOR CONFORMITY AS-
21 SESSMENT.—

22 “(1) IN GENERAL.—The Secretary shall estab-
23 lish a program under which—

24 “(A) testing laboratories meeting criteria
25 specified in guidance by the Secretary may be

1 accredited, by accreditation bodies meeting cri-
2 teria specified in guidance by the Secretary, to
3 conduct testing to support the assessment of
4 the conformity of a device to certain standards
5 recognized under this section; and

6 “(B) subject to paragraph (2), results
7 from tests conducted to support the assessment
8 of conformity of devices as described in sub-
9 paragraph (A) conducted by testing laboratories
10 accredited pursuant to this subsection shall be
11 accepted by the Secretary for purposes of dem-
12 onstrating such conformity unless the Secretary
13 finds that certain results of such tests should
14 not be so accepted.

15 “(2) SECRETARIAL REVIEW OF ACCREDITED
16 LABORATORY RESULTS.—The Secretary may—

17 “(A) review the results of tests conducted
18 by testing laboratories accredited pursuant to
19 this subsection, including by conducting peri-
20 odic audits of such results or of the processes
21 of accredited bodies or testing laboratories;

22 “(B) following such review, take additional
23 measures under this Act, as the Secretary de-
24 termines appropriate, such as—

1 “(i) suspension or withdrawal of ac-
2 creditation of a testing laboratory or rec-
3 ognition of an accreditation body under
4 paragraph (1)(A); or

5 “(ii) requesting additional information
6 with respect to a device; and

7 “(C) if the Secretary becomes aware of in-
8 formation materially bearing on the safety or
9 effectiveness of a device for which an assess-
10 ment of conformity was supported by testing
11 conducted by a testing laboratory accredited
12 under this subsection, take such additional
13 measures under this Act, as the Secretary de-
14 termines appropriate, such as—

15 “(i) suspension or withdrawal of ac-
16 creditation of a testing laboratory or rec-
17 ognition of an accreditation body under
18 paragraph (1)(A); or

19 “(ii) requesting additional information
20 with regard to such device.

21 “(3) REPORT.—The Secretary shall make avail-
22 able on the internet website of the Food and Drug
23 Administration an annual report on the progress of
24 the program under this subsection.”.

1 **SEC. 2006. REAUTHORIZATION OF THIRD-PARTY REVIEW**
2 **PROGRAM.**

3 Section 523(c) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 360m(c)) is amended by striking
5 “October 1” and inserting “December 17”.

6 **SEC. 2007. SUNSET DATES.**

7 (a) **AUTHORIZATION.**—Sections 737 and 738 of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i;
9 379j) shall cease to be effective October 1, 2027.

10 (b) **REPORTING REQUIREMENTS.**—Section 738A of
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 379j–1) shall cease to be effective January 31, 2028.

13 (c) **PREVIOUS SUNSET PROVISIONS.**—Effective Octo-
14 ber 1, 2022, subsections (a) and (b) of section 210 of the
15 FDA Reauthorization Act of 2017 (Public Law 115–52)
16 are repealed.

17 **SEC. 2008. EFFECTIVE DATE.**

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

1 **SEC. 2009. SAVINGS CLAUSE.**

2 Notwithstanding the amendments made by this title,
3 part 3 of subchapter C of chapter VII of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
5 effect on the day before the date of the enactment of this
6 title, shall continue to be in effect with respect to the sub-
7 missions listed in section 738(a)(2)(A) of such Act (as de-
8 fined in such part as of such day) that on or after October
9 1, 2017, but before October 1, 2022, were received by the
10 Food and Drug Administration with respect to assessing
11 and collecting any fee required by such part for a fiscal
12 year prior to fiscal year 2023.

13 **TITLE III—FEES RELATING TO**
14 **GENERIC DRUGS**

15 **SEC. 3001. SHORT TITLE; FINDING.**

16 (a) **SHORT TITLE.**—This title may be cited as the
17 “Generic Drug User Fee Amendments of 2022”.

18 (b) **FINDING.**—Congress finds that the fees author-
19 ized by the amendments made by this title will be dedi-
20 cated to human generic drug activities, as set forth in the
21 goals identified for purposes of part 7 of subchapter C
22 of chapter VII of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 379j–41 et seq.), in the letters from the
24 Secretary of Health and Human Services to the Chairman
25 of the Committee on Health, Education, Labor, and Pen-
26 sions of the Senate and the Chairman of the Committee

1 on Energy and Commerce of the House of Representa-
2 tives, as set forth in the Congressional Record.

3 **SEC. 3002. AUTHORITY TO ASSESS AND USE HUMAN GE-**
4 **NERIC DRUG FEES.**

5 (a) TYPES OF FEES.—Section 744B(a) of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
7 42(a)) is amended—

8 (1) in the matter preceding paragraph (1), by
9 striking “2018” and inserting “2023”;

10 (2) in paragraph (2)(C), by striking “2018
11 through 2022” and inserting “2023 through 2027”;

12 (3) in paragraph (3)(B), by striking “2018
13 through 2022” and inserting “2023 through 2027”;

14 (4) in paragraph (4)(D), by striking “2018
15 through 2022” and inserting “2023 through 2027”;

16 and

17 (5) in paragraph (5)(D), by striking “2018
18 through 2022” and inserting “2023 through 2027”.

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

22 (1) in paragraph (1)—

23 (A) in subparagraph (A)—

24 (i) in the heading, by striking “2018”
25 and inserting “2023”;

1 (ii) by striking “2018” and inserting
2 “2023”; and

3 (iii) by striking “\$493,600,000” and
4 inserting “\$582,500,000”; and

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

7 “(B) FISCAL YEARS 2024 THROUGH 2027.—

8 “(i) IN GENERAL.—For each of the
9 fiscal years 2024 through 2027, fees under
10 paragraphs (2) through (5) of subsection
11 (a) shall be established to generate a total
12 estimated revenue amount under such sub-
13 section that is equal to the base revenue
14 amount for the fiscal year under clause
15 (ii), as adjusted pursuant to subsection (c).

16 “(ii) BASE REVENUE AMOUNT.—The
17 base revenue amount for a fiscal year re-
18 ferred to in clause (i) is equal to the total
19 revenue amount established under this
20 paragraph for the previous fiscal year, not
21 including any adjustments made for such
22 previous fiscal year under subsection
23 (c)(3).”; and

24 (2) in paragraph (2)—

1 (A) in subparagraph (C), by striking “one-
2 third the amount” and inserting “twenty-four
3 percent”;

4 (B) in subparagraph (D), by striking
5 “Seven percent” and inserting “Six percent”;
6 and

7 (C) in subparagraph (E)(i), by striking
8 “Thirty-five percent” and inserting “Thirty-six
9 percent”.

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

13 (1) in paragraph (1)—

14 (A) in the matter preceding subparagraph

15 (A)—

16 (i) by striking “2019” and inserting
17 “2024”; and

18 (ii) by striking “to equal the product
19 of the total revenues established in such
20 notice for the prior fiscal year multiplied”
21 and inserting “to equal the base revenue
22 amount for the fiscal year (as specified in
23 subsection (b)(1)(B)(ii)) multiplied”; and

24 (B) in subparagraph (C), by striking
25 “Washington-Baltimore, DC–MD–VA–WV”

1 and inserting “Washington-Arlington-Alexan-
2 dria, DC–VA–MD–WV”; and

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

5 “(2) CAPACITY PLANNING ADJUSTMENT.—

6 “(A) IN GENERAL.—Beginning with fiscal
7 year 2024, the Secretary shall, in addition to
8 the adjustment under paragraph (1), further in-
9 crease the fee revenue and fees under this sec-
10 tion for a fiscal year, in accordance with this
11 paragraph, to reflect changes in the resource
12 capacity needs of the Secretary for human ge-
13 neric drug activities.

14 “(B) CAPACITY PLANNING METHOD-
15 OLOGY.—The Secretary shall establish a capac-
16 ity planning methodology for purposes of this
17 paragraph, which shall—

18 “(i) be derived from the methodology
19 and recommendations made in the report
20 titled ‘Independent Evaluation of the
21 GDUFA Resource Capacity Planning Ad-
22 justment Methodology: Evaluation and
23 Recommendations’ announced in the Fed-
24 eral Register on August 3, 2020 (85 Fed.
25 Reg. 46658); and

1 “(ii) incorporate approaches and at-
2 tributes determined appropriate by the
3 Secretary, including approaches and at-
4 tributes made in such report, except that
5 in incorporating such approaches and at-
6 tributes the workload categories used in
7 forecasting resources shall only be the
8 workload categories specified in section
9 VIII.B.2.e. of the letters described in sec-
10 tion 3001(b) of the Generic Drug User Fee
11 Amendments of 2022.

12 “(C) LIMITATIONS.—

13 “(i) IN GENERAL.—Under no cir-
14 cumstances shall an adjustment under this
15 paragraph result in fee revenue for a fiscal
16 year that is less than the sum of the
17 amounts under subsection (b)(1)(B)(ii)
18 (the base revenue amount for the fiscal
19 year) and paragraph (1) (the dollar
20 amount of the inflation adjustment for the
21 fiscal year).

22 “(ii) ADDITIONAL LIMITATION.—An
23 adjustment under this paragraph shall not
24 exceed 3 percent of the sum described in

1 clause (i) for the fiscal year, except that
2 such limitation shall be 4 percent if—

3 “(I) for purposes of a fiscal year
4 2024 adjustment, the Secretary deter-
5 mines that during the period from
6 April 1, 2021, through March 31,
7 2023—

8 “(aa) the total number of
9 abbreviated new drug applica-
10 tions submitted was greater than
11 or equal to 2,000; or

12 “(bb) thirty-five percent or
13 more of abbreviated new drug ap-
14 plications submitted related to
15 complex products (as that term is
16 defined in section XI of the let-
17 ters described in section 3001(b)
18 of the Generic Drug User Fee
19 Amendments of 2022);

20 “(II) for purposes of a fiscal year
21 2025 adjustment, the Secretary deter-
22 mines that during the period from
23 April 1, 2022, through March 31,
24 2024—

1 “(aa) the total number of
2 abbreviated new drug applica-
3 tions submitted was greater than
4 or equal to 2,300; or

5 “(bb) thirty-five percent or
6 more of abbreviated new drug ap-
7 plications submitted related to
8 complex products (as so defined);

9 “(III) for purposes of a fiscal
10 year 2026 adjustment, the Secretary
11 determines that during the period
12 from April 1, 2023, through March
13 31, 2025—

14 “(aa) the total number of
15 abbreviated new drug applica-
16 tions submitted was greater than
17 or equal to 2,300; or

18 “(bb) thirty-five percent or
19 more of abbreviated new drug ap-
20 plications submitted related to
21 complex products (as so defined);
22 and

23 “(IV) for purposes of a fiscal
24 year 2027 adjustment, the Secretary
25 determines that during the period

1 from April 1, 2024, through March
2 31, 2026—

3 “(aa) the total number of
4 abbreviated new drug applica-
5 tions submitted was greater than
6 or equal to 2,300; or

7 “(bb) thirty-five percent or
8 more of abbreviated new drug ap-
9 plications submitted related to
10 complex products (as so defined).

11 “(D) PUBLICATION IN FEDERAL REG-
12 ISTER.—The Secretary shall publish in the Fed-
13 eral Register notice referred to in subsection (a)
14 the fee revenue and fees resulting from the ad-
15 justment and the methodology under this para-
16 graph.

17 “(3) OPERATING RESERVE ADJUSTMENT.—

18 “(A) IN GENERAL.—For fiscal year 2024
19 and each subsequent fiscal year, the Secretary
20 may, in addition to adjustments under para-
21 graphs (1) and (2), further increase the fee rev-
22 enue and fees under this section for such fiscal
23 year if such an adjustment is necessary to pro-
24 vide operating reserves of carryover user fees
25 for human generic drug activities for not more

1 than the number of weeks specified in subpara-
2 graph (B) with respect to that fiscal year.

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

5 “(i) 8 weeks for fiscal year 2024;

6 “(ii) 9 weeks for fiscal year 2025; and

7 “(iii) 10 weeks for each of fiscal year
8 2026 and 2027.

9 “(C) DECREASE.—If the Secretary has
10 carryover balances for human generic drug ac-
11 tivities in excess of 12 weeks of the operating
12 reserves referred to in subparagraph (A), the
13 Secretary shall decrease the fee revenue and
14 fees referred to in such subparagraph to provide
15 for not more than 12 weeks of such operating
16 reserves.

17 “(D) RATIONALE FOR ADJUSTMENT.—If
18 an adjustment under this paragraph is made,
19 the rationale for the amount of the increase or
20 decrease (as applicable) in fee revenue and fees
21 shall be contained in the annual Federal Reg-
22 ister notice under subsection (a) publishing the
23 fee revenue and fees for the fiscal year in-
24 volved.”.

1 (d) ANNUAL FEE SETTING.—Section 744B(d)(1) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 379j–42(d)(1)) is amended—

4 (1) in the paragraph heading, by striking “2018
5 THROUGH 2022” and inserting “2023 THROUGH
6 2027”; and

7 (2) by striking “more than 60 days before the
8 first day of each of fiscal years 2018 through 2022”
9 and inserting “later than 60 days before the first
10 day of each of fiscal years 2023 through 2027”.

11 (e) EFFECT OF FAILURE TO PAY FEES.—The head-
12 ing of paragraph (3) of section 744B(g) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(g)) is
14 amended by striking “AND PRIOR APPROVAL SUPPLEMENT
15 FEE”.

16 (f) CREDITING AND AVAILABILITY OF FEES.—Sec-
17 tion 744B(i)(3) of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 379j–42(i)(3)) is amended by striking “fis-
19 cal years 2018 through 2022” and inserting “fiscal years
20 2023 through 2027”.

21 **SEC. 3003. REAUTHORIZATION; REPORTING REQUIRE-**
22 **MENTS.**

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

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

3 (2) by striking “Generic Drug User Fee
4 Amendments of 2017” each place it appears and in-
5 serting “Generic Drug User Fee Amendments of
6 2022”;

7 (3) in subsection (a)(2), by striking “Not later
8 than 30 calendar days after the end of the second
9 quarter of fiscal year 2018, and not later than 30
10 calendar days after the end of each quarter of each
11 fiscal year thereafter” and inserting “Not later than
12 30 calendar days after the end of each quarter of
13 each fiscal year for which fees are collected under
14 this part”;

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

17 (5) in subsection (b), by striking “Beginning
18 with fiscal year 2018, not” and inserting “Not”;

19 (6) in subsection (c), by striking “Beginning
20 with fiscal year 2018, for” and inserting “For”; and

21 (7) in subsection (f)—

22 (A) in paragraph (1), in the matter pre-
23 ceding subparagraph (A), by striking “fiscal
24 year 2022” and inserting “fiscal year 2027”;

25 and

1 (B) in paragraph (5), by striking “January
2 15, 2022” and inserting “January 15, 2027”.

3 **SEC. 3004. SUNSET DATES.**

4 (a) AUTHORIZATION.—Sections 744A and 744B of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 379j–41; 379j–42) shall cease to be effective October 1,
7 2027.

8 (b) REPORTING REQUIREMENTS.—Section 744C of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 379j–43) shall cease to be effective January 31, 2028.

11 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
12 ber 1, 2022, subsections (a) and (b) of section 305 of the
13 FDA Reauthorization Act of 2017 (Public Law 115–52)
14 are repealed.

15 **SEC. 3005. EFFECTIVE DATE.**

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

1 **SEC. 3006. SAVINGS CLAUSE.**

2 Notwithstanding the amendments made by this title,
3 part 7 of subchapter C of chapter VII of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 379j–41 et seq.), as
5 in effect on the day before the date of the enactment of
6 this title, shall continue to be in effect with respect to ab-
7 breviated new drug applications (as defined in such part
8 as of such day) that were received by the Food and Drug
9 Administration within the meaning of section 505(j)(5)(A)
10 of such Act (21 U.S.C. 355(j)(5)(A)), prior approval sup-
11 plements that were submitted, and drug master files for
12 Type II active pharmaceutical ingredients that were first
13 referenced on or after October 1, 2017, but before October
14 1, 2022, with respect to assessing and collecting any fee
15 required by such part for a fiscal year prior to fiscal year
16 2023.

17 **TITLE IV—FEES RELATING TO**
18 **BIOSIMILAR BIOLOGICAL**
19 **PRODUCTS**

20 **SEC. 4001. SHORT TITLE; FINDING.**

21 (a) **SHORT TITLE.**—This title may be cited as the
22 “Biosimilar User Fee Amendments of 2022”.

23 (b) **FINDING.**—Congress finds that the fees author-
24 ized by the amendments made by this title will be dedi-
25 cated to expediting the process for the review of biosimilar
26 biological product applications, including postmarket safe-

1 ty activities, as set forth in the goals identified for pur-
2 poses of part 8 of subchapter C of chapter VII of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51
4 et seq.), in the letters from the Secretary of Health and
5 Human Services to the Chairman of the Committee on
6 Health, Education, Labor, and Pensions of the Senate and
7 the Chairman of the Committee on Energy and Commerce
8 of the House of Representatives, as set forth in the Con-
9 gressional Record.

10 **SEC. 4002. DEFINITIONS.**

11 (a) **ADJUSTMENT FACTOR.**—Section 744G(1) of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
13 51(1)) is amended to read as follows:

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

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

24 (1) by striking subclause (II) (relating to an al-
25 lergenic extract product); and

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

3 **SEC. 4003. AUTHORITY TO ASSESS AND USE BIOSIMILAR BI-**
4 **OLOGICAL PRODUCT FEES.**

5 (a) TYPES OF FEES.—

6 (1) IN GENERAL.—The matter preceding para-
7 graph (1) in section 744H(a) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is
9 amended by striking “fiscal year 2018” and insert-
10 ing “fiscal year 2023”.

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

17 (3) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT
18 DEVELOPMENT FEE.—Section 744H(a)(1)(B) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 379j–52(a)(1)(B)) is amended—

21 (A) in clause (i), by inserting before the
22 period at the end the following: “, except that,
23 in the case that such product (including, where
24 applicable, ownership of the relevant investiga-
25 tional new drug application) is transferred to a

1 licensee, assignee, or successor of such person,
2 and written notice of such transfer is provided
3 to the Secretary, such licensee, assignee, or suc-
4 cessor shall pay the annual biosimilar biological
5 product development fee”;

6 (B) in clause (iii)—

7 (i) in subclause (I), by striking “or”
8 at the end;

9 (ii) in subclause (II), by striking the
10 period at the end and inserting “; or”; and

11 (iii) by adding at the end the fol-
12 lowing:

13 “(III) been administratively re-
14 moved from the biosimilar biological
15 product development program for the
16 product under subparagraph (E)(v).”;
17 and

18 (C) in clause (iv), by striking “is accepted
19 for filing on or after October 1 of such fiscal
20 year” and inserting “is subsequently accepted
21 for filing”.

22 (4) REACTIVATION FEE.—Section
23 744H(a)(1)(D) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 379j-52(a)(1)(D)) is amended
25 to read as follows:

1 “(D) REACTIVATION FEE.—

2 “(i) IN GENERAL.—A person that has
3 discontinued participation in the biosimilar
4 biological product development program for
5 a product under subparagraph (C), or who
6 has been administratively removed from
7 such program for a product under sub-
8 paragraph (E)(v), shall, if the person seeks
9 to resume participation in such program,
10 pay all annual biosimilar biological product
11 development fees previously assessed for
12 such product and still owed and a fee (re-
13 ferred to in this section as ‘reactivation
14 fee’) by the earlier of the following:

15 “(I) Not later than 7 days after
16 the Secretary grants a request by
17 such person for a biosimilar biological
18 product development meeting for the
19 product (after the date on which such
20 participation was discontinued or the
21 date of administrative removal, as ap-
22 plicable).

23 “(II) Upon the date of submis-
24 sion (after the date on which such
25 participation was discontinued or the

1 date of administrative removal, as ap-
2 plicable) by such person of an inves-
3 tigational new drug application de-
4 scribing an investigation that the Sec-
5 retary determines is intended to sup-
6 port a biosimilar biological product
7 application for that product.

8 “(ii) APPLICATION OF ANNUAL
9 FEE.—A person that pays a reactivation
10 fee for a product shall pay for such prod-
11 uct, beginning in the next fiscal year, the
12 annual biosimilar biological product devel-
13 opment fee under subparagraph (B), ex-
14 cept that, in the case that such product
15 (including, where applicable, ownership of
16 the relevant investigational new drug appli-
17 cation) is transferred to a licensee, as-
18 signee, or successor of such person, and
19 written notice of such transfer is provided
20 to the Secretary, such licensee, assignee, or
21 successor shall pay the annual biosimilar
22 biological product development fee.”.

23 (5) EFFECT OF FAILURE TO PAY FEES.—Sec-
24 tion 744H(a)(1)(E) of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 379j–52(a)(1)(E)) is
2 amended by adding at the end the following:

3 “(v) ADMINISTRATIVE REMOVAL FROM
4 THE BIOSIMILAR BIOLOGICAL PRODUCT
5 DEVELOPMENT PROGRAM.—If a person has
6 failed to pay an annual biosimilar biological
7 product development fee for a product
8 as required under subparagraph (B) for a
9 period of 2 consecutive fiscal years, the
10 Secretary may administratively remove
11 such person from the biosimilar biological
12 product development program for the prod-
13 uct. At least 30 days prior to administra-
14 tively removing a person from the bio-
15 similar biological product development pro-
16 gram for a product under this clause, the
17 Secretary shall provide written notice to
18 such person of the intended administrative
19 removal.”.

20 (6) BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-
21 TION FEE.—Section 744H(a)(2)(D) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
23 52(a)(2)(D)) is amended by inserting after “or was
24 withdrawn” the following: “prior to approval”.

1 (7) BIOSIMILAR BIOLOGICAL PRODUCT PRO-
2 GRAM FEE.—Section 744H(a)(3) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
4 52(a)(3)) is amended—

5 (A) in subparagraph (A)—

6 (i) in clause (i), by striking “and” at
7 the end;

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

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

12 “(ii) may be dispensed only under pre-
13 scription pursuant to section 503(b); and”;
14 and

15 (B) by adding at the end the following:

16 “(E) MOVEMENT TO DISCONTINUED
17 LIST.—

18 “(i) DATE OF INCLUSION.—If a writ-
19 ten request to place a product on the list
20 referenced in subparagraph (A) of discon-
21 tinued biosimilar biological products is sub-
22 mitted to the Secretary on behalf of an ap-
23 plicant, and the request identifies the date
24 the product is, or will be, withdrawn from
25 sale, then for purposes of assessing the

1 biosimilar biological product program fee,
2 the Secretary shall consider such product
3 to have been included on such list on the
4 later of—

5 “(I) the date such request was
6 received; or

7 “(II) if the product will be with-
8 drawn from sale on a future date,
9 such future date when the product is
10 withdrawn from sale.

11 “(ii) TREATMENT AS WITHDRAWN
12 FROM SALE.—For purposes of clause (i), a
13 product shall be considered withdrawn
14 from sale once the applicant has ceased its
15 own distribution of the product, whether or
16 not the applicant has ordered recall of all
17 previously distributed lots of the product,
18 except that a routine, temporary interrup-
19 tion in supply shall not render a product
20 withdrawn from sale.

21 “(iii) SPECIAL RULE FOR PRODUCTS
22 REMOVED FROM DISCONTINUED LIST.—If
23 a biosimilar biological product that is iden-
24 tified in a biosimilar biological product ap-
25 plication approved as of October 1 of a fis-

1 cal year appears, as of October 1 of such
2 fiscal year, on the list referenced in sub-
3 paragraph (A) of discontinued biosimilar
4 biological products, and on any subsequent
5 day during such fiscal year the biosimilar
6 biological product does not appear on such
7 list, except as provided in subparagraph
8 (D), each person who is named as the ap-
9 plicant in a biosimilar biological product
10 application with respect to such product
11 shall pay the annual biosimilar biological
12 product program fee established for a fis-
13 cal year under subsection (c)(5) for such
14 biosimilar biological product. Notwith-
15 standing subparagraph (B), such fee shall
16 be due on the last business day of such fis-
17 cal year and shall be paid only once for
18 each such product for each fiscal year.”.

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

23 (b) FEE REVENUE AMOUNTS.—Subsection (b) of sec-
24 tion 744H of the Federal Food, Drug, and Cosmetic Act
25 (21 U.S.C. 379j–52) is amended—

1 (1) by striking paragraph (1);

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

4 (3) by amending paragraph (1) (as so redesign-
5 nated) to read as follows:

6 “(1) IN GENERAL.—For each of the fiscal years
7 2023 through 2027, fees under subsection (a) shall,
8 except as provided in subsection (c), be established
9 to generate a total revenue amount equal to the sum
10 of—

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

13 “(B) the dollar amount equal to the infla-
14 tion adjustment for the fiscal year (as deter-
15 mined under subsection (c)(1));

16 “(C) the dollar amount equal to the stra-
17 tegic hiring and retention adjustment (as deter-
18 mined under subsection (c)(2));

19 “(D) the dollar amount equal to the capac-
20 ity planning adjustment for the fiscal year (as
21 determined under subsection (c)(3));

22 “(E) the dollar amount equal to the oper-
23 ating reserve adjustment for the fiscal year, if
24 applicable (as determined under subsection
25 (c)(4));

1 “(F) for fiscal year 2023 an additional
2 amount of \$4,428,886; and

3 “(G) for fiscal year 2024 an additional
4 amount of \$320,569.”;

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

6 (A) in the paragraph heading, by striking
7 “; LIMITATIONS ON FEE AMOUNTS”;

8 (B) by striking subparagraph (B); and

9 (C) by redesignating subparagraphs (C)
10 and (D) as subparagraphs (B) and (C), respec-
11 tively; and

12 (5) by amending paragraph (3) (as so redesign-
13 ated) to read as follows:

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

17 “(A) for fiscal year 2023, \$43,376,922;
18 and

19 “(B) for fiscal years 2024 through 2027,
20 the dollar amount of the total revenue amount
21 established under paragraph (1) for the pre-
22 vious fiscal year, excluding any adjustments to
23 such revenue amount under subsection (c)(4).”.

1 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
2 744H(e) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 379j–52(e)) is amended—

4 (1) in paragraph (1)—

5 (A) in subparagraph (A)—

6 (i) in the matter preceding clause (i),
7 by striking “subsection (b)(2)(B)” and in-
8 serting “subsection (b)(1)(B)”; and

9 (ii) in clause (i), by striking “sub-
10 section (b)” and inserting “subsection
11 (b)(1)(A)”; and

12 (B) in subparagraph (B)(ii), by striking
13 “Washington-Baltimore, DC–MD–VA–WV”
14 and inserting “Washington-Arlington-Alexan-
15 dria, DC–VA–MD–WV”;

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

18 “(2) STRATEGIC HIRING AND RETENTION AD-
19 JUSTMENT.—For each fiscal year, after the annual
20 base revenue under subsection (b)(1)(A) is adjusted
21 for inflation in accordance with paragraph (1), the
22 Secretary shall further increase the fee revenue and
23 fees by \$150,000.

24 “(3) CAPACITY PLANNING ADJUSTMENT.—

1 “(A) IN GENERAL.—For each fiscal year,
2 the Secretary shall, in addition to the adjust-
3 ments under paragraphs (1) and (2), further
4 adjust the fee revenue and fees under this sec-
5 tion for a fiscal year to reflect changes in the
6 resource capacity needs of the Secretary for the
7 process for the review of biosimilar biological
8 product applications.

9 “(B) METHODOLOGY.—For purposes of
10 this paragraph, the Secretary shall employ the
11 capacity planning methodology utilized by the
12 Secretary in setting fees for fiscal year 2021, as
13 described in the notice titled ‘Biosimilar User
14 Fee Rates for Fiscal Year 2021’ published in
15 the Federal Register on August 4, 2020 (85
16 Fed. Reg. 47220). The workload categories
17 used in applying such methodology in fore-
18 casting shall include only the activities de-
19 scribed in that notice and, as feasible, addi-
20 tional activities that are directly related to the
21 direct review of biosimilar biological product ap-
22 plications and supplements, including additional
23 formal meeting types, the direct review of post-
24 marketing commitments and requirements, the
25 direct review of risk evaluation and mitigation

1 strategies, and the direct review of annual re-
2 ports for approved biosimilar biological prod-
3 ucts. Subject to the exceptions in the preceding
4 sentence, the Secretary shall not include as
5 workload categories in applying such method-
6 ology in forecasting any non-core review activi-
7 ties, including those activities that the Sec-
8 retary referenced for potential future use in
9 such notice but did not utilize in setting fees for
10 fiscal year 2021.

11 “(C) LIMITATIONS.—Under no cir-
12 cumstances shall an adjustment under this
13 paragraph result in fee revenue for a fiscal year
14 that is less than the sum of the amounts under
15 subsections (b)(1)(A) (the annual base revenue
16 for the fiscal year), (b)(1)(B) (the dollar
17 amount of the inflation adjustment for the fis-
18 cal year), and (b)(1)(C) (the dollar amount of
19 the strategic hiring and retention adjustment).

20 “(D) PUBLICATION IN FEDERAL REG-
21 ISTER.—The Secretary shall publish in the Fed-
22 eral Register notice under paragraph (5) the fee
23 revenue and fees resulting from the adjustment
24 and the methodologies under this paragraph.

25 “(4) OPERATING RESERVE ADJUSTMENT.—

1 “(A) INCREASE.—For fiscal year 2023 and
2 subsequent fiscal years, the Secretary shall, in
3 addition to adjustments under paragraphs (1),
4 (2), and (3), further increase the fee revenue
5 and fees if such an adjustment is necessary to
6 provide for at least 10 weeks of operating re-
7 serves of carryover user fees for the process for
8 the review of biosimilar biological product appli-
9 cations.

10 “(B) DECREASE.—

11 “(i) FISCAL YEAR 2023.—For fiscal
12 year 2023, if the Secretary has carryover
13 balances for such process in excess of 33
14 weeks of such operating reserves, the Sec-
15 retary shall decrease such fee revenue and
16 fees to provide for not more than 33 weeks
17 of such operating reserves.

18 “(ii) FISCAL YEAR 2024.—For fiscal
19 year 2024, if the Secretary has carryover
20 balances for such process in excess of 27
21 weeks of such operating reserves, the Sec-
22 retary shall decrease such fee revenue and
23 fees to provide for not more than 27 weeks
24 of such operating reserves.

1 “(iii) FISCAL YEAR 2025 AND SUBSE-
2 QUENT FISCAL YEARS.—For fiscal year
3 2025 and subsequent fiscal years, if the
4 Secretary has carryover balances for such
5 process in excess of 21 weeks of such oper-
6 ating reserves, the Secretary shall decrease
7 such fee revenue and fees to provide for
8 not more than 21 weeks of such operating
9 reserves.

10 “(C) FEDERAL REGISTER NOTICE.—If an
11 adjustment under subparagraph (A) or (B) is
12 made, the rationale for the amount of the in-
13 crease or decrease (as applicable) in fee revenue
14 and fees shall be contained in the annual Fed-
15 eral Register notice under paragraph (5)(B) es-
16 tablishing fee revenue and fees for the fiscal
17 year involved.”; and

18 (3) in paragraph (5), in the matter preceding
19 subparagraph (A), by striking “2018” and inserting
20 “2023”.

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

1 (e) WRITTEN REQUESTS FOR WAIVERS AND RE-
2 TURNS; DISPUTES CONCERNING FEES.—Section 744H(h)
3 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 379j–52(h)) is amended to read as follows:

5 “(h) WRITTEN REQUESTS FOR WAIVERS AND RE-
6 TURNS; DISPUTES CONCERNING FEES.—To qualify for
7 consideration for a waiver under subsection (d), or for the
8 return of any fee paid under this section, including if the
9 fee is claimed to have been paid in error, a person shall
10 submit to the Secretary a written request justifying such
11 waiver or return and, except as otherwise specified in this
12 section, such written request shall be submitted to the Sec-
13 retary not later than 180 days after such fee is due. A
14 request submitted under this paragraph shall include any
15 legal authorities under which the request is made.”.

16 **SEC. 4004. REAUTHORIZATION; REPORTING REQUIRE-**
17 **MENTS.**

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

20 (1) in subsection (a)(1), by striking “Beginning
21 with fiscal year 2018, not” and inserting “Not”;

22 (2) by striking “Biosimilar User Fee Amend-
23 ments of 2017” each place it appears and inserting
24 “Biosimilar User Fee Amendments of 2022”;

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

3 (4) in subsection (a)(3)(A), by striking “Not
4 later than 30 calendar days after the end of the sec-
5 ond quarter of fiscal year 2018, and not later than
6 30 calendar days after the end of each quarter of
7 each fiscal year thereafter” and inserting “Not later
8 than 30 calendar days after the end of each quarter
9 of each fiscal year for which fees are collected under
10 this part”;

11 (5) in subsection (b), by striking “Not later
12 than 120 days after the end of fiscal year 2018 and
13 each subsequent fiscal year for which fees are col-
14 lected under this part” and inserting “Not later
15 than 120 days after the end of each fiscal year for
16 which fees are collected under this part”;

17 (6) in subsection (c), by striking “Beginning
18 with fiscal year 2018, and for” and inserting “For”;
19 and

20 (7) in subsection (f)—

21 (A) in paragraph (1), in the matter pre-
22 ceding subparagraph (A), by striking “fiscal
23 year 2022” and inserting “fiscal year 2027”;
24 and

1 (B) in paragraph (3), by striking “January
2 15, 2022” and inserting “January 15, 2027”.

3 **SEC. 4005. SUNSET DATES.**

4 (a) AUTHORIZATION.—Sections 744G and 744H of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 379j–51, 379j–52) shall cease to be effective October 1,
7 2027.

8 (b) REPORTING REQUIREMENTS.—Section 744I of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 379j–53) shall cease to be effective January 31, 2028.

11 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
12 ber 1, 2022, subsections (a) and (b) of section 405 of the
13 FDA Reauthorization Act of 2017 (Public Law 115–52)
14 are repealed.

15 **SEC. 4006. EFFECTIVE DATE.**

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

1 **SEC. 4007. SAVINGS CLAUSE.**

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

13 **TITLE V—REAUTHORIZATION OF**
14 **OTHER PROVISIONS**

15 **SEC. 5001. REAUTHORIZATION OF THE BEST PHARMA-**
16 **CEUTICALS FOR CHILDREN PROGRAM.**

17 Section 409I(d)(1) of the Public Health Service Act
18 (42 U.S.C. 284m(d)(1)) is amended by striking
19 “\$25,000,000 for each of fiscal years 2018 through 2022”
20 and inserting “\$5,273,973 for the period beginning on Oc-
21 tober 1, 2022 and ending on December 16, 2022”.

22 **SEC. 5002. REAUTHORIZATION OF THE HUMANITARIAN DE-**
23 **VICE EXEMPTION INCENTIVE.**

24 Section 520(m)(6)(A)(iv) of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is

1 amended by striking “October 1” and inserting “Decem-
2 ber 17”.

3 **SEC. 5003. REAUTHORIZATION OF THE PEDIATRIC DEVICE**
4 **CONSORTIA PROGRAM.**

5 Section 305(e) of the Food and Drug Administration
6 Amendments Act of 2007 (Public Law 110–85; 42 U.S.C.
7 282 note) is amended by striking “\$5,250,000 for each
8 of fiscal years 2018 through 2022” and inserting
9 “\$1,107,534 for the period beginning on October 1, 2022,
10 and ending on December 16, 2022”.

11 **SEC. 5004. REAUTHORIZATION OF PROVISION PERTAINING**
12 **TO DRUGS CONTAINING SINGLE**
13 **ENANTIOMERS.**

14 Section 505(u)(4) of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by strik-
16 ing “October 1” and inserting “December 17”.

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

19 Section 566(f) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking
21 “\$6,000,000 for each of fiscal years 2018 through 2022”
22 and inserting “\$1,265,753 for the period beginning on Oc-
23 tober 1, 2022 and ending on December 16, 2022”.

1 **SEC. 5006. REAUTHORIZATION OF ORPHAN DRUG GRANTS.**

2 Section 5(c) of the Orphan Drug Act (21 U.S.C.
3 360ee(c)) is amended by striking “\$30,000,000 for each
4 of fiscal years 2018 through 2022” and inserting
5 “\$6,328,767 for the period beginning on October 1, 2022,
6 and ending on December 16, 2022”.

7 **SEC. 5007. REAUTHORIZATION OF CERTAIN DEVICE IN-**
8 **SPECTIONS.**

9 Section 704(g)(11) of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by strik-
11 ing “October 1” and inserting “December 17”.

12 **SEC. 5008. REAUTHORIZATION OF REPORTING REQUIRE-**
13 **MENTS RELATED TO PENDING GENERIC**
14 **DRUG APPLICATIONS AND PRIORITY REVIEW**
15 **APPLICATIONS.**

16 Section 807 of the FDA Reauthorization Act of 2017
17 (Public Law 115–52) is amended, in the matter preceding
18 paragraph (1), by striking “October 1” and inserting “De-
19 cember 16”.

1 **DIVISION G—HERMIT’S PEAK/
2 CALF CANYON FIRE ASSIST-
3 ANCE ACT**

4 **SEC. 101. SHORT TITLE.**

5 This division may be cited as the “Hermit’s Peak/
6 Calf Canyon Fire Assistance Act”.

7 **SEC. 102. FINDINGS AND PURPOSES.**

8 (a) FINDINGS.—Congress finds that—

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

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

21 (3) on April 19, 2022, the Calf Canyon Fire,
22 also in San Miguel County, New Mexico, began
23 burning on Federal land and was later identified as
24 the result of a pile burn in January 2022 that re-

1 mained dormant under the surface before re-
2 emerging;

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

8 (5) by May 2, 2022, the fire had grown in size
9 and caused evacuations in multiple villages and com-
10 munities in San Miguel County and Mora County,
11 including in the San Miguel county jail, the State's
12 psychiatric hospital, the United World College, and
13 New Mexico Highlands University;

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

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

21 (8) the U.S. Forest Service has assumed re-
22 sponsibility for the Hermit's Peak/Calf Canyon Fire;

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

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

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

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

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

9 **SEC. 103. DEFINITIONS.**

10 In this Act:

11 (1) ADMINISTRATOR.—The term “Adminis-
12 trator” means—

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

15 (B) if a Manager is appointed under sec-
16 tion 104(a)(3), the Manager.

17 (2) HERMIT’S PEAK/CALF CANYON FIRE.—The
18 term “Hermit’s Peak/Calf Canyon Fire” means—

19 (A) the fire resulting from the initiation by
20 the Forest Service of a prescribed burn in the
21 Santa Fe National Forest in San Miguel Coun-
22 ty, New Mexico, on April 6, 2022;

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

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

5 (3) INDIAN TRIBE.—The term “Indian Tribe”
6 means the recognized governing body of any Indian
7 or Alaska Native Tribe, band, nation, pueblo, village,
8 community, component band, or component reserva-
9 tion individually identified (including parenthetically)
10 in the list published most recently as of the date of
11 enactment of this Act pursuant to section 104 of the
12 Federally Recognized Indian Tribe List Act of 1994
13 (25 U.S.C. 5131).

14 (4) INJURED PERSON.—The term “injured per-
15 son” means—

16 (A) an individual, regardless of the citizen-
17 ship or alien status of the individual; or

18 (B) an Indian Tribe, corporation, Tribal
19 corporation, partnership, company, association,
20 county, township, city, State, school district, or
21 other non-Federal entity (including a legal rep-
22 resentative) that suffered injury resulting from
23 the Hermit’s Peak/Calf Canyon Fire.

24 (5) INJURY.—The term “injury” has the same
25 meaning as the term “injury or loss of property, or

1 personal injury or death” as used in section
2 1346(b)(1) of title 28, United States Code.

3 (6) MANAGER.—The term “Manager” means
4 an Independent Claims Manager appointed under
5 section 104(a)(3).

6 (7) OFFICE.—The term “Office” means the Of-
7 fice of Hermit’s Peak/Calf Canyon Fire Claims es-
8 tablished by section 104(a)(2).

9 (8) TRIBAL ENTITY.—The term “Tribal entity”
10 includes any Indian Tribe, tribal organization, In-
11 dian-controlled organization serving Indians, Native
12 Hawaiian organization, or Alaska Native entity, as
13 such terms are defined or used in section 166 of the
14 Workforce Innovation and Opportunity Act (29
15 U.S.C. 3221).

16 **SEC. 104. COMPENSATION FOR VICTIMS OF HERMIT’S PEAK/
17 CALF CANYON FIRE.**

18 (a) IN GENERAL.—

19 (1) COMPENSATION.—Each injured person shall
20 be eligible to receive from the United States com-
21 pensation for injury suffered by the injured person
22 as a result of the Hermit’s Peak/Calf Canyon Fire,
23 subject to the availability of appropriations and sub-
24 ject to the Administrator making the determinations
25 required under subsection (d).

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

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

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

10 (C) FUNDING.—The Office—

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

14 (ii) may appoint and fix the com-
15 pensation of such temporary personnel as
16 may be necessary, without regard to the
17 provisions of title 5, United States Code,
18 governing appointments in competitive
19 service; and

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

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

1 (A) head the Office; and

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

4 (4) DETAIL.—Upon the request of the Adminis-
5 trator, the head of any Federal department or agen-
6 cy may detail, on a reimbursable basis, any of the
7 personnel of that department or agency to the Fed-
8 eral Emergency Management Agency to assist the
9 Agency in carrying out the duties under this Act.

10 (b) SUBMISSION OF CLAIMS.—Not later than 2 years
11 after the date on which regulations are first promulgated
12 under subsection (f), an injured person may submit to the
13 Administrator a written claim for 1 or more injuries suf-
14 fered by the injured person in accordance with such re-
15 quirements as the Administrator determines to be appro-
16 priate.

17 (c) INVESTIGATION OF CLAIMS.—

18 (1) IN GENERAL.—In accordance with sub-
19 section (d), the Administrator shall, on behalf of the
20 United States, investigate, consider, ascertain, ad-
21 just, determine, grant, deny, or settle any claim for
22 money damages asserted under subsection (b).

23 (2) APPLICABILITY OF STATE LAW.—Except as
24 otherwise provided in this Act, the laws of the State

1 of New Mexico shall apply to the calculation of dam-
2 ages under subsection (d)(4).

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

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

7 (B) shall not include—

8 (i) interest before settlement or pay-
9 ment of a claim; or

10 (ii) punitive damages.

11 (d) PAYMENT OF CLAIMS.—

12 (1) DETERMINATION AND PAYMENT OF
13 AMOUNT.—

14 (A) IN GENERAL.—

15 (i) PAYMENT.—Not later than 180
16 days after the date on which a claim is
17 submitted under this Act, the Adminis-
18 trator shall determine and fix the amount,
19 if any, to be paid for the claim.

20 (ii) PRIORITY.—The Administrator, to
21 the maximum extent practicable, shall pay
22 subrogation claims submitted under this
23 Act only after paying claims submitted by
24 injured parties that are not insurance com-
25 panies seeking payment as subrogees.

1 (B) PARAMETERS OF DETERMINATION.—

2 In determining and settling a claim under this
3 Act, the Administrator shall determine only—

4 (i) whether the claimant is an injured
5 person;

6 (ii) whether the injury that is the sub-
7 ject of the claim resulted from the Her-
8 mit's Peak/Calf Canyon Fire;

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

12 (iv) whether sufficient funds are avail-
13 able for payment and, if so, the amount, if
14 any, to be allowed and paid under this Act.

15 (C) INSURANCE AND OTHER BENEFITS.—

16 (i) IN GENERAL.—In determining the
17 amount of, and paying, a claim under this
18 Act, to prevent recovery by a claimant in
19 excess of actual compensatory damages,
20 the Administrator shall reduce the amount
21 to be paid for the claim by an amount that
22 is equal to the total of insurance benefits
23 (excluding life insurance benefits) or other
24 payments or settlements of any nature that

1 were paid, or will be paid, with respect to
2 the claim.

3 (ii) GOVERNMENT LOANS.—This sub-
4 paragraph shall not apply to the receipt by
5 a claimant of any government loan that is
6 required to be repaid by the claimant.

7 (2) PARTIAL PAYMENT.—

8 (A) IN GENERAL.—At the request of a
9 claimant, the Administrator may make 1 or
10 more advance or partial payments, subject to
11 the determination required under paragraph
12 (1)(B), before the final settlement of a claim,
13 including final settlement on any portion or as-
14 pect of a claim that is determined to be sever-
15 able.

16 (B) JUDICIAL DECISION.—If a claimant re-
17 ceives a partial payment on a claim under this
18 Act, but further payment on the claim is subse-
19 quently denied by the Administrator, the claim-
20 ant may—

21 (i) seek judicial review under sub-
22 section (i); and

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

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

3 (II) fraudulently procured the
4 compensation.

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

12 (4) ALLOWABLE DAMAGES.—

13 (A) LOSS OF PROPERTY.—A claim that is
14 paid for loss of property under this Act may in-
15 clude otherwise uncompensated damages result-
16 ing from the Hermit's Peak/Calf Canyon Fire
17 for—

18 (i) an uninsured or underinsured
19 property loss;

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

22 (iii) damage to physical infrastruc-
23 ture, including irrigation infrastructure
24 such as acequia systems;

1 (iv) a cost resulting from lost subsist-
2 ence from hunting, fishing, firewood gath-
3 ering, timbering, grazing, or agricultural
4 activities conducted on land damaged by
5 the Hermit's Peak/Calf Canyon Fire;

6 (v) a cost of reforestation or revegeta-
7 tion on Tribal or non-Federal land, to the
8 extent that the cost of reforestation or re-
9 vegetation is not covered by any other Fed-
10 eral program; and

11 (vi) any other loss that the Adminis-
12 trator determines to be appropriate for in-
13 clusion as loss of property.

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

19 (i) Damage to tangible assets or in-
20 ventory, including natural resources.

21 (ii) Business interruption losses.

22 (iii) Overhead costs.

23 (iv) Employee wages for work not per-
24 formed.

25 (v) Loss of business net income.

1 (vi) Any other loss that the Adminis-
2 trator determines to be appropriate for in-
3 clusion as business loss.

4 (C) FINANCIAL LOSS.—A claim that is
5 paid for injury under this Act may include dam-
6 ages resulting from the Hermit’s Peak/Calf
7 Canyon Fire for the following types of other-
8 wise uncompensated financial loss:

9 (i) Increased mortgage interest costs.

10 (ii) An insurance deductible.

11 (iii) A temporary living or relocation
12 expense.

13 (iv) Lost wages or personal income.

14 (v) Emergency staffing expenses.

15 (vi) Debris removal and other cleanup
16 costs.

17 (vii) Costs of reasonable efforts, as
18 determined by the Administrator, to reduce
19 the risk of wildfire, flood, or other natural
20 disaster in the counties impacted by the
21 Hermit’s Peak/Calf Canyon Fire to risk
22 levels prevailing in those counties before
23 the Hermit’s Peak/Calf Canyon Fire, that
24 are incurred not later than the date that is
25 3 years after the date on which the regula-

1 tions under subsection (f) are first promul-
2 gated.

3 (viii) A premium for flood insurance
4 that is required to be paid on or before
5 May 31, 2024, if, as a result of the Her-
6 mit's Peak/Calf Canyon Fire, a person that
7 was not required to purchase flood insur-
8 ance before the Hermit's Peak/Calf Can-
9 yon Fire is required to purchase flood in-
10 surance.

11 (ix) A disaster assistance loan re-
12 ceived from the Small Business Adminis-
13 tration.

14 (x) Any other loss that the Adminis-
15 trator determines to be appropriate for in-
16 clusion as financial loss.

17 (e) ACCEPTANCE OF AWARD.—The acceptance by a
18 claimant of any payment under this Act, except an ad-
19 vance or partial payment made under subsection (d)(2),
20 shall—

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

24 (2) constitute a complete release of all claims
25 against the United States (including any agency or

1 employee of the United States) under chapter 171 of
2 title 28, United States Code (commonly known as
3 the “Federal Tort Claims Act”), or any other Fed-
4 eral or State law, arising out of or relating to the
5 same subject matter.

6 (f) REGULATIONS AND PUBLIC INFORMATION.—

7 (1) REGULATIONS.—Notwithstanding any other
8 provision of law, not later than 45 days after the
9 date of enactment of this Act, the Administrator
10 shall promulgate and publish in the Federal Register
11 interim final regulations for the processing and pay-
12 ment of claims under this Act.

13 (2) PUBLIC INFORMATION.—

14 (A) IN GENERAL.—At the time at which
15 the Administrator promulgates regulations
16 under paragraph (1), the Administrator shall
17 publish, online and in print, in newspapers of
18 general circulation in the State of New Mexico,
19 a clear, concise, and easily understandable ex-
20 planation, in English and Spanish, of—

21 (i) the rights conferred under this
22 Act; and

23 (ii) the procedural and other require-
24 ments of the regulations promulgated
25 under paragraph (1).

1 (B) DISSEMINATION THROUGH OTHER
2 MEDIA.—The Administrator shall disseminate
3 the explanation published under subparagraph
4 (A) through websites, blogs, social media, bro-
5 chures, pamphlets, radio, television, and other
6 media that the Administrator determines are
7 likely to reach prospective claimants.

8 (g) CONSULTATION.—In administering this Act, the
9 Administrator shall consult with the Secretary of the Inte-
10 rior, the Secretary of Energy, the Secretary of Agri-
11 culture, the Administrator of the Small Business Adminis-
12 tration, other Federal agencies, and State, local, and Trib-
13 al authorities, as determined to be necessary by the Ad-
14 ministrator, to—

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

17 (2) provide for local concerns.

18 (h) ELECTION OF REMEDY.—

19 (1) IN GENERAL.—An injured person may elect
20 to seek compensation from the United States for 1
21 or more injuries resulting from the Hermit’s Peak/
22 Calf Canyon Fire by—

23 (A) submitting a claim under this Act;

24 (B) filing a claim or bringing a civil action
25 under chapter 171 of title 28, United States

1 Code (commonly known as the “Federal Tort
2 Claims Act”); or

3 (C) bringing an authorized civil action
4 under any other provision of law.

5 (2) EFFECT OF ELECTION.—In accordance with
6 subsection (e), an election by an injured person to
7 seek compensation in any manner described in para-
8 graph (1) shall be final and conclusive on the claim-
9 ant with respect to all injuries resulting from the
10 Hermit’s Peak/Calf Canyon Fire that are suffered
11 by the claimant upon acceptance of an award.

12 (3) ARBITRATION.—

13 (A) IN GENERAL.—Not later than 45 days
14 after the date of enactment of this Act, the Ad-
15 ministrator shall establish by regulation proce-
16 dures under which a dispute regarding a claim
17 submitted under this Act may be settled by ar-
18 bitration.

19 (B) ARBITRATION AS REMEDY.—On estab-
20 lishment of arbitration procedures under sub-
21 paragraph (A), an injured person that submits
22 a disputed claim under this Act may elect to
23 settle the claim through arbitration.

1 (C) BINDING EFFECT.—An election by an
2 injured person to settle a claim through arbitra-
3 tion under this paragraph shall—

4 (i) be binding; and

5 (ii) preclude any exercise by the in-
6 jured person of the right to judicial review
7 of a claim described in subsection (i).

8 (4) NO EFFECT ON ENTITLEMENTS.—The value
9 of compensation that may be provided under this
10 Act shall not be considered income or resources for
11 any purpose under any Federal, State, or local laws,
12 including laws relating to taxation, welfare, and pub-
13 lic assistance programs, and no State or political
14 subdivision thereof shall decrease any assistance oth-
15 erwise provided to an injured person because of the
16 receipt of benefits under this Act.

17 (i) JUDICIAL REVIEW.—

18 (1) IN GENERAL.—Any claimant aggrieved by a
19 final decision of the Administrator under this Act
20 may, not later than 60 days after the date on which
21 the decision is issued, bring a civil action in the
22 United States District Court for the District of New
23 Mexico, to modify or set aside the decision, in whole
24 or in part.

1 (2) RECORD.—The court shall hear a civil ac-
2 tion under paragraph (1) on the record made before
3 the Administrator.

4 (3) STANDARD.—The decision of the Adminis-
5 trator incorporating the findings of the Adminis-
6 trator shall be upheld if the decision is supported by
7 substantial evidence on the record considered as a
8 whole.

9 (j) ATTORNEY'S AND AGENT'S FEES.—

10 (1) IN GENERAL.—No attorney or agent, acting
11 alone or in combination with any other attorney or
12 agent, shall charge, demand, receive, or collect, for
13 services rendered in connection with a claim sub-
14 mitted under this Act, fees in excess of the limita-
15 tions established under section 2678 of title 28,
16 United States Code.

17 (2) VIOLATION.—An attorney or agent who vio-
18 lates paragraph (1) shall be fined not more than
19 \$10,000.

20 (k) WAIVER OF REQUIREMENT FOR MATCHING
21 FUNDS.—

22 (1) STATE AND LOCAL PROJECT.—

23 (A) IN GENERAL.—Notwithstanding any
24 other provision of law, a State or local project
25 that is determined by the Administrator to be

1 carried out in response to the Hermit's Peak/
2 Calf Canyon Fire under any Federal program
3 that applies to an area affected by the Hermit's
4 Peak/Calf Canyon Fire shall not be subject to
5 any requirement for State or local matching
6 funds to pay the cost of the project under the
7 Federal program.

8 (B) FEDERAL SHARE.—The Federal share
9 of the costs of a project described in subpara-
10 graph (A) shall be 100 percent.

11 (2) OTHER NEEDS PROGRAM ASSISTANCE.—
12 Notwithstanding section 408(g)(2) of the Robert T.
13 Stafford Disaster Relief and Emergency Assistance
14 Act (42 U.S.C. 5174(g)(2)), for any emergency or
15 major disaster declared by the President under that
16 Act for the Hermit's Peak/Calf Canyon Fire, the
17 Federal share of assistance provided under that sec-
18 tion shall be 100 percent.

19 (3) AGRICULTURAL PROGRAM ASSISTANCE.—

20 (A) IN GENERAL.—Notwithstanding any
21 other provision of law, a State, local, or indi-
22 vidual project that is determined by the Sec-
23 retary of Agriculture to be carried out in re-
24 sponse to the Hermit's Peak/Calf Canyon Fire
25 under any Federal program that applies to an

1 area affected by the Hermit's Peak/Calf Canyon
2 Fire shall not be subject to any requirement for
3 State, local, or individual matching funds to
4 pay the cost of the project under the Federal
5 program.

6 (B) FEDERAL SHARE.—The Federal share
7 of the costs of a project described in subpara-
8 graph (A) shall be 100 percent.

9 (I) APPLICABILITY OF DEBT COLLECTION REQUIRE-
10 MENTS.—Section 3711(a) of title 31, United States Code,
11 shall not apply to any payment under this Act, unless—

12 (1) there is evidence of civil or criminal fraud,
13 misrepresentation, presentation of a false claim; or

14 (2) a claimant was not eligible under subsection
15 (d)(2) of this Act to any partial payment.

16 (m) INDIAN COMPENSATION.—Notwithstanding any
17 other provision of law, in the case of an Indian Tribe, a
18 Tribal entity, or a member of an Indian Tribe that sub-
19 mits a claim under this Act—

20 (1) the Bureau of Indian Affairs shall have no
21 authority over, or any trust obligation regarding,
22 any aspect of the submission of, or any payment re-
23 ceived for, the claim;

24 (2) the Indian Tribe, Tribal entity, or member
25 of an Indian Tribe shall be entitled to proceed under

1 this Act in the same manner and to the same extent
2 as any other injured person; and

3 (3) except with respect to land damaged by the
4 Hermit's Peak/Calf Canyon Fire that is the subject
5 of the claim, the Bureau of Indian Affairs shall have
6 no responsibility to restore land damaged by the
7 Hermit's Peak/Calf Canyon Fire.

8 (n) REPORT.—Not later than 1 year after the date
9 of promulgation of regulations under subsection (f)(1),
10 and annually thereafter, the Administrator shall submit
11 to Congress a report that describes the claims submitted
12 under this Act during the year preceding the date of sub-
13 mission of the report, including, for each claim—

14 (1) the amount claimed;

15 (2) a brief description of the nature of the
16 claim; and

17 (3) the status or disposition of the claim, in-
18 cluding the amount of any payment under this Act.

19 (o) AUTHORIZATION OF APPROPRIATIONS.—There
20 are authorized to be appropriated such sums as are nec-
21 essary to carry out this Act.