

In the Senate of the United States,

September 29, 2022.

Resolved, That the bill from the House of Representatives (H.R. 6833) entitled “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.”, do pass with the following

AMENDMENT:

Strike all after the enacting clause and insert the following:

1 ***SECTION 1. SHORT TITLE.***

2 *This Act may be cited as the “Continuing Appropriations and Ukraine Supplemental Appropriations Act,*
3 *tions and Ukraine Supplemental Appropriations Act,*
4 *2023”.*

5 ***SEC. 2. TABLE OF CONTENTS.***

Sec. 1. Short Title.

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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 fis-*
8 *cal 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 appropria-*
11 *tions Acts for fiscal year 2022 and under the authority and*
12 *conditions provided in such Acts, for continuing projects*
13 *or activities (including the costs of direct loans and loan*
14 *guarantees) that are not otherwise specifically provided for*
15 *in this Act, that were conducted in fiscal year 2022, and*
16 *for which appropriations, funds, or other authority were*
17 *made available in the following appropriations Acts:*

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

1 (2) *The Commerce, Justice, Science, and Related*
2 *Agencies Appropriations Act, 2022 (division B of*
3 *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 Re-*
7 *lated Agencies Appropriations Act, 2022 (division D*
8 *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 including*
16 *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, 2022*
19 *(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 Pub-*
24 *lic Law 117–43.*

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

5 (10) *The Military Construction, Veterans Affairs,*
6 *and Related Agencies Appropriations Act, 2022 (divi-*
7 *sion 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 the
11 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 of*
23 *any project, activity, operation, or organization (de-*
24 *defined as any project, subproject, activity, budget ac-*
25 *tivity, program element, and subprogram within a*

1 *program element, and for any investment items de-*
2 *finied 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 available*
7 *during fiscal year 2022.*

8 *(b) No appropriation or funds made available or au-*
9 *thority granted pursuant to section 101 for the Department*
10 *of Defense shall be used to initiate multi-year procurements*
11 *utilizing advance procurement funding for economic order*
12 *quantity procurement unless specifically appropriated*
13 *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 102,*
18 *no appropriation or funds made available or authority*
19 *granted pursuant to section 101 shall be used to initiate*
20 *or resume any project or activity for which appropriations,*
21 *funds, or other authority were not available during fiscal*
22 *year 2022.*

23 *SEC. 105. Appropriations made and authority granted*
24 *pursuant to this Act shall cover all obligations or expendi-*
25 *tures incurred for any project or activity during the period*

1 *for which funds or authority for such project or activity*
2 *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 2023,*
5 *appropriations and funds made available and authority*
6 *granted pursuant to this Act shall be available until which-*
7 *ever 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 ap-*
11 *propriations 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 avail-*
20 *able by or authority granted pursuant to this Act may be*
21 *used without regard to the time limitations for submission*
22 *and approval of apportionments set forth in section 1513*
23 *of title 31, United States Code, but nothing in this Act may*
24 *be construed to waive any other provision of law governing*
25 *the apportionment of funds.*

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

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

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

22 *(b) Notwithstanding section 106, obligations for man-*
23 *datory payments due on or about the first day of any month*
24 *that begins after October 2022 but not later than 30 days*

1 *after the date specified in section 106(3) may continue to*
2 *be made, and funds shall be available for such payments.*

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

13 *SEC. 113. Funds appropriated by this Act may be obli-*
14 *gated and expended notwithstanding section 10 of Public*
15 *Law 91–672 (22 U.S.C. 2412), section 15 of the State De-*
16 *partment Basic Authorities Act of 1956 (22 U.S.C. 2680),*
17 *section 313 of the Foreign Relations Authorization Act, Fis-*
18 *cal Years 1994 and 1995 (22 U.S.C. 6212), and section*
19 *504(a)(1) of the National Security Act of 1947 (50 U.S.C.*
20 *3094(a)(1)).*

21 *SEC. 114. Each amount incorporated by reference in*
22 *this Act that was previously designated by the Congress as*
23 *an emergency requirement pursuant to sections 4001(a)(1)*
24 *and 4001(b) of S. Con. Res. 14 (117th Congress), the con-*
25 *current resolution on the budget for fiscal year 2022, or as*

1 *being for disaster relief pursuant to section 4005(f) of such*
2 *concurrent resolution, is designated as being an emergency*
3 *requirement pursuant to section 4001(a)(1) of such concur-*
4 *rent resolution and section 1(e) of H. Res. 1151 (117th Con-*
5 *gress), as engrossed in the House of Representatives on June*
6 *8, 2022, or as being for disaster relief pursuant to section*
7 *1(f) of such House resolution, respectively.*

8 *SEC. 115. (a) Rescissions or cancellations of discre-*
9 *tionary budget authority that continue pursuant to section*
10 *101 in Treasury Appropriations Fund Symbols (TAFS)—*

11 *(1) to which other appropriations are not pro-*
12 *vided by this Act, but for which there is a current ap-*
13 *plicable TAFS that does receive an appropriation in*
14 *this Act; or*

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

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

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

23 *(1) the amount specified for rescission or can-*
24 *cellation in the applicable appropriations Act ref-*
25 *erenced in section 101 of this Act; or*

1 (2) *the amount of balances available, as of Octo-*
2 *ber 1, 2022, from the funds specified for rescission or*
3 *cancellation in the applicable appropriations Act ref-*
4 *erenced in section 101 of this Act.*

5 (c) *No later than November 21, 2022, the Director of*
6 *the Office of Management and Budget shall provide to the*
7 *Committees on Appropriations of the House of Representa-*
8 *tives and the Senate a comprehensive list of the rescissions*
9 *or cancellations that will continue pursuant to section 101:*
10 *Provided, That the information in such comprehensive list*
11 *shall be periodically updated to reflect any subsequent*
12 *changes in the amount of balances available, as of October*
13 *1, 2022, from the funds specified for rescission or cancella-*
14 *tion in the applicable appropriations Act referenced in sec-*
15 *tion 101, and such updates shall be transmitted to the Com-*
16 *mittees on Appropriations of the House of Representatives*
17 *and the Senate upon request.*

18 SEC. 116. *Amounts made available by section 101 for*
19 *“Farm Service Agency—Agricultural Credit Insurance*
20 *Fund Program Account” may be apportioned up to the rate*
21 *for operations necessary to accommodate approved applica-*
22 *tions for direct and guaranteed farm ownership loans, as*
23 *authorized by 7 U.S.C. 1922 et seq.*

24 SEC. 117. *Amounts made available by section 101 to*
25 *the Department of Agriculture for “Rural Business—Coop-*

1 *erative Service—Rural Microentrepreneur Assistance Pro-*
2 *gram” may be used for the costs of loans, including the cost*
3 *of modifying such loans, as defined in section 502 of the*
4 *Congressional Budget Act of 1974, under the same terms*
5 *and conditions as authorized by section 379E of the Con-*
6 *solidated Farm and Rural Development Act (7 U.S.C.*
7 *2008s).*

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

14 *SEC. 119. Amounts made available by section 101 to*
15 *the Department of Commerce for “Economic Development*
16 *Administration—Salaries and Expenses” may be appor-*
17 *tioned up to the rate for operations necessary to maintain*
18 *agency operations.*

19 *SEC. 120. Amounts made available by section 101 for*
20 *“Department of Commerce—National Telecommunications*
21 *and Information Administration—Salaries and Expenses”*
22 *may be apportioned up to the rate for operations necessary*
23 *to ensure continued oversight of public safety communica-*
24 *tions programs.*

1 *SEC. 121. In addition to amounts otherwise provided*
2 *by section 101, for “Department of Justice—Federal Bu-*
3 *reau of Investigation—Salaries and Expenses”, there is ap-*
4 *propriated \$15,300,000, for an additional amount for fiscal*
5 *year 2023, to remain available until September 30, 2023,*
6 *for investigative activities associated with Afghan resettle-*
7 *ment operations: Provided, That such amount is designated*
8 *by the Congress as being for an emergency requirement pur-*
9 *suant to section 4001(a)(1) of S. Con. Res. 14 (117th Con-*
10 *gress), the concurrent resolution on the budget for fiscal year*
11 *2022, and section 1(e) of H. Res. 1151 (117th Congress),*
12 *as engrossed in the House of Representatives on June 8,*
13 *2022.*

14 *SEC. 122. (a) Notwithstanding sections 101 and 106,*
15 *through September 30, 2023, the Secretary of Defense may*
16 *transfer up to \$3,000,000,000 from unobligated balances*
17 *from amounts made available under the heading “Depart-*
18 *ment of Defense—Operation and Maintenance—Overseas*
19 *Humanitarian, Disaster, and Civic Aid” in division C of*
20 *Public Law 117–43 and division B of Public Law 117–*
21 *70 to any appropriation account under the headings “De-*
22 *partment of State and Related Agency—Department of*
23 *State—Administration of Foreign Affairs”, “Bilateral Eco-*
24 *nomics Assistance—Department of State—Migration and*
25 *Refugee Assistance”, and “Bilateral Economic Assistance—*

1 *Department of State—United States Emergency Refugee*
2 *and Migration Assistance Fund” for support of Operation*
3 *Allies Welcome or any successor operation: Provided, That*
4 *upon transfer, such funds shall be merged with the appro-*
5 *priation to which such funds are transferred except that*
6 *such funds may be made available for such purposes not-*
7 *withstanding any requirement or limitation applicable to*
8 *the appropriation to which transferred, including sections*
9 *2(c)(1) and 2(c)(2) of the Migration and Refugee Assistance*
10 *Act of 1962 with respect to the United States Emergency*
11 *Refugee and Migration Assistance Fund and in sections*
12 *4(a) and 4(b) of the State Department Basic Authorities*
13 *Act of 1956 with respect to funds transferred to the Emer-*
14 *gencies in the Diplomatic and Consular Service account:*
15 *Provided further, That section 2215 of title 10, United*
16 *States Code, shall not apply to a transfer of funds under*
17 *this subsection: Provided further, That the exercise of the*
18 *authority of this subsection shall be subject to prior con-*
19 *sultation with, and the regular notification procedures of,*
20 *the Committees on Appropriations of the House of Rep-*
21 *resentatives and the Senate: Provided further, That any*
22 *funds transferred pursuant to this subsection that were pre-*
23 *viously designated by the Congress as an emergency require-*
24 *ment pursuant to the concurrent resolution on the budget*
25 *are designated by the Congress as being for an emergency*

1 *requirement pursuant to section 4001(a)(1) of S. Con. Res.*
2 *14 (117th Congress), the concurrent resolution on the budget*
3 *for fiscal year 2022, and section 1(e) of H. Res. 1151 (117th*
4 *Congress), as engrossed in the House of Representatives on*
5 *June 8, 2022.*

6 *(b) Not later than November 1, 2022 and prior to any*
7 *transfer of funds pursuant to subsection (a), the Director*
8 *of the Office of Management and Budget shall provide to*
9 *the Committees on Appropriations of the House of Rep-*
10 *resentatives and the Senate a written report on Operation*
11 *Allies Welcome or any successor operation: Provided, That*
12 *such report shall describe the number and status of Afghans*
13 *residing at Department of Defense and Department of*
14 *State-managed facilities and any anticipated future arriv-*
15 *als at such facilities; the strategy and plan, including*
16 *timeline, for adjudicating and relocating all Afghans resid-*
17 *ing at Department of Defense or overseas civilian facilities*
18 *and for the transition of operations and responsibilities*
19 *under Operation Allies Welcome or any successor operation*
20 *from the Department of Defense to the Department of State*
21 *during fiscal year 2023; the activities and responsibilities*
22 *assigned to each Federal agency involved in such strategy*
23 *and plan; and a spend plan, containing an estimate of the*
24 *costs, including additional construction and security costs,*
25 *to be incurred by each such agency for carrying out such*

1 *strategy and plan, and the sources of funds: Provided fur-*
2 *ther, That prior to the initial obligation of funds trans-*
3 *ferred to the Department of State pursuant to subsection*
4 *(a), the Secretary of State shall submit a report to such*
5 *Committees detailing the roles and responsibilities of De-*
6 *partment of State bureaus and offices in Operation Allies*
7 *Welcome or any successor operation.*

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

11 *SEC. 124. (a) Of the remaining unobligated balances,*
12 *as of September 30, 2022, from amounts provided under*
13 *the heading “Afghanistan Security Forces Fund” in title*
14 *IX of division C of Public Law 116–260, \$100,000,000 is*
15 *hereby permanently rescinded, and in addition to amounts*
16 *otherwise provided by section 101, an amount of additional*
17 *new budget authority equivalent to the amount rescinded*
18 *pursuant to this subsection is hereby appropriated on Sep-*
19 *tember 30, 2022, for an additional amount for fiscal year*
20 *2022, to remain available until September 30, 2025, for the*
21 *same purposes and under the same authorities provided*
22 *under such heading in Public Law 116–260, in addition*
23 *to other funds as may be available for such purposes.*

24 *(b)(1) Subject to paragraph (2), this section shall be-*
25 *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 ef-*
3 *fect on September 30, 2022.*

4 *SEC. 125. In addition to amounts otherwise provided*
5 *by section 101, for “Corps of Engineers—Civil—Construc-*
6 *tion”, there is appropriated \$20,000,000, for an additional*
7 *amount for fiscal year 2023, to remain available until ex-*
8 *pende, for necessary expenses related to water and waste-*
9 *water infrastructure under section 219 of the Water Re-*
10 *sources Development Act of 1992 (106 Stat. 4835): Pro-*
11 *vided, That such amount is designated by the Congress as*
12 *being for an emergency requirement pursuant to section*
13 *4001(a)(1) of S. Con. Res. 14 (117th Congress), the concur-*
14 *rent resolution on the budget for fiscal year 2022, and sec-*
15 *tion 1(e) of H. Res. 1151 (117th Congress), as engrossed*
16 *in the House of Representatives on June 8, 2022.*

17 *SEC. 126. (a) During the period covered by this Act,*
18 *title I of Public Law 108–361 (the Calfed Bay-Delta Au-*
19 *thorization Act) (118 Stat. 1681), as amended by section*
20 *204 of division D of Public Law 117–103, shall be applied*
21 *by substituting “2023” for “2022” each place it appears.*

22 *(b) During the period covered by this Act, section*
23 *103(f)(4)(A) of title I of Public Law 108–361 (the Calfed*
24 *Bay-Delta Authorization Act) (118 Stat. 1696) shall be ap-*
25 *plied by substituting “\$25,650,000” for “\$25,000,000”.*

1 *SEC. 127. (a) During the period covered by this Act,*
2 *section 9106(g)(2) of Public Law 111–11 (Omnibus Public*
3 *Land Management Act of 2009) shall be applied by sub-*
4 *stituting “2023” for “2022”.*

5 *(b) During the period covered by this Act, section*
6 *104(c) of the Reclamation States Emergency Drought Relief*
7 *Act of 1991 (43 U.S.C. 2214(c)) shall be applied by sub-*
8 *stituting “2023” for “2022”.*

9 *(c) During the period covered by this Act, section 301*
10 *of the Reclamation States Emergency Drought Relief Act*
11 *of 1991 (43 U.S.C. 2241) shall be applied by substituting*
12 *“2023” for “2022”.*

13 *SEC. 128. In addition to amounts otherwise provided*
14 *by section 101, amounts are provided for “Department of*
15 *the Treasury—Alcohol and Tobacco Tax and Trade Bu-*
16 *reau—Salaries and Expenses” at a rate for operations of*
17 *\$14,929,000, for an additional amount to administer the*
18 *Craft Beverage Modernization Act import claims program,*
19 *as required by the Taxpayer Certainty and Disaster Tax*
20 *Relief Act of 2020, and such amounts may be apportioned*
21 *up to the rate for operations necessary to establish and im-*
22 *plement a new import claims program.*

23 *SEC. 129. Notwithstanding section 101, title II of divi-*
24 *sion E of Public Law 117–103 shall be applied by adding*
25 *the following new heading and appropriation language*

1 *under the heading “Executive Office of the President and*
2 *Funds Appropriated to the President”:*

3 *“OFFICE OF THE NATIONAL CYBER DIRECTOR*

4 *“SALARIES AND EXPENSES*

5 *“For necessary expenses of the Office of the National*
6 *Cyber Director, as authorized by section 1752 of the Wil-*
7 *liam M. (Mac) Thornberry National Defense Authorization*
8 *Act for Fiscal Year 2021 (Public Law 116–283),*
9 *\$21,000,000, of which not to exceed \$5,000 shall be available*
10 *for official reception and representation expenses.”.*

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

15 *SEC. 131. In addition to amounts otherwise provided*
16 *by section 101, for “The Judiciary—Courts of Appeals, Dis-*
17 *trict Courts, and Other Judicial Services—Court Security”,*
18 *there is appropriated \$112,500,000, for an additional*
19 *amount for fiscal year 2023, to remain available until ex-*
20 *pended, for security improvements at United States court-*
21 *houses and Federal court facilities: Provided, That not later*
22 *than 90 days after the date of enactment of this Act, and*
23 *every 90 days thereafter until all funds provided by this*
24 *section have been expended, the Director of the Administra-*
25 *tive Office of the United States Courts shall provide, in an*

1 appropriate format, quarterly reports on the obligations
2 and expenditures of the funds provided under this section
3 to the Committees on Appropriations of the House of Rep-
4 resentatives and the Senate: Provided further, That such
5 amount is designated by the Congress as being for an emer-
6 gency requirement pursuant to section 4001(a)(1) of S. Con-
7 Res. 14 (117th Congress), the concurrent resolution on the
8 budget for fiscal year 2022, and section 1(e) of H. Res. 1151
9 (117th Congress), as engrossed in the House of Representa-
10 tives on June 8, 2022.

11 *SEC. 132. Notwithstanding any other provision of this*
12 *Act, except section 106, the District of Columbia may ex-*
13 *pend local funds made available under the heading “Dis-*
14 *trict of Columbia—District of Columbia Funds” for such*
15 *programs and activities under the District of Columbia Ap-*
16 *propriations Act, 2022 (title IV of division E of Public Law*
17 *117–103) at the rate set forth in the Fiscal Year 2023 Local*
18 *Budget Act of 2022 (D.C. Act 24–486), as modified as of*
19 *the date of enactment of this Act.*

20 *SEC. 133. In addition to amounts otherwise provided*
21 *by section 101, amounts are provided for “Small Business*
22 *Administration—Salaries and Expenses” at a rate for op-*
23 *erations of \$20,000,000, for an additional amount for costs*
24 *associated with the establishment and implementation of a*
25 *Government-wide service-disabled veteran-owned small*

1 *business certification program within the Small Business*
2 *Administration, as required by section 36 of the Small*
3 *Business Act (15 U.S.C. 657f) and section 862 of Public*
4 *Law 116–283: Provided, That such amounts may be appor-*
5 *tioned up to the rate for operations necessary to establish*
6 *and implement such certification program: Provided fur-*
7 *ther, That such amounts may be obligated in the account*
8 *and budget structure set forth in H.R. 8294, as passed by*
9 *the House of Representatives on July 20, 2022.*

10 *SEC. 134. Amounts made available by section 101 for*
11 *“Small Business Administration—Business Loans Pro-*
12 *gram Account” may be apportioned up to the rate for oper-*
13 *ations necessary to accommodate increased demand for*
14 *commitments for general business loans authorized under*
15 *paragraphs (1) through (35) of section 7(a) of the Small*
16 *Business Act (15 U.S.C. 636(a)), for guarantees of trust cer-*
17 *tificates authorized by section 5(g) of the Small Business*
18 *Act (15 U.S.C. 634(g)), for commitments to guarantee loans*
19 *under section 503 of the Small Business Investment Act of*
20 *1958 (15 U.S.C. 697), and for commitments to guarantee*
21 *loans for debentures under section 303(b) of the Small Busi-*
22 *ness Investment Act of 1958 (15 U.S.C. 683(b)).*

23 *SEC. 135. Amounts made available by section 101 to*
24 *the Department of Homeland Security under the heading*
25 *“Federal Emergency Management Agency—Disaster Relief*

1 *Fund*” may be apportioned up to the rate for operations
2 necessary to carry out response and recovery activities
3 under the Robert T. Stafford Disaster Relief and Emer-
4 gency Assistance Act (42 U.S.C. 5121 et seq.).

5 SEC. 136. Notwithstanding sections 101, 104, and 106,
6 to carry out the Hermit’s Peak/Calf Canyon Fire Assistance
7 Act, there is appropriated \$2,500,000,000, to remain avail-
8 able until expended, to the Department of Homeland Secu-
9 rity for “Federal Emergency Management Agency—Her-
10 mit’s Peak/Calf Canyon Fire Assistance Account”, which
11 shall be derived by transfer from amounts made available
12 under the heading “Federal Emergency Management Agen-
13 cy—Disaster Relief Fund” in title VI of division B of the
14 Coronavirus Aid, Relief, and Economic Security Act (Pub-
15 lic Law 116–136), of which \$1,000,000 shall be transferred
16 to “Office of the Inspector General—Operations and Sup-
17 port” for oversight of activities authorized by the Hermit’s
18 Peak/Calf Canyon Fire Assistance Act: Provided, That no
19 amounts may be derived from amounts made available for
20 major disasters declared pursuant to the Robert T. Stafford
21 Disaster Relief and Emergency Assistance Act (42 U.S.C.
22 5121 et seq.): Provided further, That amounts provided by
23 this section shall be subject to the same authorities and con-
24 ditions as if such amounts were provided by title III of
25 the Department of Homeland Security Appropriations Act,

1 2022 (division F of Public Law 117–103): Provided further,
2 That not later than 90 days after the date of enactment
3 of this Act, and every 90 days thereafter until all funds
4 provided by this section have been expended, the Adminis-
5 trator of the Federal Emergency Management Agency shall
6 provide, in an appropriate format, quarterly reports to the
7 Committees on Appropriations of the Senate and the House
8 of Representatives on the obligations and expenditures of
9 the funds made available by this section: Provided further,
10 That amounts transferred by this section that were pre-
11 viously designated by the Congress as an emergency require-
12 ment pursuant to the Balanced Budget and Emergency Def-
13 icit Control Act of 1985 or a concurrent resolution on the
14 budget are designated as an emergency requirement pursu-
15 ant to section 4001(a)(1) of S. Con. Res. 14 (117th Con-
16 gress), the concurrent resolution on the budget for fiscal year
17 2022, and section 1(e) of H. Res. 1151 (117th Congress),
18 as engrossed in the House of Representatives on June 8,
19 2022.

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

1 *SEC. 138. During the period covered by this Act, sec-*
2 *tion 822(a) of the Homeland Security Act of 2002 (6 U.S.C.*
3 *383(a)) shall be applied by substituting “2023” for “2022”.*

4 *SEC. 139. (a) Sections 1309(a) and 1319 of the Na-*
5 *tional Flood Insurance Act of 1968 (42 U.S.C. 4016(a) and*
6 *4026) shall be applied by substituting the date specified in*
7 *section 106(3) of this Act for “September 30, 2022”.*

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

10 *(2) If this Act is enacted after September 30,*
11 *2022, this section shall be applied as if it were in ef-*
12 *fect on September 30, 2022.*

13 *SEC. 140. Section 880(g) of the National Defense Au-*
14 *thorization Act for Fiscal Year 2017 (Public Law 114–328)*
15 *shall be applied by substituting the date specified in section*
16 *106(3) of this Act for “September 30, 2022”.*

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

22 *SEC. 142. Amounts made available by section 101 for*
23 *“Department of the Interior—National Park Service—Na-*
24 *tional Recreation and Preservation” for heritage partner-*
25 *ship programs may be used to provide financial assistance*

1 *to any national heritage area, national heritage corridor,*
2 *cultural heritage corridor, national heritage partnership,*
3 *national heritage route, national heritage canalway, and*
4 *battlefields national historic district established as of Sep-*
5 *tember 1, 2022, notwithstanding any statutory sunset pro-*
6 *vision terminating the Secretary’s authority to provide as-*
7 *sistance to any such area and notwithstanding any limita-*
8 *tion on amounts authorized to be appropriated with respect*
9 *to any such area.*

10 *SEC. 143. Amounts made available by section 101 to*
11 *the Department of the Interior under the heading “Working*
12 *Capital Fund” may be apportioned up to the rate for oper-*
13 *ations necessary to implement enterprise cybersecurity safe-*
14 *guards.*

15 *SEC. 144. (a) In addition to amounts otherwise pro-*
16 *vided by section 101, amounts are provided for “Depart-*
17 *ment of Health and Human Services—Indian Health Serv-*
18 *ice—Indian Health Services” at a rate for operations of*
19 *\$16,721,000, 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 *(b) In addition to amounts otherwise provided by sec-*
25 *tion 101, amounts are provided for “Department of Health*

1 *and Human Services—Indian Health Service—Indian*
2 *Health Facilities” at a rate for operations of \$1,201,000,*
3 *for an additional amount for costs of staffing and operating*
4 *facilities that were opened, renovated, or expanded in fiscal*
5 *years 2022 and 2023, and such amounts may be appor-*
6 *tioned up to the rate for operations necessary to staff and*
7 *operate such facilities.*

8 *SEC. 145. In addition to amounts otherwise provided*
9 *by section 101, for “Department of Health and Human*
10 *Services—Substance Abuse and Mental Health Services Ad-*
11 *ministration—Mental Health”, there is appropriated*
12 *\$62,000,000, for an additional amount for fiscal year 2023,*
13 *to remain available until September 30, 2023, for carrying*
14 *out 988 Suicide Lifeline activities and behavioral health*
15 *crisis services.*

16 *SEC. 146. In addition to amounts otherwise provided*
17 *by section 101, for “Department of Health and Human*
18 *Services—Administration for Children and Families—Low*
19 *Income Home Energy Assistance”, there is appropriated*
20 *\$1,000,000,000, for an additional amount for fiscal year*
21 *2023, to remain available until September 30, 2023, for*
22 *making payments under subsection (b) of section 2602 of*
23 *the Low-Income Home Energy Assistance Act of 1981 (42*
24 *U.S.C. 8621 et seq.): Provided, That of the funds made*
25 *available by this section, \$500,000,000 shall be allocated as*

1 *though the total appropriation for such payments for fiscal*
2 *year 2023 was less than \$1,975,000,000: Provided further,*
3 *That such amount is designated by the Congress as being*
4 *for an emergency requirement pursuant to section*
5 *4001(a)(1) of S. Con. Res. 14 (117th Congress), the concur-*
6 *rent resolution on the budget for fiscal year 2022, and sec-*
7 *tion 1(e) of H. Res. 1151 (117th Congress), as engrossed*
8 *in the House of Representatives on June 8, 2022.*

9 *SEC. 147. In addition to amounts otherwise provided*
10 *by section 101, for “Department of Health and Human*
11 *Services—Administration for Children and Families—Ref-*
12 *ugee and Entrant Assistance”, there is appropriated*
13 *\$1,775,000,000, for an additional amount for fiscal year*
14 *2023, to remain available until September 30, 2025, to*
15 *carry out section 462 of the Homeland Security Act of 2002*
16 *and section 235 of the William Wilberforce Trafficking Vic-*
17 *tims Protection Reauthorization Act of 2008, and for ref-*
18 *ugee and entrant assistance activities authorized by section*
19 *414 of the Immigration and Nationality Act and section*
20 *501 of the Refugee Education Assistance Act of 1980: Pro-*
21 *vided, That such amount is designated by the Congress as*
22 *being for an emergency requirement pursuant to section*
23 *4001(a)(1) of S. Con. Res. 14 (117th Congress), the concur-*
24 *rent resolution on the budget for fiscal year 2022, and sec-*

1 *tion 1(e) of H. Res. 1151 (117th Congress), as engrossed*
2 *in the House of Representatives on June 8, 2022.*

3 *SEC. 148. Notwithstanding section 101, the first para-*
4 *graph under the heading “Social Security Administra-*
5 *tion—Limitation on Administrative Expenses” in title IV*
6 *of division H of Public Law 117–103 shall be applied by*
7 *substituting “\$13,602,945,000” for “\$13,202,945,000”.*

8 *SEC. 149. (a) During the period covered by this Act,*
9 *subsection (a)(1)(A) of section 2502 of the Afghanistan Sup-*
10 *plemental Appropriations Act, 2022 (division C of Public*
11 *Law 117–43) shall be applied by substituting the date speci-*
12 *fied in section 106(3) for “September 30, 2022”.*

13 *(b) The amount provided by this section is designated*
14 *as an emergency requirement pursuant to section*
15 *4001(a)(1) of S. Con. Res. 14 (117th Congress), the concur-*
16 *rent resolution on the budget for fiscal year 2022, and sec-*
17 *tion 1(e) of H. Res. 1151 (117th Congress), as engrossed*
18 *in the House of Representatives on June 8, 2022.*

19 *SEC. 150. Activities authorized by part A of title IV*
20 *(other than under section 403(c) or 418) and section*
21 *1108(b) of the Social Security Act shall continue through*
22 *the date specified in section 106(3), in the manner author-*
23 *ized for fiscal year 2022, and out of any money in the*
24 *Treasury of the United States not otherwise appropriated,*

1 *there are hereby appropriated such sums as may be nec-*
2 *essary for such purpose.*

3 *SEC. 151. Notwithstanding section 101, section 126 of*
4 *division J of Public Law 117–103 shall be applied during*
5 *the period covered by this Act by substituting “fiscal year*
6 *2017 and fiscal year 2018” for “fiscal year 2017”.*

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

9 *(1) “Department of State and Related Agency—*
10 *Department of State—Administration of Foreign Af-*
11 *fairs—Diplomatic Programs” at a rate for operations*
12 *of \$9,228,789,000;*

13 *(2) “Bilateral Economic Assistance—Funds Ap-*
14 *propriated to the President—International Disaster*
15 *Assistance” at a rate for operations of \$4,555,460,000;*

16 *(3) “Bilateral Economic Assistance—Funds Ap-*
17 *propriated to the President—Transition Initiatives”*
18 *at a rate for operations of \$100,000,000;*

19 *(4) “Bilateral Economic Assistance—Funds Ap-*
20 *propriated to the President—Assistance for Europe,*
21 *Eurasia and Central Asia” at a rate for operations*
22 *of \$850,000,000;*

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

1 (6) “*International Security Assistance—Depart-*
2 *ment of State—International Narcotics Control and*
3 *Law Enforcement*” at a rate for operations of
4 \$1,421,004,000; and

5 (7) “*International Security Assistance—Funds*
6 *Appropriated to the President—Foreign Military Fi-*
7 *nancing Program*” at a rate for operations of
8 \$6,190,424,000.

9 SEC. 153. *During the period covered by this Act, sec-*
10 *tion 579 of the Multifamily Assisted Housing Reform and*
11 *Affordability Act of 1997 (42 U.S.C. 1437f note) shall be*
12 *applied by substituting “2023” for “2022” each place it ap-*
13 *pears.*

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

22 SEC. 155. *In addition to amounts otherwise provided*
23 *by section 101, for “Department of Housing and Urban De-*
24 *velopment—Community Planning and Development—*
25 *Community Development Fund”, there is appropriated*

1 \$2,000,000,000, for an additional amount for fiscal year
2 2023, to remain available until expended, for the same pur-
3 poses and under the same terms and conditions as funds
4 appropriated under such heading in title VIII of the Dis-
5 aster Relief Supplemental Appropriations Act, 2022 (divi-
6 sion B of Public Law 117–43), except that such amounts
7 shall be for major disasters that occurred in 2021 or 2022
8 and the fourth, twentieth, and twenty-first provisos under
9 such heading in such Act shall not apply: Provided, That
10 amounts made available under this section and under such
11 heading in such Act may be used by a grantee to assist
12 utilities as part of a disaster-related eligible activity under
13 section 105(a) of the Housing and Community Development
14 Act of 1974 (42 U.S.C. 5305(a)): Provided further, That
15 such amount is designated by the Congress as being for an
16 emergency requirement pursuant to section 4001(a)(1) of
17 S. Con. Res. 14 (117th Congress), the concurrent resolution
18 on the budget for fiscal year 2022, and section 1(e) of H.
19 Res. 1151 (117th Congress), as engrossed in the House of
20 Representatives on June 8, 2022.

21 SEC. 156. Notwithstanding section 106 of this Act, at
22 any time during fiscal year 2023, the Secretary of Housing
23 and Urban Development may transfer up to \$1,300,000 in
24 unobligated balances from amounts made available in prior
25 Acts under the heading “Housing Programs—Project-Based

1 *Rental Assistance” to Treasury Appropriation Fund Sym-*
2 *bol 86 X 0148 for the liquidation of obligations incurred*
3 *in fiscal year 2018 in connection with the continued provi-*
4 *sion of interest reduction payments authorized under sec-*
5 *tion 236 of the National Housing Act (12 U.S.C. 1715z–*
6 *1).*

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

23 *(b) The remaining unobligated balances, as of Sep-*
24 *tember 30, 2022, from amounts made available to the De-*
25 *partment of Transportation in section 105 of division L*

1 *of the Consolidated Appropriations Act, 2021 (Public Law*
2 *116–260) are hereby permanently rescinded, and in addi-*
3 *tion to amounts otherwise provided by section 101, an*
4 *amount of additional new budget authority equivalent to*
5 *the amount rescinded pursuant to this subsection is hereby*
6 *appropriated on September 30, 2022, for an additional*
7 *amount for fiscal year 2022, to remain available until Sep-*
8 *tember 30, 2023, and shall be available, without additional*
9 *competition, for completing the funding of awards made*
10 *pursuant to the fiscal year 2019 national infrastructure in-*
11 *vestments program, in addition to other funds as may be*
12 *available for such purposes.*

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

15 *(2) If this Act is enacted after September 30,*
16 *2022, this section shall be applied as if it were in ef-*
17 *fect on September 30, 2022.*

18 *This division may be cited as the “Continuing Appro-*
19 *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 September*
13 *30, 2023, to respond to the situation in Ukraine and for*
14 *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 related*
19 *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 and*
24 *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 and*
5 *for related expenses.*

6 *OPERATION AND MAINTENANCE*7 *OPERATION AND MAINTENANCE, ARMY*

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

12 *OPERATION AND MAINTENANCE, NAVY*

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

17 *OPERATION AND MAINTENANCE, MARINE CORPS*

18 *For an additional amount for “Operation and Mainte-*
19 *nance, 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 Mainte-*
24 *nance, Air Force”, \$267,084,000, to remain available until*

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

3 *OPERATION AND MAINTENANCE, SPACE FORCE*

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

8 *OPERATION AND MAINTENANCE, DEFENSE-WIDE*

9 *(INCLUDING TRANSFER OF FUNDS)*

10 *For an additional amount for “Operation and Mainte-*
11 *nance, Defense-Wide”, \$4,713,544,000, to remain available*
12 *until September 30, 2023, to respond to the situation in*
13 *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 Se-*
18 *curity Assistance Initiative shall be available to the Sec-*
19 *retary of Defense under the same terms and conditions as*
20 *are provided for in section 8139 of the Department of De-*
21 *fense Appropriations Act, 2022 (division C of Public Law*
22 *117–103): Provided further, That of the total amount pro-*
23 *vided under this heading in this Act, up to \$1,500,000,000,*
24 *to remain available until September 30, 2024, may be*
25 *transferred to accounts under the headings “Operation and*

1 *Maintenance” and “Procurement” for replacement of de-*
2 *fense articles from the stocks of the Department of Defense,*
3 *and for reimbursement for defense services of the Depart-*
4 *ment of Defense and military education and training, pro-*
5 *vided to the government of Ukraine or to foreign countries*
6 *that have provided support to Ukraine at the request of the*
7 *United States: Provided further, That funds transferred*
8 *pursuant to a transfer authority provided under this head-*
9 *ing in this Act shall be merged with and available for the*
10 *same purposes and for the same time period as the appro-*
11 *priations to which the funds are transferred: Provided fur-*
12 *ther, That the Secretary of Defense shall notify the congres-*
13 *sional defense committees of the details of such transfers not*
14 *less than 15 days before any such transfer: Provided further,*
15 *That upon a determination that all or part of the funds*
16 *transferred from this appropriation are not necessary for*
17 *the purposes provided herein, such amounts may be trans-*
18 *ferred back and merged with this appropriation: Provided*
19 *further, That the transfer authority provided under this*
20 *heading in this Act is in addition to any other transfer*
21 *authority provided by law.*

22 *PROCUREMENT*

23 *MISSILE PROCUREMENT, ARMY*

24 *For an additional amount for “Missile Procurement,*
25 *Army”, \$450,000,000, to remain available until September*

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

3 *PROCUREMENT OF AMMUNITION, ARMY*

4 *For an additional amount for “Procurement of Am-*
5 *munition, Army”, \$540,000,000, to remain available until*
6 *September 30, 2025, for expansion of public and private*
7 *plants, including the land necessary therefor, and procure-*
8 *ment and installation of equipment, appliances, and ma-*
9 *chine tools in such plants, for the purpose of increasing pro-*
10 *duction of critical munitions to replace defense articles pro-*
11 *vided to the Government of Ukraine or foreign countries*
12 *that have provided support to Ukraine at the request of the*
13 *United States.*

14 *OTHER PROCUREMENT, ARMY*

15 *For an additional amount for “Other Procurement,*
16 *Army”, \$3,890,000, to remain available until September*
17 *30, 2025, to respond to the situation in Ukraine and for*
18 *related expenses.*

19 *OTHER PROCUREMENT, NAVY*

20 *For an additional amount for “Other Procurement,*
21 *Navy”, \$2,170,000, to remain available until September 30,*
22 *2025, to respond to the situation in Ukraine and for related*
23 *expenses.*

1 *OTHER PROCUREMENT, AIR FORCE*

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

6 *PROCUREMENT, DEFENSE-WIDE*

7 *For an additional amount for “Procurement, Defense-*
8 *Wide”, \$9,770,000, to remain available until September 30,*
9 *2025, to respond to the situation in Ukraine and for related*
10 *expenses.*

11 *RESEARCH, DEVELOPMENT, TEST AND*
12 *EVALUATION*

13 *RESEARCH, DEVELOPMENT, TEST AND EVALUATION, ARMY*
14 *For an additional amount for “Research, Develop-*
15 *ment, Test and Evaluation, Army”, \$3,300,000, to remain*
16 *available until September 30, 2024, to respond to the situa-*
17 *tion in Ukraine and for related expenses.*

18 *RESEARCH, DEVELOPMENT, TEST AND EVALUATION, NAVY*

19 *For an additional amount for “Research, Develop-*
20 *ment, Test and Evaluation, Navy”, \$2,077,000, to remain*
21 *available until September 30, 2024, to respond to the situa-*
22 *tion in Ukraine and for related expenses.*

1 *RESEARCH, DEVELOPMENT, TEST AND EVALUATION, AIR*
2 *FORCE*

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

7 *RESEARCH, DEVELOPMENT, TEST AND EVALUATION,*
8 *DEFENSE-WIDE*

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

13 *OTHER DEPARTMENT OF DEFENSE PROGRAMS*
14 *OFFICE OF THE INSPECTOR GENERAL*

15 *For an additional amount for “Office of the Inspector*
16 *General”, \$2,000,000, to remain available until September*
17 *30, 2023, to carry out reviews of the activities of the Depart-*
18 *ment of Defense to execute funds appropriated in this title,*
19 *including assistance provided to Ukraine: Provided, That*
20 *the Inspector General of the Department of Defense shall*
21 *provide to the congressional defense committees a briefing*
22 *not later than 90 days after the date of enactment of this*
23 *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 coordina-*
10 *tion with the Secretary of State, shall submit a report to*
11 *the Committees on Appropriations, Armed Services, and*
12 *Foreign Affairs of the House of Representatives and the*
13 *Committees on Appropriations, Armed Services, and For-*
14 *ign Relations of the Senate on measures being taken to*
15 *account for United States defense articles designated for*
16 *Ukraine since the February 24, 2022, Russian invasion of*
17 *Ukraine, particularly measures with regard to such articles*
18 *that require enhanced end-use monitoring; measures to en-*
19 *sure that such articles reach their intended recipients and*
20 *are used for their intended purposes; and any other meas-*
21 *ures to promote accountability for the use of such articles:*
22 *Provided, That such report shall include a description of*
23 *any occurrences of articles not reaching their intended re-*
24 *cipients or used for their intended purposes and a descrip-*
25 *tion of any remedies taken: Provided further, That such re-*

1 *port shall be submitted in unclassified form, but may be*
 2 *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 through*
 5 *fiscal year 2023, the Secretary of Defense, in coordination*
 6 *with the Secretary of State, shall provide a written report*
 7 *to the Committees on Appropriations, Armed Services, and*
 8 *Foreign Affairs of the House of Representatives and the*
 9 *Committees on Appropriations, Armed Services, and For-*
 10 *ign Relations of the Senate describing United States secu-*
 11 *rity assistance provided to Ukraine since the February 24,*
 12 *2022, Russian invasion of Ukraine, including a comprehen-*
 13 *sive list of the defense articles and services provided to*
 14 *Ukraine and the associated authority and funding used to*
 15 *provide such articles and services: Provided, That such re-*
 16 *port shall be submitted in unclassified form, but may be*
 17 *accompanied by a classified annex.*

18

TITLE II

19

DEPARTMENT OF ENERGY

20

ATOMIC ENERGY DEFENSE ACTIVITIES

21

NATIONAL NUCLEAR SECURITY ADMINISTRATION

22

DEFENSE NUCLEAR NONPROLIFERATION

23

24 *For an additional amount for “Defense Nuclear Non-*
proliferation”, \$35,000,000, to remain available until ex-

1 *pending, to respond to the situation in Ukraine and for re-*
 2 *lated expenses.*

3 *TITLE III*

4 *BILATERAL ECONOMIC ASSISTANCE*

5 *FUNDS APPROPRIATED TO THE PRESIDENT*

6 *ECONOMIC SUPPORT FUND*

7 *For an additional amount for “Economic Support*
 8 *Fund”, \$4,500,000,000, to remain available until Sep-*
 9 *tember 30, 2024, for assistance for Ukraine: Provided, That*
 10 *funds appropriated under this heading in this Act may be*
 11 *made available notwithstanding any other provision of law*
 12 *that restricts assistance to foreign countries and may be*
 13 *made available as contributions.*

14 *GENERAL PROVISIONS—THIS TITLE*

15 *SEC. 1301. During fiscal year 2023, section 506(a)(1)*
 16 *of the Foreign Assistance Act of 1961 (22 U.S.C.*
 17 *2318(a)(1)) shall be applied by substituting*
 18 *“\$3,700,000,000” for “\$100,000,000”.*

19 *SEC. 1302. (a) Funds appropriated by this title shall*
 20 *be made available for direct financial support for the Gov-*
 21 *ernment of Ukraine, including for Ukrainian first respond-*
 22 *ers, and may be made available as a cash transfer subject*
 23 *to the requirements of subsection (b): Provided, That such*
 24 *funds shall be provided on a reimbursable basis and*
 25 *matched by sources other than the United States Govern-*

1 *ment, to the maximum extent practicable: Provided further,*
2 *That the Secretary of State or the Administrator of the*
3 *United States Agency for International Development, as*
4 *appropriate, shall ensure third-party monitoring of such*
5 *funds: Provided further, That at least 15 days prior to the*
6 *initial obligation of such funds, the Secretary of State, fol-*
7 *lowing consultation with the Administrator of the United*
8 *States Agency for International Development, shall certify*
9 *and report to the appropriate congressional committees that*
10 *mechanisms for monitoring and oversight of such funds are*
11 *in place and functioning and that the Government of*
12 *Ukraine has in place substantial safeguards to prevent cor-*
13 *ruption and ensure accountability of such funds: Provided*
14 *further, That not less than 45 days after the initial obliga-*
15 *tion of such funds, the Inspectors General of the Department*
16 *of State and the United States Agency for International*
17 *Development shall submit a report to the appropriate con-*
18 *gressional committees detailing and assessing the mecha-*
19 *nisms for monitoring and safeguards described in the pre-*
20 *vious proviso.*

21 *(b) Funds made available to the Government of*
22 *Ukraine as a cash transfer under subsection (a) shall be*
23 *subject to a memorandum of understanding between the*
24 *Governments of the United States and Ukraine that de-*
25 *scribes how the funds proposed to be made available will*

1 *be used and the appropriate safeguards to ensure trans-*
2 *parency and accountability: Provided, That such assistance*
3 *shall be maintained in a separate, auditable account and*
4 *may not be comingled with any other funds.*

5 *(c) The Secretary of State or the Administrator of the*
6 *United States Agency for International Development, as*
7 *appropriate, shall report to the appropriate congressional*
8 *committees on the uses of funds provided for direct financial*
9 *support to the Government of Ukraine pursuant to sub-*
10 *section (a) not later than 45 days after the date of enact-*
11 *ment of this Act and every 45 days thereafter until all such*
12 *funds have been expended: Provided, That such report shall*
13 *include a detailed description of the use of such funds, in-*
14 *cluding categories and amounts, the intended results and*
15 *the results achieved, a summary of other donor contribu-*
16 *tions, and a description of the efforts undertaken by the Sec-*
17 *retary and Administrator to increase other donor contribu-*
18 *tions for direct financial support: Provided further, That*
19 *such report shall also include the metrics established to*
20 *measure such results.*

21 *(d) Funds made available for the purposes of sub-*
22 *section (a) shall be subject to the regular notification proce-*
23 *dures of the Committees on Appropriations of the House*
24 *of Representatives and the Senate.*

1

TITLE IV

2

GENERAL PROVISIONS—THIS ACT

3

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

6

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

9

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

14

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

21

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

22

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 1934*
 7 *(47 U.S.C. 309(j)(11)) is amended by striking “September*
 8 *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 2022”.*

20 *(b) AMENDMENT OF SENTENCING REFORM ACT OF*
 21 *1984.—For purposes of section 235(b) of the Sentencing Re-*
 22 *form Act of 1984 (18 U.S.C. 3551 note; Public Law 98–*
 23 *473; 98 Stat. 2032), as such section relates to chapter 311*
 24 *of title 18, United States Code, and the United States Pa-*
 25 *role Commission, each reference in such section to “35*

1 *years” or “35-year period” shall be deemed a reference to*
 2 *“35 years and 46 days” or “35-year and 46-day period”,*
 3 *respectively.*

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

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

10 **TITLE II—BUDGETARY EFFECTS**

11 **SEC. 201. BUDGETARY EFFECTS.**

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

17 *(b) SENATE PAYGO SCORECARDS.—The budgetary ef-*
 18 *fects of this division and each succeeding division shall not*
 19 *be entered on any PAYGO scorecard maintained for pur-*
 20 *poses of section 4106 of H. Con. Res. 71 (115th Congress).*

21 *(c) CLASSIFICATION OF BUDGETARY EFFECTS.—Not-*
 22 *withstanding Rule 3 of the Budget Scorekeeping Guidelines*
 23 *set forth in the joint explanatory statement of the committee*
 24 *of conference accompanying Conference Report 105–217*
 25 *and section 250(c)(8) of the Balanced Budget and Emer-*

1 *gency Deficit Control Act of 1985, the budgetary effects of*
2 *this division and each succeeding division shall not be esti-*
3 *mated—*

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

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

8 *(3) for purposes of paragraph (4)(C) of section*
9 *3 of the Statutory Pay-As-You-Go Act of 2010 as*
10 *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 and*
12 *subsequent fiscal years” and inserting “during the*
13 *portion of fiscal year 2023 beginning on December 17,*
14 *2022, and ending on September 30, 2023, and in fis-*
15 *cal year 2024 and subsequent fiscal years”;*

16 (2) *in subparagraph (C)(i)—*

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

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

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

24 (B) *in subclause (III), by inserting “and*
25 *the portion of fiscal year 2023 beginning on Oc-*

1 tober 1, 2022, and ending on December 16,
2 2022” after “through 2022”; and

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

8 (3) in subparagraph (D)—

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

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

18 (b) *IMPLEMENTATION.*—Notwithstanding any other
19 provision of law, the Secretary of Health and Human Serv-
20 ices may implement the provisions of, including the amend-
21 ments made by, this section by program instruction or oth-
22 erwise.

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

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

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

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

9 (b) *CONFORMING AMENDMENTS.*—

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

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

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

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

1 *fiscal year 2023 beginning on October 1, 2022, and*
 2 *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 U.S.C.*
 6 *1396d(ff)) is amended by striking “December 13” each place*
 7 *it appears and inserting “December 16” in each such place.*

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

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

12 **TITLE II—HUMAN SERVICES**

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

15 *Activities authorized by section 511 of the Social Secu-*
 16 *rity Act shall continue through December 16, 2022, in the*
 17 *manner authorized for fiscal year 2022, and out of any*
 18 *money in the Treasury of the United States not otherwise*
 19 *appropriated, there is hereby appropriated for such purpose*
 20 *an amount equal to the pro rata portion of the amount ap-*
 21 *propriated for such activities for fiscal year 2022.*

22 **SEC. 202. EXTENSION OF CHILD AND FAMILY SERVICES**
 23 **PROGRAMS.**

24 *Activities authorized by part B of title IV of the Social*
 25 *Security Act shall continue through December 16, 2022, in*

1 *the manner authorized for fiscal year 2022, and out of any*
 2 *money in the Treasury of the United States not otherwise*
 3 *appropriated, there are hereby appropriated such sums as*
 4 *may be necessary for such purpose.*

5 ***TITLE III—PUBLIC HEALTH***

6 ***SEC. 301. EXTENSION OF THE PROGRAM TO DEEM CERTAIN***
 7 ***HEALTH PROFESSIONAL VOLUNTEERS EM-***
 8 ***PLOYEES OF THE PUBLIC HEALTH SERVICE***
 9 ***UNDER CERTAIN CIRCUMSTANCES.***

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

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

15 (1) *in subsection (g)(1)(H)(iv), by striking “this*
 16 *section.” and inserting “this section).”;*

17 (2) *in subsection (k)(3), by inserting “governing*
 18 *board members,” after “officers,”;*

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

21 (4) *in subsection (q)(5)(A), by striking “and*
 22 *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) shall*
8 *apply to such leave by substituting “2022” for “2020” in*
9 *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 in-*
14 *serting “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 Code,*
10 *is amended by striking “September 30, 2022” and inserting*
11 *“September 30, 2024”.*

12 ***SEC. 102. EXTENSION OF REQUIREMENT TO PROVIDE NURS-***
13 ***ING HOME CARE TO CERTAIN VETERANS***
14 ***WITH SERVICE-CONNECTED DISABILITIES.***

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

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

20 *Section 8111(d)(3) of title 38, United States Code, is*
21 *amended by striking “September 30, 2023” and inserting*
22 *“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 Authorization*
6 *Act for Fiscal Year 2010 (Public Law 111–84; 123 Stat.*
7 *2573), as most recently amended by section 715 of the Na-*
8 *tional Defense Authorization Act for Fiscal Year 2022 (Pub-*
9 *lic Law 117–81; 135 Stat. 1787), is amended by striking*
10 *“September 30, 2023” and inserting “September 30, 2024”.*

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

15 *Section 104(a) of the Honoring America’s Veterans*
16 *and Caring for Camp Lejeune Families Act of 2012 (Public*
17 *Law 112–154; 126 Stat. 1169), as most recently amended*
18 *by section 3 of the Department of Veterans Affairs Expiring*
19 *Authorities Act of 2021 (Public Law 117–42; 135 Stat.*
20 *342), is amended by striking “September 30, 2022” and*
21 *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, is*
8 *amended by striking “September 30, 2022” and inserting*
9 *“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 ADMINIS-**
18 **TRATIVE 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 AS-**
10 **SISTIVE 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 Code,*
21 *is amended by striking “2022” and inserting “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, is*
6 *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 “September*
12 *30, 2022” and inserting “September 30, 2024”.*

13 *(b) ADDITIONAL SERVICES AT CERTAIN LOCATIONS.—*
14 *Section 2033(d) of such title is amended by striking “Sep-*
15 *tember 30, 2022” and inserting “September 30, 2024”.*

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

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

1 Code, is amended by striking “and 2022” and inserting
2 “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) of
6 such section is amended by striking “. for each of fiscal
7 years 2010 through 2020”.

8 **SEC. 403. EXTENSION OF ADVISORY COMMITTEE ON MINOR-**
9 **ITY 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 COMMITTEE**
14 **ON EDUCATION.**

15 Section 3692(c) 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, is
21 amended by striking “September 30, 2022” and inserting
22 “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 Re-*
 5 *authorization 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.

Sec. 4004. Reauthorization; reporting requirements.

Sec. 4005. Sunset dates.
Sec. 4006. Effective date.
Sec. 4007. Savings clause.

TITLE V—REAUTHORIZATION OF OTHER PROVISIONS

Sec. 5001. Reauthorization of the best pharmaceuticals for children program.
Sec. 5002. Reauthorization of the humanitarian device exemption incentive.
Sec. 5003. Reauthorization of the pediatric device consortia program.
Sec. 5004. Reauthorization of provision pertaining to drugs containing single enantiomers.
Sec. 5005. Reauthorization of the critical path public-private partnership.
Sec. 5006. Reauthorization of orphan drug grants.
Sec. 5007. Reauthorization of certain device inspections.
Sec. 5008. Reauthorization of reporting requirements related to pending generic drug applications and priority review applications.

1 **TITLE I—FEES RELATING TO**
 2 **DRUGS**

3 **SEC. 1001. SHORT TITLE; FINDING.**

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

6 (b) *FINDING.*—*Congress finds that the fees authorized*
 7 *by the amendments made by this title will be dedicated to-*
 8 *ward expediting the drug development process and the proc-*
 9 *ess for the review of human drug applications, including*
 10 *postmarket drug safety activities, as set forth in the goals*
 11 *identified for purposes of part 2 of subchapter C of chapter*
 12 *VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 13 *379g et seq.), in the letters from the Secretary of Health*
 14 *and 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 Congres-*
 18 *sional Record.*

1 **SEC. 1002. DEFINITIONS.**

2 (a) *HUMAN DRUG APPLICATION*.—Section 735(1) of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 379g(1)) is amended, in the matter following subparagraph
5 (B), by striking “an allergenic extract product, or” and in-
6 serting “does not include an application with respect to an
7 allergenic extract product licensed before October 1, 2022,
8 does not include an application with respect to a standard-
9 ized allergenic extract product submitted pursuant to a no-
10 tification to the applicant from the Secretary regarding the
11 existence of a potency test that measures the allergenic ac-
12 tivity of an allergenic extract product licensed by the appli-
13 cant before October 1, 2022, does not include an application
14 with respect to”.

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

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

20 (2) by striking “(3) The term” and inserting
21 “(3)(A) The term”;

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

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

25 (4) by striking “an allergenic extract product,”
26 and inserting “an allergenic extract product licensed

1 *before October 1, 2022, a standardized allergenic ex-*
2 *tract product submitted pursuant to a notification to*
3 *the applicant from the Secretary regarding the exist-*
4 *ence of a potency test that measures the allergenic ac-*
5 *tivity of an allergenic extract product licensed by the*
6 *applicant before October 1, 2022,” ; and*

7 *(5) by adding at the end the following:*

8 *“(C)(i) If a written request to place a prod-*
9 *uct in the discontinued section of either of the*
10 *lists referenced in subparagraph (A)(iii) is sub-*
11 *mitted to the Secretary on behalf of an appli-*
12 *cant, and the request identifies the date the prod-*
13 *uct is, or will be, withdrawn from sale, then for*
14 *purposes of assessing the prescription drug pro-*
15 *gram fee under section 736(a)(2), the Secretary*
16 *shall consider such product to have been included*
17 *in the discontinued section on the later of—*

18 *“(I) the date such request was received;*

19 *or*

20 *“(II) if the product will be withdrawn*
21 *from sale on a future date, such future date*
22 *when the product is withdrawn from sale.*

23 *“(ii) For purposes of this subparagraph, a*
24 *product shall be considered withdrawn from sale*
25 *once the applicant has ceased its own distribu-*

1 tion of the product, whether or not the applicant
2 has ordered recall of all previously distributed
3 lots of the product, except that a routine, tem-
4 porary interruption in supply shall not render a
5 product withdrawn from sale.”.

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

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

10 “(A) means a product—

11 “(i) for prick, scratch, intradermal, or
12 subcutaneous administration;

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

16 “(iii) not intended to be a preventive
17 or therapeutic intervention; and

18 “(iv) intended to detect an immediate-
19 or delayed-type skin hypersensitivity reac-
20 tion to aid in the diagnosis of—

21 “(I) an allergy to an anti-
22 microbial agent;

23 “(II) an allergy that is not to an
24 antimicrobial agent, if the diagnostic

1 *product was authorized for marketing*
2 *prior to October 1, 2022; or*

3 *“(III) infection with fungal or*
4 *mycobacterial pathogens; and*

5 *“(B) includes positive and negative controls*
6 *required to interpret the results of a product de-*
7 *scribed in subparagraph (A).”.*

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

9 *(a) TYPES OF FEES.—*

10 *(1) HUMAN DRUG APPLICATION FEE.—Section*
11 *736(a) of the Federal Food, Drug, and Cosmetic Act*
12 *(21 U.S.C. 379h(a)) is amended—*

13 *(A) in the matter preceding paragraph (1),*
14 *by striking “fiscal year 2018” and inserting “fis-*
15 *cal year 2023”;*

16 *(B) in paragraph (1)(A), by striking*
17 *“(c)(5)” each place it appears and inserting*
18 *“(c)(6)”;*

19 *(C) in paragraph (1)(C), by inserting*
20 *“prior to approval” after “or was withdrawn”;*
21 *and*

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

24 *“(H) EXCEPTION FOR SKIN-TEST DIAG-*
25 *NOSTIC PRODUCTS.—A human drug application*

1 *for a skin-test diagnostic product shall not be*
2 *subject to a fee under subparagraph (A).”.*

3 (2) *PRESCRIPTION DRUG PROGRAM FEE.—Section*
4 *736(a)(2) of the Federal Food, Drug, and Cos-*
5 *metic Act (21 U.S.C. 379h(a)(2)) is amended—*

6 *(A) in subparagraph (A)—*

7 *(i) by striking “Except as provided in*
8 *subparagraphs (B) and (C)” and inserting*
9 *the following:*

10 *“(i) PAYMENT OF FEES.—Except as*
11 *provided in subparagraphs (B) and (C)”;*

12 *(ii) by striking “subsection (c)(5)” and*
13 *inserting “subsection (c)(6)”;* and

14 *(iii) by adding at the end the fol-*
15 *lowing:*

16 *“(ii) SPECIAL RULE FOR PREVIOUSLY*
17 *DISCONTINUED DRUG PRODUCTS.—If a drug*
18 *product that is identified in a human drug*
19 *application approved as of October 1 of a*
20 *fiscal year is not a prescription drug prod-*
21 *uct as of that date because the drug product*
22 *is in the discontinued section of a list ref-*
23 *erenced in section 735(3)(A)(iii), and on*
24 *any subsequent day during such fiscal year*
25 *the drug product is a prescription drug*

1 *product, then except as provided in sub-*
2 *paragraphs (B) and (C), each person who is*
3 *named as the applicant in a human drug*
4 *application with respect to such product,*
5 *and who, after September 1, 1992, had*
6 *pending before the Secretary a human drug*
7 *application or supplement, shall pay the*
8 *annual prescription drug program fee estab-*
9 *lished for a fiscal year under subsection*
10 *(c)(6) for such prescription drug product.*
11 *Such fee shall be due on the last business*
12 *day of such fiscal year and shall be paid*
13 *only once for each such product for a fiscal*
14 *year in which the fee is payable.”; and*

15 *(B) by amending subparagraph (B) to read*
16 *as follows:*

17 *“(B) EXCEPTION FOR CERTAIN PRESCRIP-*
18 *TION DRUG PRODUCTS.—A prescription drug*
19 *program fee shall not be assessed for a prescrip-*
20 *tion drug product under subparagraph (A) if*
21 *such product is—*

22 *“(i) a large volume parenteral product*
23 *(a sterile aqueous drug product packaged in*
24 *a single-dose container with a volume great-*
25 *er than or equal to 100 mL, not including*

1 *powders for reconstitution or pharmacy*
2 *bulk packages) identified on the list com-*
3 *plied under section 505(j)(7);*

4 *“(ii) pharmaceutically equivalent (as*
5 *defined in section 314.3 of title 21, Code of*
6 *Federal Regulations (or any successor regu-*
7 *lation)) to another product on the list of*
8 *products compiled under section 505(j)(7)*
9 *(not including the discontinued section of*
10 *such list); or*

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

12 *(b) FEE REVENUE AMOUNTS.—*

13 *(1) IN GENERAL.—Paragraph (1) of section*
14 *736(b) of the Federal Food, Drug, and Cosmetic Act*
15 *(21 U.S.C. 379h(b)) is amended to read as follows:*

16 *“(1) IN GENERAL.—For each of the fiscal years*
17 *2023 through 2027, fees under subsection (a) shall, ex-*
18 *cept as provided in subsections (c), (d), (f), and (g),*
19 *be established to generate a total revenue amount*
20 *under such subsection that is equal to the sum of—*

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

23 *“(B) the dollar amount equal to the infla-*
24 *tion adjustment for the fiscal year (as deter-*
25 *mined under subsection (c)(1));*

1 “(C) the dollar amount equal to the stra-
2 tegic hiring and retention adjustment for the fis-
3 cal year (as determined under subsection (c)(2));

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

7 “(E) the dollar amount equal to the oper-
8 ating reserve adjustment for the fiscal year, if
9 applicable (as determined under subsection
10 (c)(4));

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

14 “(G) additional dollar amounts for each fis-
15 cal year as follows:

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

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

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

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

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

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

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

4 “(A) *for fiscal year 2023, \$1,151,522,958;*

5 *and*

6 “(B) *for fiscal years 2024 through 2027, the*
7 *dollar amount of the total revenue amount estab-*
8 *lished under paragraph (1) for the previous fis-*
9 *cal year, not including any adjustments made*
10 *under subsection (c)(4) or (c)(5).”.*

11 *(c) ADJUSTMENTS; ANNUAL FEE SETTING.—*

12 (1) *INFLATION ADJUSTMENT.—Section*
13 *736(c)(1)(B)(ii) of the Federal Food, Drug, and Cos-*
14 *metic Act (21 U.S.C. 379h(c)(1)(B)(ii)) is amended*
15 *by striking “Washington-Baltimore, DC–MD–VA–*
16 *WV” and inserting “Washington-Arlington-Alexan-*
17 *dria, DC–VA–MD–WV”.*

18 (2) *STRATEGIC HIRING AND RETENTION ADJUST-*
19 *MENT.—Section 736(c) of the Federal Food, Drug,*
20 *and Cosmetic Act (21 U.S.C. 379h(c)) is amended—*

21 (A) *by redesignating paragraphs (2)*
22 *through (6) as paragraphs (3) through (7), re-*
23 *spectively; and*

24 (B) *by inserting after paragraph (1) the fol-*
25 *lowing:*

1 “(2) *STRATEGIC HIRING AND RETENTION AD-*
2 *JUSTMENT.*—*For each fiscal year, after the annual*
3 *base revenue established in subsection (b)(1)(A) is ad-*
4 *justed for inflation in accordance with paragraph (1),*
5 *the Secretary shall further increase the fee revenue*
6 *and fees by the following amounts:*

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

8 “(B) *For each of fiscal years 2024 through*
9 *2027, \$4,000,000.”.*

10 (3) *CAPACITY PLANNING ADJUSTMENT.*—*Para-*
11 *graph (3), as redesignated, of section 736(c) of the*
12 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
13 *379h(c)) is amended to read as follows:*

14 “(3) *CAPACITY PLANNING ADJUSTMENT.*—

15 “(A) *IN GENERAL.*—*For each fiscal year,*
16 *after the annual base revenue established in sub-*
17 *section (b)(1)(A) is adjusted in accordance with*
18 *paragraphs (1) and (2), such revenue shall be*
19 *adjusted further for such fiscal year, in accord-*
20 *ance with this paragraph, to reflect changes in*
21 *the resource capacity needs of the Secretary for*
22 *the process for the review of human drug appli-*
23 *cations.*

24 “(B) *METHODOLOGY.*—*For purposes of this*
25 *paragraph, the Secretary shall employ the capac-*

1 *ity planning methodology utilized by the Sec-*
2 *retary in setting fees for fiscal year 2021, as de-*
3 *scribed in the notice titled ‘Prescription Drug*
4 *User Fee Rates for Fiscal Year 2021’ published*
5 *in the Federal Register on August 3, 2020 (85*
6 *Fed. Reg. 46651). The workload categories used*
7 *in applying such methodology in forecasting*
8 *shall include only the activities described in that*
9 *notice and, as feasible, additional activities that*
10 *are directly related to the direct review of appli-*
11 *cations and supplements, including additional*
12 *formal meeting types, the direct review of post-*
13 *marketing commitments and requirements, the*
14 *direct review of risk evaluation and mitigation*
15 *strategies, and the direct review of annual re-*
16 *ports for approved prescription drug products.*
17 *Subject to the exceptions in the preceding sen-*
18 *tence, the Secretary shall not include as work-*
19 *load categories in applying such methodology in*
20 *forecasting any non-core review activities, in-*
21 *cluding those activities that the Secretary ref-*
22 *erenced for potential future use in such notice*
23 *but did not utilize in setting fees for fiscal year*
24 *2021.*

1 “(C) *LIMITATION.*—Under no circumstances
2 shall an adjustment under this paragraph result
3 in fee revenue for a fiscal year that is less than
4 the sum of the amounts under subsections
5 (b)(1)(A) (the annual base revenue for the fiscal
6 year), (b)(1)(B) (the dollar amount of the infla-
7 tion adjustment for the fiscal year), and
8 (b)(1)(C) (the dollar amount of the strategic hir-
9 ing and retention adjustment for the fiscal year).

10 “(D) *PUBLICATION IN FEDERAL REG-*
11 *ISTER.*—The Secretary shall publish in the Fed-
12 eral Register notice under paragraph (6) of the
13 fee revenue and fees resulting from the adjust-
14 ment and the methodologies under this para-
15 graph.”.

16 (4) *OPERATING RESERVE ADJUSTMENT.*—Para-
17 graph (4), as redesignated, of section 736(c) of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 379h(c)) is amended—

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

22 “(A) *INCREASE.*—For fiscal year 2023 and
23 subsequent fiscal years, the Secretary shall, in
24 addition to adjustments under paragraphs (1),
25 (2), and (3), further increase the fee revenue and

1 *fees if such an adjustment is necessary to provide*
2 *for operating reserves of carryover user fees for*
3 *the process for the review of human drug appli-*
4 *cations for each fiscal year in at least the fol-*
5 *lowing amounts:*

6 “(i) *For fiscal year 2023, at least 8*
7 *weeks of operating reserves.*”

8 “(ii) *For fiscal year 2024, at least 9*
9 *weeks of operating reserves.*”

10 “(iii) *For fiscal year 2025 and subse-*
11 *quent fiscal years, at least 10 weeks of oper-*
12 *ating reserves.*”; and

13 *(B) in subparagraph (C), by striking*
14 *“paragraph (5)” and inserting “paragraph (6)”.*

15 (5) *ADDITIONAL DIRECT COST ADJUSTMENT.—*
16 *Paragraph (5), as redesignated, of section 736(c) of*
17 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
18 *379h(c)) is amended to read as follows:*

19 “(5) *ADDITIONAL DIRECT COST ADJUSTMENT.—*

20 “(A) *INCREASE.—The Secretary shall, in*
21 *addition to adjustments under paragraphs (1),*
22 *(2), (3), and (4), further increase the fee revenue*
23 *and fees—*

24 “(i) *for fiscal year 2023, by*
25 *\$44,386,150; and*

1 “(i) for each of fiscal years 2024
2 through 2027, by the amount set forth in
3 clauses (i) through (iv) of subparagraph
4 (B), as applicable, multiplied by the Con-
5 sumer Price Index for urban consumers
6 (Washington-Arlington-Alexandria, DC-
7 VA-MD-WV; Not Seasonally Adjusted; All
8 Items; Annual Index) for the most recent
9 year of available data, divided by such
10 Index for 2021.

11 “(B) APPLICABLE AMOUNTS.—The amounts
12 referred to in subparagraph (A)(i) are the fol-
13 lowing:

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

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

16 “(iii) For fiscal year 2026, \$35,799,
17 314.

18 “(iv) For fiscal year 2027,
19 \$35,799,314.”.

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

1 (d) *CREDITING AND AVAILABILITY OF FEES.*—Section
2 736(g)(3) of the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 379h(g)(3)) is amended by striking “fiscal years
4 2018 through 2022” and inserting “fiscal years 2023
5 through 2027”.

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

10 “(i) *WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS,*
11 *EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING*
12 *FEES.*—To qualify for consideration for a waiver or reduc-
13 tion under subsection (d), an exemption under subsection
14 (k), or the return of any fee paid under this section, includ-
15 ing if the fee is claimed to have been paid in error, a person
16 shall—

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

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

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

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

4 (2) by amending paragraph (2) to read as fol-
5 lows:

6 “(2) *EVIDENCE OF QUALIFICATION.*—An exemp-
7 tion under paragraph (1) applies with respect to a
8 drug only if the applicant involved submits a certifi-
9 cation that the applicant’s gross annual revenues did
10 not exceed \$50,000,000 for the last calendar year end-
11 ing prior to the fiscal year for which the exemption
12 is requested. Such certification shall be supported
13 by—

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

16 “(B) as necessary, other appropriate finan-
17 cial information.”.

18 **SEC. 1004. REAUTHORIZATION; REPORTING REQUIRE-**
19 **MENTS.**

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

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

24 (2) by striking “Prescription Drug User Fee
25 Amendments of 2017” each place it appears and in-

1 serting “Prescription Drug User Fee Amendments of
2 2022”;

3 (3) 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 each
7 fiscal year thereafter” and inserting “Not later than
8 30 calendar days after the end of each quarter of each
9 fiscal year for which fees are collected under this
10 part”;

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

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

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

17 (7) in subsection (f)—

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

22 (B) in paragraph (5), by striking “January
23 15, 2022” and inserting “January 15, 2027”.

1 **SEC. 1005. SUNSET DATES.**

2 (a) *AUTHORIZATION.*—Sections 735 and 736 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
4 379h) shall cease to be effective October 1, 2027.

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

8 (c) *PREVIOUS SUNSET PROVISION.*—Effective October
9 1, 2022, subsections (a) and (b) of section 104 of the FDA
10 Reauthorization Act of 2017 (Public Law 115–52) are re-
11 pealed.

12 **SEC. 1006. EFFECTIVE DATE.**

13 *The amendments made by this title shall take effect*
14 *on October 1, 2022, or the date of the enactment of this*
15 *Act, whichever is later, except that fees under part 2 of sub-*
16 *chapter C of chapter VII of the Federal Food, Drug, and*
17 *Cosmetic Act (21 U.S.C. 379g et seq.) shall be assessed for*
18 *all human drug applications received on or after October*
19 *1, 2022, regardless of the date of the enactment of this Act.*

20 **SEC. 1007. SAVINGS CLAUSE.**

21 *Notwithstanding the amendments made by this title,*
22 *part 2 of subchapter C of chapter VII of the Federal Food,*
23 *Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), as in effect*
24 *on the day before the date of the enactment of this title,*
25 *shall continue to be in effect with respect to human drug*
26 *applications and supplements (as defined in such part as*

1 of such day) that were accepted by the Food and Drug Ad-
2 ministration for filing on or after October 1, 2017, but be-
3 fore October 1, 2022, with respect to assessing and collecting
4 any fee required by such part for a fiscal year prior to fiscal
5 year 2023.

6 **TITLE II—FEES RELATING TO**
7 **DEVICES**

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

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

11 (b) *FINDING.*—Congress finds that the fees authorized
12 under the amendments made by this title will be dedicated
13 toward expediting the process for the review of device appli-
14 cations and for assuring the safety and effectiveness of de-
15 vices, as set forth in the goals identified for purposes of part
16 3 of subchapter C of chapter VII of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 379i et seq.), in the letters
18 from the Secretary of Health and Human Services to the
19 Chairman of the Committee on Health, Education, Labor,
20 and Pensions of the Senate and the Chairman of the Com-
21 mittee on Energy and Commerce of the House of Represent-
22 atives, as set forth in the Congressional Record.

23 **SEC. 2002. DEFINITIONS.**

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

1 (1) in paragraph (9)—

2 (A) in the matter preceding subparagraph
3 (A), by striking “and premarket notification
4 submissions” and inserting “premarket notifica-
5 tion submissions, and de novo classification re-
6 quests”;

7 (B) in subparagraph (D), by striking “and
8 submissions” and inserting “submissions, and de
9 novo classification requests”;

10 (C) in subparagraph (F), by striking “and
11 premarket notification submissions” and insert-
12 ing “premarket notification submissions, and de
13 novo classification requests”;

14 (D) in each of subparagraphs (G) and (H),
15 by striking “or submissions” and inserting “sub-
16 missions, or requests”; and

17 (E) in subparagraph (K), by striking “or
18 premarket notification submissions” and insert-
19 ing “premarket notification submissions, or de
20 novo classification requests”; and

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

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

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

5 (1) in paragraph (1), by striking “fiscal year
6 2018” and inserting “fiscal year 2023”; and

7 (2) in paragraph (2)—

8 (A) in subparagraph (A)—

9 (i) in the matter preceding clause (i),
10 by striking “October 1, 2017” and inserting
11 “October 1, 2022”;

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

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

16 (B) in subparagraph (B)(iii), by striking
17 “or premarket notification submission” and in-
18 serting “premarket notification submission, or de
19 novo classification request”; and

20 (C) in subparagraph (C), by striking “or
21 periodic reporting concerning a class III device”
22 and inserting “periodic reporting concerning a
23 class III device, or de novo classification re-
24 quest”.

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

4 (1) in paragraph (1), by striking “2018 through
 5 2022” and inserting “2023 through 2027”;

6 (2) by amending paragraph (2) to read as fol-
 7 lows:

8 “(2) *BASE FEE AMOUNTS SPECIFIED*.—For pur-
 9 poses of paragraph (1), the base fee amounts specified
 10 in this paragraph are as follows:

<i>“Fee Type</i>	<i>Fiscal Year 2023</i>	<i>Fiscal Year 2024</i>	<i>Fiscal Year 2025</i>	<i>Fiscal Year 2026</i>	<i>Fiscal Year 2027</i>
<i>Premarket Application</i>	\$425,000	\$435,000	\$445,000	\$455,000	\$470,000
<i>Establishment Registration</i>	\$6,250	\$6,875	\$7,100	\$7,575	\$8,465”;
					<i>and</i>

11 (3) by amending paragraph (3) to read as fol-
 12 lows:

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

16 “(A) \$312,606,000 for fiscal year 2023.

17 “(B) \$335,750,000 for fiscal year 2024.

18 “(C) \$350,746,400 for fiscal year 2025.

19 “(D) \$366,486,300 for fiscal year 2026.

20 “(E) \$418,343,000 for fiscal year 2027.”.

21 (c) *ANNUAL FEE SETTING; ADJUSTMENTS*.—Section
 22 738(c) of the Federal Food, Drug, and Cosmetic Act (21
 23 U.S.C. 379j(c)) is amended—

1 (1) in paragraph (1), by striking “2017” and in-
2 serting “2022”;

3 (2) in paragraph (2)—

4 (A) in subparagraph (A), by striking
5 “2018” and inserting “2023”;

6 (B) in subparagraph (B)—

7 (i) in the matter preceding clause (i),
8 by striking “fiscal year 2018” and inserting
9 “fiscal year 2023”; and

10 (ii) in clause (ii), by striking “fiscal
11 year 2016” and inserting “fiscal year
12 2022”;

13 (C) in subparagraph (C), by striking
14 “Washington-Baltimore, DC–MD–VA–WV” and
15 inserting “Washington-Arlington-Alexandria,
16 DC–VA–MD–WV”; and

17 (D) in subparagraph (D), in the matter
18 preceding clause (i), by striking “fiscal years
19 2018 through 2022” and inserting “fiscal years
20 2023 through 2027”;

21 (3) in paragraph (3), by striking “2018 through
22 2022” and inserting “2023 through 2027”;

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

1 (5) by inserting after paragraph (3) the fol-
2 lowing:

3 “(4) *PERFORMANCE IMPROVEMENT ADJUST-*
4 *MENT.—*

5 “(A) *IN GENERAL.—*For each of fiscal years
6 2025 through 2027, after the adjustments under
7 paragraphs (2) and (3), the base establishment
8 registration fee amounts for such fiscal year shall
9 be increased to reflect changes in the resource
10 needs of the Secretary due to improved review
11 performance goals for the process for the review
12 of device applications identified in the letters de-
13 scribed in section 2001(b) of the Medical Device
14 User Fee Amendments of 2022, as the Secretary
15 determines necessary to achieve an increase in
16 total fee collections for such fiscal year equal to
17 the following amounts, as applicable:

18 “(i) For fiscal year 2025, the product
19 of—

20 “(I) the amount determined under
21 subparagraph (B)(i)(I); and

22 “(II) the applicable inflation ad-
23 justment under paragraph (2)(B) for
24 such fiscal year.

1 “(ii) For fiscal year 2026, the product
2 of—

3 “(I) the sum of the amounts deter-
4 mined under subparagraphs (B)(i)(II),
5 (B)(ii)(I), and (B)(iii)(I); and

6 “(II) the applicable inflation ad-
7 justment under paragraph (2)(B) for
8 such fiscal year.

9 “(iii) For fiscal year 2027, the product
10 of—

11 “(I) the sum of the amounts deter-
12 mined under subparagraphs
13 (B)(i)(III), (B)(ii)(II), and
14 (B)(iii)(II); and

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

18 “(B) AMOUNTS.—

19 “(i) *PRESUBMISSION AMOUNT.*—For
20 purposes of subparagraph (A), with respect
21 to the Presubmission Written Feedback goal,
22 the amounts determined under this sub-
23 paragraph are as follows:

1 “(I) For fiscal year 2025,
2 \$15,396,600 if such goal for fiscal year
3 2023 is met.

4 “(II) For fiscal year 2026:

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

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

11 “(III) For fiscal year 2027:

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

16 “(bb) \$36,792,200 if such
17 goal for fiscal year 2024 is met
18 and such goal for fiscal year 2025
19 is not met.

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

22 “(ii) *DE NOVO CLASSIFICATION RE-*
23 *QUEST AMOUNT.—For purposes of subpara-*
24 *graph (A), with respect to the De Novo De-*

1 *cision goal, the amounts determined under*
2 *this subparagraph are as follows:*

3 *“(I) For fiscal year 2026,*
4 *\$6,323,500 if such goal for fiscal year*
5 *2023 is met.*

6 *“(II) For fiscal year 2027:*

7 *“(aa) \$6,323,500 if such goal*
8 *for fiscal year 2023 is met and*
9 *such goal for fiscal year 2024 is*
10 *not met.*

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

13 *“(iii) PREMARKET NOTIFICATION AND*
14 *PREMARKET APPROVAL AMOUNT.—For pur-*
15 *poses of subparagraph (A), with respect to*
16 *the 510(k) decision goal, 510(k) Shared*
17 *Outcome Total Time to Decision goal, PMA*
18 *decision goal, and PMA Shared Outcome*
19 *Total Time to Decision goal, the amounts*
20 *determined under this subparagraph are as*
21 *follows:*

22 *“(I) For fiscal year 2026,*
23 *\$1,020,000 if the 4 goals for fiscal year*
24 *2023 are met.*

25 *“(II) For fiscal year 2027:*

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

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

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

13 “(i) The performance of the Pre-
14 submission Written Feedback goal shall be
15 based on data available as of—

16 “(I) for fiscal year 2023, March
17 31, 2024;

18 “(II) for fiscal year 2024, March
19 31, 2025; and

20 “(III) for fiscal year 2025, March
21 31, 2026.

22 “(ii) The performance of the De Novo
23 Decision goal, 510(k) decision goal, 510(k)
24 Shared Outcome Total Time to Decision
25 goal, PMA decision goal, and PMA Shared

1 *Outcome Total Time to Decision goal shall*
2 *be based on data available as of—*

3 *“(I) for fiscal year 2023, March*
4 *31, 2025; and*

5 *“(II) for fiscal year 2024, March*
6 *31, 2026.*

7 *“(D) GOALS DEFINED.—For purposes of*
8 *this paragraph, the terms ‘Presubmission Writ-*
9 *ten Feedback goal’, ‘De Novo Decision goal’,*
10 *‘510(k) decision goal’, ‘510(k) Shared Outcome*
11 *Total Time to Decision goal’, ‘PMA decision*
12 *goal’, and ‘PMA Shared Outcome Total Time to*
13 *Decision goal’ refer to the goals identified by the*
14 *same names in the letters described in section*
15 *2001(b) of the Medical Device User Fee Amend-*
16 *ments of 2022.*

17 *“(5) HIRING ADJUSTMENT.—*

18 *“(A) IN GENERAL.—For each of fiscal years*
19 *2025 through 2027, after the adjustments under*
20 *paragraphs (2), (3), and (4), if applicable, if the*
21 *number of hires to support the process for the re-*
22 *view of device applications falls below the thresh-*
23 *olds specified in subparagraph (B) for the appli-*
24 *cable fiscal years, the base establishment registra-*
25 *tion fee amounts shall be decreased as the Sec-*

1 *retary determines necessary to achieve a reduc-*
2 *tion in total fee collections equal to the hiring*
3 *adjustment amount under subparagraph (C).*

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

6 *“(i) For fiscal year 2025, the threshold*
7 *is 123 hires for fiscal year 2023.*

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

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

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

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

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

23 *“(i) the number of hires by which the*
24 *hiring goal specified in subparagraph (D)*

1 for the fiscal year before the prior fiscal
2 year was not met;

3 “(ii) \$72,877; and

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

7 “(D) *HIRING GOALS.*—The hiring goals for
8 each of fiscal years 2023 through 2025 are as fol-
9 lows:

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

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

12 “(iii) For fiscal year 2025:

13 “(I) 24 hires if the base establish-
14 ment registration fees are not increased
15 by the amount determined under para-
16 graph (4)(A)(i).

17 “(II) 83 hires if the base establish-
18 ment registration fees are increased by
19 the amount determined under para-
20 graph (4)(A)(i).

21 “(E) *NUMBER OF HIRES.*—For purposes of
22 this paragraph, the number of hires for a fiscal
23 year shall be determined by the Secretary as set
24 forth in the letters described in section 2001(b)

1 *of the Medical Device User Fee Amendments of*
2 *2022.*

3 “(6) *OPERATING RESERVE ADJUSTMENT.*—

4 “(A) *IN GENERAL.*—*For each of fiscal years*
5 *2023 through 2027, after the adjustments under*
6 *paragraphs (2), (3), (4), and (5), if applicable,*
7 *if the Secretary has operating reserves of carry-*
8 *over user fees for the process for the review of de-*
9 *vice applications in excess of the designated*
10 *amount in subparagraph (B), the Secretary shall*
11 *decrease the base establishment registration fee*
12 *amounts to provide for not more than such des-*
13 *ignated amount of operating reserves.*

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

18 “(i) *13 weeks of operating reserves of*
19 *carryover user fees; and*

20 “(ii) *1 month of operating reserves*
21 *maintained pursuant to paragraph (8).*

22 “(C) *EXCLUDED AMOUNT.*—*For the period*
23 *of fiscal years 2023 through 2026, a total*
24 *amount equal to \$118,000,000 shall not be con-*
25 *sidered part of the designated amount under sub-*

1 *paragraph (B) and shall not be subject to the de-*
2 *crease under subparagraph (A).”.*

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

5 (1) *in paragraph (1)(A), by striking*
6 *“\$320,825,000” and inserting “\$398,566,000”; and*

7 (2) *in paragraph (2), by inserting “de novo clas-*
8 *sification requests,” after “class III device,”.*

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

12 “(3) *AUTHORIZATION OF APPROPRIATIONS.—*

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

19 “(B) *REVENUE AMOUNT.—For purposes of*
20 *this paragraph, the revenue amount for each fis-*
21 *cal 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 sub-*
25 *section (c); and*

1 “(ii) the performance improvement ad-
2 justment amount for the fiscal year under
3 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 subsection
12 (c)(6), if applicable.”.

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

15 (a) *PERFORMANCE REPORTS.*—Section 738A(a) of the
16 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
17 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 through
8 2022” and inserting “2023 through 2027”.

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

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

14 (2) in paragraph (5), by striking “2022” and in-
15 serting “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 establish
23 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 the*
4 *conformity of a device to certain standards rec-*
5 *ognized under this section; and*

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

15 “(2) *SECRETARIAL REVIEW OF ACCREDITED LAB-*
16 *ORATORY RESULTS.—The Secretary may—*

17 “(A) *review the results of tests conducted by*
18 *testing laboratories accredited pursuant to this*
19 *subsection, including by conducting periodic au-*
20 *ditions of such results or of the processes of accred-*
21 *ited bodies or testing laboratories;*

22 “(B) *following such review, take additional*
23 *measures under this Act, as the Secretary deter-*
24 *mines 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 ef-
9 fectiveness of a device for which an assessment of
10 conformity was supported by testing conducted
11 by a testing laboratory accredited under this
12 subsection, take such additional measures under
13 this Act, as the Secretary determines appro-
14 priate, 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 Ad-
23 ministration an annual report on the progress of the
24 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 “Oc-*
5 *tober 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 the*
11 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
12 *1) shall cease to be effective January 31, 2028.*

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

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 sub-*
21 *chapter C of chapter VII of the Federal Food, Drug, and*
22 *Cosmetic Act (21 U.S.C. 379i et seq.) shall be assessed for*
23 *all submissions listed in section 738(a)(2)(A) of such Act*
24 *received on or after October 1, 2022, regardless of the date*
25 *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 effect*
5 *on the day before the date of the enactment of this title,*
6 *shall continue to be in effect with respect to the submissions*
7 *listed in section 738(a)(2)(A) of such Act (as defined in such*
8 *part as of such day) that on or after October 1, 2017, but*
9 *before October 1, 2022, were received by the Food and Drug*
10 *Administration with respect to assessing and collecting any*
11 *fee required by such part for a fiscal year prior to fiscal*
12 *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 “Ge-*
17 *neric Drug User Fee Amendments of 2022”.*

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

1 *of the House of Representatives, as set forth in the Congres-*
2 *sional 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 Federal
6 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(a)) is*
7 *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 the
20 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
21 *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 fis-
9 cal years 2024 through 2027, fees under
10 paragraphs (2) through (5) of subsection (a)
11 shall be established to generate a total esti-
12 mated revenue amount under such sub-
13 section that is equal to the base revenue
14 amount for the fiscal year under clause (ii),
15 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).”;

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

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

1 inserting “Washington-Arlington-Alexandria,
2 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 the
8 adjustment under paragraph (1), further in-
9 crease the fee revenue and fees under this section
10 for a fiscal year, in accordance with this para-
11 graph, to reflect changes in the resource capacity
12 needs of the Secretary for human generic drug
13 activities.

14 “(B) *CAPACITY PLANNING METHODOLOGY.*—
15 The Secretary shall establish a capacity plan-
16 ning methodology for purposes of this paragraph,
17 which shall—

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

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

11 “(C) LIMITATIONS.—

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

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

1 “(I) for purposes of a fiscal year
2 2024 adjustment, the Secretary deter-
3 mines that during the period from
4 April 1, 2021, through March 31,
5 2023—

6 “(aa) the total number of ab-
7 breviated new drug applications
8 submitted was greater than or
9 equal to 2,000; or

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

18 “(II) for purposes of a fiscal year
19 2025 adjustment, the Secretary deter-
20 mines that during the period from
21 April 1, 2022, through March 31,
22 2024—

23 “(aa) the total number of ab-
24 breviated new drug applications

1 *submitted was greater than or*
2 *equal to 2,300; or*

3 “(bb) *thirty-five percent or*
4 *more of abbreviated new drug ap-*
5 *lications submitted related to*
6 *complex products (as so defined);*

7 “(III) *for purposes of a fiscal year*
8 *2026 adjustment, the Secretary deter-*
9 *mines that during the period from*
10 *April 1, 2023, through March 31,*
11 *2025—*

12 “(aa) *the total number of ab-*
13 *breivated new drug applications*
14 *submitted was greater than or*
15 *equal to 2,300; or*

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

21 “(IV) *for purposes of a fiscal year*
22 *2027 adjustment, the Secretary deter-*
23 *mines that during the period from*
24 *April 1, 2024, through March 31,*
25 *2026—*

1 “(aa) the total number of ab-
2 breviated new drug applications
3 submitted was greater than or
4 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 “(D) PUBLICATION IN FEDERAL REG-
10 ISTER.—The Secretary shall publish in the Fed-
11 eral Register notice referred to in subsection (a)
12 the fee revenue and fees resulting from the ad-
13 justment and the methodology under this para-
14 graph.

15 “(3) OPERATING RESERVE ADJUSTMENT.—

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

1 “(B) *NUMBER OF WEEKS.*—*The number of*
2 *weeks specified in this subparagraph is—*

3 “(i) *8 weeks for fiscal year 2024;*

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

5 “(iii) *10 weeks for each of fiscal year*
6 *2026 and 2027.*

7 “(C) *DECREASE.*—*If the Secretary has car-*
8 *ryover balances for human generic drug activi-*
9 *ties in excess of 12 weeks of the operating re-*
10 *serves referred to in subparagraph (A), the Sec-*
11 *retary shall decrease the fee revenue and fees re-*
12 *ferred to in such subparagraph to provide for not*
13 *more than 12 weeks of such operating reserves.*

14 “(D) *RATIONALE FOR ADJUSTMENT.*—*If an*
15 *adjustment under this paragraph is made, the*
16 *rationale for the amount of the increase or de-*
17 *crease (as applicable) in fee revenue and fees*
18 *shall be contained in the annual Federal Reg-*
19 *ister notice under subsection (a) publishing the*
20 *fee revenue and fees for the fiscal year involved.”.*

21 “(d) *ANNUAL FEE SETTING.*—*Section 744B(d)(1) of the*
22 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
23 *42(d)(1)) is amended—*

1 (1) *in the paragraph heading, by striking “2018*
 2 *THROUGH 2022” and inserting “2023 THROUGH 2027”;*
 3 *and*

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

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

12 (f) *CREDITING AND AVAILABILITY OF FEES.—Section*
 13 *744B(i)(3) of the Federal Food, Drug, and Cosmetic Act*
 14 *(21 U.S.C. 379j–42(i)(3)) is amended by striking “fiscal*
 15 *years 2018 through 2022” and inserting “fiscal years 2023*
 16 *through 2027”.*

17 **SEC. 3003. REAUTHORIZATION; REPORTING REQUIRE-**
 18 **MENTS.**

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

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

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

1 (3) in subsection (a)(2), by striking “Not later
2 than 30 calendar days after the end of the second
3 quarter of fiscal year 2018, and not later than 30 cal-
4 endar days after the end of each quarter of each fiscal
5 year thereafter” and inserting “Not later than 30 cal-
6 endar days after the end of each quarter of each fiscal
7 year for which fees are collected under this part”;

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

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

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

14 (7) in subsection (f)—

15 (A) in paragraph (1), in the matter pre-
16 ceding subparagraph (A), by striking “fiscal
17 year 2022” and inserting “fiscal year 2027”;
18 and

19 (B) in paragraph (5), by striking “January
20 15, 2022” and inserting “January 15, 2027”.

21 **SEC. 3004. SUNSET DATES.**

22 (a) *AUTHORIZATION.*—Sections 744A and 744B of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
24 41; 379j–42) shall cease to be effective October 1, 2027.

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

4 (c) *PREVIOUS SUNSET PROVISION.*—Effective October
5 1, 2022, subsections (a) and (b) of section 305 of the *FDA*
6 *Reauthorization Act of 2017* (Public Law 115–52) are re-
7 pealed.

8 **SEC. 3005. EFFECTIVE DATE.**

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

17 **SEC. 3006. SAVINGS CLAUSE.**

18 *Notwithstanding the amendments made by this title,*
19 *part 7 of subchapter C of chapter VII of the Federal Food,*
20 *Drug, and Cosmetic Act* (21 U.S.C. 379j–41 *et seq.*), as in
21 *effect on the day before the date of the enactment of this*
22 *title, shall continue to be in effect with respect to abbrevi-*
23 *ated new drug applications (as defined in such part as*
24 *of such day) that were received by the Food and Drug Ad-*
25 *ministration within the meaning of section 505(j)(5)(A) of*

1 *such Act (21 U.S.C. 355(j)(5)(A)), prior approval supple-*
2 *ments that were submitted, and drug master files for Type*
3 *II active pharmaceutical ingredients that were first ref-*
4 *erenced on or after October 1, 2017, but before October 1,*
5 *2022, with respect to assessing and collecting any fee re-*
6 *quired by such part for a fiscal year prior to fiscal year*
7 *2023.*

8 **TITLE IV—FEES RELATING TO**
9 **BIOSIMILAR BIOLOGICAL**
10 **PRODUCTS**

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

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

14 (b) *FINDING.*—*Congress finds that the fees authorized*
15 *by the amendments made by this title will be dedicated to*
16 *expediting the process for the review of biosimilar biological*
17 *product applications, including postmarket safety activi-*
18 *ties, as set forth in the goals identified for purposes of part*
19 *8 of subchapter C of chapter VII of the Federal Food, Drug,*
20 *and Cosmetic Act (21 U.S.C. 379j–51 et seq.), in the letters*
21 *from the Secretary of Health and Human Services to the*
22 *Chairman of the Committee on Health, Education, Labor,*
23 *and Pensions of the Senate and the Chairman of the Com-*
24 *mittee on Energy and Commerce of the House of Represent-*
25 *atives, as set forth in the Congressional Record.*

1 **SEC. 4002. DEFINITIONS.**

2 (a) *ADJUSTMENT FACTOR.*—Section 744G(1) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
4 51(1)) is amended to read as follows:

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

11 (b) *BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-*
12 *TION.*—Section 744G(4)(B)(iii) of the Federal Food, Drug,
13 and Cosmetic Act (21 U.S.C. 379j–51(4)(B)(iii)) is amend-
14 ed—

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

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

19 **SEC. 4003. AUTHORITY TO ASSESS AND USE BIOSIMILAR BI-**
20 **OLOGICAL PRODUCT FEES.**

21 (a) *TYPES OF FEES.*—

22 (1) *IN GENERAL.*—The matter preceding para-
23 graph (1) in section 744H(a) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is
25 amended by striking “fiscal year 2018” and inserting
26 “fiscal year 2023”.

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

7 (3) *ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT*
8 *DEVELOPMENT FEE.*—*Section 744H(a)(1)(B) of the*
9 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
10 *379j–52(a)(1)(B)) is amended—*

11 (A) *in clause (i), by inserting before the pe-*
12 *riod at the end the following: “, except that, in*
13 *the case that such product (including, where ap-*
14 *plicable, ownership of the relevant investiga-*
15 *tional new drug application) is transferred to a*
16 *licensee, assignee, or successor of such person,*
17 *and written notice of such transfer is provided to*
18 *the Secretary, such licensee, assignee, or successor*
19 *shall pay the annual biosimilar biological prod-*
20 *uct development fee”;*

21 (B) *in clause (iii)—*

22 (i) *in subclause (I), by striking “or” at*
23 *the end;*

24 (ii) *in subclause (II), by striking the*
25 *period at the end and inserting “; or”;* and

1 (iii) by adding at the end the fol-
2 lowing:

3 “(III) been administratively re-
4 moved from the biosimilar biological
5 product development program for the
6 product under subparagraph (E)(v).”;
7 and

8 (C) in clause (iv), by striking “is accepted
9 for filing on or after October 1 of such fiscal
10 year” and inserting “is subsequently accepted for
11 filing”.

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

16 “(D) REACTIVATION FEE.—

17 “(i) IN GENERAL.—A person that has
18 discontinued participation in the biosimilar
19 biological product development program for
20 a product under subparagraph (C), or who
21 has been administratively removed from
22 such program for a product under subpara-
23 graph (E)(v), shall, if the person seeks to re-
24 sume participation in such program, pay
25 all annual biosimilar biological product de-

1 *velopment fees previously assessed for such*
2 *product and still owed and a fee (referred to*
3 *in this section as ‘reactivation fee’) by the*
4 *earlier of the following:*

5 *“(I) Not later than 7 days after*
6 *the Secretary grants a request by such*
7 *person for a biosimilar biological prod-*
8 *uct development meeting for the prod-*
9 *uct (after the date on which such par-*
10 *ticipation was discontinued or the date*
11 *of administrative removal, as applica-*
12 *ble).*

13 *“(II) Upon the date of submission*
14 *(after the date on which such partici-*
15 *pation was discontinued or the date of*
16 *administrative removal, as applicable)*
17 *by such person of an investigational*
18 *new drug application describing an in-*
19 *vestigation that the Secretary deter-*
20 *mines is intended to support a bio-*
21 *similar biological product application*
22 *for that product.*

23 *“(ii) APPLICATION OF ANNUAL FEE.—*
24 *A person that pays a reactivation fee for a*
25 *product shall pay for such product, begin-*

1 *ning in the next fiscal year, the annual bio-*
2 *similar biological product development fee*
3 *under subparagraph (B), except that, in the*
4 *case that such product (including, where*
5 *applicable, ownership of the relevant inves-*
6 *tigational new drug application) is trans-*
7 *ferred to a licensee, assignee, or successor of*
8 *such person, and written notice of such*
9 *transfer is provided to the Secretary, such*
10 *licensee, assignee, or successor shall pay the*
11 *annual biosimilar biological product devel-*
12 *opment fee.”.*

13 (5) *EFFECT OF FAILURE TO PAY FEES.—Section*
14 *744H(a)(1)(E) of the Federal Food, Drug, and Cos-*
15 *metic Act (21 U.S.C. 379j–52(a)(1)(E)) is amended*
16 *by adding at the end the following:*

17 *“(v) ADMINISTRATIVE REMOVAL FROM*
18 *THE BIOSIMILAR BIOLOGICAL PRODUCT DE-*
19 *VELOPMENT PROGRAM.—If a person has*
20 *failed to pay an annual biosimilar biologi-*
21 *cal product development fee for a product as*
22 *required under subparagraph (B) for a pe-*
23 *riod of 2 consecutive fiscal years, the Sec-*
24 *retary may administratively remove such*
25 *person from the biosimilar biological prod-*

1 *uct development program for the product.*
2 *At least 30 days prior to administratively*
3 *removing a person from the biosimilar bio-*
4 *logical product development program for a*
5 *product under this clause, the Secretary*
6 *shall provide written notice to such person*
7 *of the intended administrative removal.”.*

8 (6) *BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-*
9 *TION FEE.*—Section 744H(a)(2)(D) of the Federal
10 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
11 *52(a)(2)(D)) is amended by inserting after “or was*
12 *withdrawn” the following: “prior to approval”.*

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

17 (A) *in subparagraph (A)—*

18 (i) *in clause (i), by striking “and” at*
19 *the end;*

20 (ii) *by redesignating clause (ii) as*
21 *clause (iii); and*

22 (iii) *by inserting after clause (i) the*
23 *following:*

1 “(ii) may be dispensed only under pre-
2 scription pursuant to section 503(b); and”;
3 and

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

5 “(E) MOVEMENT TO DISCONTINUED LIST.—

6 “(i) DATE OF INCLUSION.—If a writ-
7 ten request to place a product on the list
8 referenced in subparagraph (A) of discon-
9 tinued biosimilar biological products is sub-
10 mitted to the Secretary on behalf of an ap-
11 plicant, and the request identifies the date
12 the product is, or will be, withdrawn from
13 sale, then for purposes of assessing the bio-
14 similar biological product program fee, the
15 Secretary shall consider such product to
16 have been included on such list on the later
17 of—

18 “(I) the date such request was re-
19 ceived; or

20 “(II) if the product will be with-
21 drawn from sale on a future date, such
22 future date when the product is with-
23 drawn from sale.

24 “(ii) TREATMENT AS WITHDRAWN
25 FROM SALE.—For purposes of clause (i), a

1 *product shall be considered withdrawn from*
2 *sale once the applicant has ceased its own*
3 *distribution of the product, whether or not*
4 *the applicant has ordered recall of all pre-*
5 *viously distributed lots of the product, ex-*
6 *cept that a routine, temporary interruption*
7 *in supply shall not render a product with-*
8 *drawn from sale.*

9 *“(iii) SPECIAL RULE FOR PRODUCTS*
10 *REMOVED FROM DISCONTINUED LIST.—If a*
11 *biosimilar biological product that is identi-*
12 *fied in a biosimilar biological product ap-*
13 *plication approved as of October 1 of a fis-*
14 *cal year appears, as of October 1 of such fis-*
15 *cal year, on the list referenced in subpara-*
16 *graph (A) of discontinued biosimilar bio-*
17 *logical products, and on any subsequent day*
18 *during such fiscal year the biosimilar bio-*
19 *logical product does not appear on such list,*
20 *except as provided in subparagraph (D),*
21 *each person who is named as the applicant*
22 *in a biosimilar biological product applica-*
23 *tion with respect to such product shall pay*
24 *the annual biosimilar biological product*
25 *program fee established for a fiscal year*

1 under subsection (c)(5) for such biosimilar
2 biological product. Notwithstanding sub-
3 paragraph (B), such fee shall be due on the
4 last business day of such fiscal year and
5 shall be paid only once for each such prod-
6 uct for each fiscal year.”.

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

11 (b) *FEE REVENUE AMOUNTS.*—Subsection (b) of sec-
12 tion 744H of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 379j–52) is amended—

14 (1) by striking paragraph (1);

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

17 (3) by amending paragraph (1) (as so redesign-
18 ated) to read as follows:

19 “(1) *IN GENERAL.*—For each of the fiscal years
20 2023 through 2027, fees under subsection (a) shall, ex-
21 cept as provided in subsection (c), be established to
22 generate a total revenue amount equal to the sum
23 of—

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

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

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

7 “(D) the dollar amount equal to the capaci-
8 ty planning adjustment for the fiscal year (as
9 determined under subsection (c)(3));

10 “(E) the dollar amount equal to the oper-
11 ating reserve adjustment for the fiscal year, if
12 applicable (as determined under subsection
13 (c)(4));

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

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

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

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

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

22 (C) by redesignating subparagraphs (C)
23 and (D) as subparagraphs (B) and (C), respec-
24 tively; and

1 (5) *by amending paragraph (3) (as so redesign-*
2 *ated) to read as follows:*

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

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

7 “(B) *for fiscal years 2024 through 2027, the*
8 *dollar amount of the total revenue amount estab-*
9 *lished under paragraph (1) for the previous fis-*
10 *cal year, excluding any adjustments to such rev-*
11 *enue amount under subsection (c)(4).”.*

12 (c) *ADJUSTMENTS; ANNUAL FEE SETTING.—Section*
13 *744H(c) of the Federal Food, Drug, and Cosmetic Act (21*
14 *U.S.C. 379j–52(c)) is amended—*

15 (1) *in paragraph (1)—*

16 (A) *in subparagraph (A)—*

17 (i) *in the matter preceding clause (i),*
18 *by striking “subsection (b)(2)(B)” and in-*
19 *serting “subsection (b)(1)(B)”;* and

20 (ii) *in clause (i), by striking “sub-*
21 *section (b)” and inserting “subsection*
22 *(b)(1)(A)”;* and

23 (B) *in subparagraph (B)(ii), by striking*
24 *“Washington-Baltimore, DC–MD–VA–WV” and*

1 inserting “Washington-Arlington-Alexandria,
2 DC-VA-MD-WV”;

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

5 “(2) *STRATEGIC HIRING AND RETENTION AD-*
6 *JUSTMENT.—For each fiscal year, after the annual*
7 *base revenue under subsection (b)(1)(A) is adjusted*
8 *for inflation in accordance with paragraph (1), the*
9 *Secretary shall further increase the fee revenue and*
10 *fees by \$150,000.*

11 “(3) *CAPACITY PLANNING ADJUSTMENT.—*

12 “(A) *IN GENERAL.—For each fiscal year,*
13 *the Secretary shall, in addition to the adjust-*
14 *ments under paragraphs (1) and (2), further ad-*
15 *just the fee revenue and fees under this section*
16 *for a fiscal year to reflect changes in the resource*
17 *capacity needs of the Secretary for the process*
18 *for the review of biosimilar biological product*
19 *applications.*

20 “(B) *METHODOLOGY.—For purposes of this*
21 *paragraph, the Secretary shall employ the capac-*
22 *ity planning methodology utilized by the Sec-*
23 *retary in setting fees for fiscal year 2021, as de-*
24 *scribed in the notice titled ‘Biosimilar User Fee*
25 *Rates for Fiscal Year 2021’ published in the Fed-*

1 *eral Register on August 4, 2020 (85 Fed. Reg.*
2 *47220). The workload categories used in apply-*
3 *ing such methodology in forecasting shall include*
4 *only the activities described in that notice and,*
5 *as feasible, additional activities that are directly*
6 *related to the direct review of biosimilar biologi-*
7 *cal product applications and supplements, in-*
8 *cluding additional formal meeting types, the di-*
9 *rect review of postmarketing commitments and*
10 *requirements, the direct review of risk evaluation*
11 *and mitigation strategies, and the direct review*
12 *of annual reports for approved biosimilar bio-*
13 *logical products. Subject to the exceptions in the*
14 *preceding sentence, the Secretary shall not in-*
15 *clude as workload categories in applying such*
16 *methodology in forecasting any non-core review*
17 *activities, including those activities that the Sec-*
18 *retary referenced for potential future use in such*
19 *notice but did not utilize in setting fees for fiscal*
20 *year 2021.*

21 “(C) *LIMITATIONS.—Under no cir-*
22 *cumstances shall an adjustment under this para-*
23 *graph result in fee revenue for a fiscal year that*
24 *is less than the sum of the amounts under sub-*
25 *sections (b)(1)(A) (the annual base revenue for*

1 the fiscal year), (b)(1)(B) (the dollar amount of
2 the inflation adjustment for the fiscal year), and
3 (b)(1)(C) (the dollar amount of the strategic hir-
4 ing and retention adjustment).

5 “(D) PUBLICATION IN FEDERAL REG-
6 ISTER.—The Secretary shall publish in the Fed-
7 eral Register notice under paragraph (5) the fee
8 revenue and fees resulting from the adjustment
9 and the methodologies under this paragraph.

10 “(4) OPERATING RESERVE ADJUSTMENT.—

11 “(A) INCREASE.—For fiscal year 2023 and
12 subsequent fiscal years, the Secretary shall, in
13 addition to adjustments under paragraphs (1),
14 (2), and (3), further increase the fee revenue and
15 fees if such an adjustment is necessary to provide
16 for at least 10 weeks of operating reserves of car-
17 ryover user fees for the process for the review of
18 biosimilar biological product applications.

19 “(B) DECREASE.—

20 “(i) FISCAL YEAR 2023.—For fiscal
21 year 2023, if the Secretary has carryover
22 balances for such process in excess of 33
23 weeks of such operating reserves, the Sec-
24 retary shall decrease such fee revenue and

1 *fees to provide for not more than 33 weeks*
2 *of such operating reserves.*

3 “(ii) *FISCAL YEAR 2024.—For fiscal*
4 *year 2024, if the Secretary has carryover*
5 *balances for such process in excess of 27*
6 *weeks of such operating reserves, the Sec-*
7 *retary shall decrease such fee revenue and*
8 *fees to provide for not more than 27 weeks*
9 *of such operating reserves.*

10 “(iii) *FISCAL YEAR 2025 AND SUBSE-*
11 *QUENT FISCAL YEARS.—For fiscal year*
12 *2025 and subsequent fiscal years, if the Sec-*
13 *retary has carryover balances for such proc-*
14 *ess in excess of 21 weeks of such operating*
15 *reserves, the Secretary shall decrease such*
16 *fee revenue and fees to provide for not more*
17 *than 21 weeks of such operating reserves.*

18 “(C) *FEDERAL REGISTER NOTICE.—If an*
19 *adjustment under subparagraph (A) or (B) is*
20 *made, the rationale for the amount of the in-*
21 *crease or decrease (as applicable) in fee revenue*
22 *and fees shall be contained in the annual Federal*
23 *Register notice under paragraph (5)(B) estab-*
24 *lishing fee revenue and fees for the fiscal year in-*
25 *volved.”; and*

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

4 (d) *CREDITING AND AVAILABILITY OF FEES.*—Sub-
5 section (f)(3) of section 744H of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 379j–52(f)(3)) is amended by
7 striking “2018 through 2022” and inserting “2023 through
8 2027”.

9 (e) *WRITTEN REQUESTS FOR WAIVERS AND RETURNS;*
10 *DISPUTES CONCERNING FEES.*—Section 744H(h) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
12 52(h)) is amended to read as follows:

13 “(h) *WRITTEN REQUESTS FOR WAIVERS AND RE-*
14 *URNS; DISPUTES CONCERNING FEES.*—To qualify for con-
15 sideration for a waiver under subsection (d), or for the re-
16 turn of any fee paid under this section, including if the
17 fee is claimed to have been paid in error, a person shall
18 submit to the Secretary a written request justifying such
19 waiver or return and, except as otherwise specified in this
20 section, such written request shall be submitted to the Sec-
21 retary not later than 180 days after such fee is due. A re-
22 quest submitted under this paragraph shall include any
23 legal authorities under which the request is made.”.

1 **SEC. 4004. REAUTHORIZATION; REPORTING REQUIRE-**
2 **MENTS.**

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

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

7 *(2) by striking “Biosimilar User Fee Amend-*
8 *ments of 2017” each place it appears and inserting*
9 *“Biosimilar User Fee Amendments of 2022”;*

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

12 *(4) in subsection (a)(3)(A), by striking “Not*
13 *later than 30 calendar days after the end of the sec-*
14 *ond quarter of fiscal year 2018, and not later than*
15 *30 calendar days after the end of each quarter of each*
16 *fiscal year thereafter” and inserting “Not later than*
17 *30 calendar days after the end of each quarter of each*
18 *fiscal year for which fees are collected under this*
19 *part”;*

20 *(5) in subsection (b), by striking “Not later than*
21 *120 days after the end of fiscal year 2018 and each*
22 *subsequent fiscal year for which fees are collected*
23 *under this part” and inserting “Not later than 120*
24 *days after the end of each fiscal year for which fees*
25 *are collected under this part”;*

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

4 (7) in subsection (f)—

5 (A) in paragraph (1), in the matter pre-
6 ceding subparagraph (A), by striking “fiscal
7 year 2022” and inserting “fiscal year 2027”;
8 and

9 (B) in paragraph (3), by striking “January
10 15, 2022” and inserting “January 15, 2027”.

11 **SEC. 4005. SUNSET DATES.**

12 (a) *AUTHORIZATION*.—Sections 744G and 744H of the
13 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
14 51, 379j–52) shall cease to be effective October 1, 2027.

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

18 (c) *PREVIOUS SUNSET PROVISION*.—Effective October
19 1, 2022, subsections (a) and (b) of section 405 of the *FDA*
20 *Reauthorization Act of 2017* (Public Law 115–52) are re-
21 pealed.

22 **SEC. 4006. EFFECTIVE DATE.**

23 *The amendments made by this title shall take effect*
24 *on October 1, 2022, or the date of the enactment of this*
25 *Act, whichever is later, except that fees under part 8 of sub-*

1 *chapter C of chapter VII of the Federal Food, Drug, and*
2 *Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be assessed*
3 *for all biosimilar biological product applications received*
4 *on or after October 1, 2022, regardless of the date of the*
5 *enactment of this Act.*

6 **SEC. 4007. SAVINGS CLAUSE.**

7 *Notwithstanding the amendments made by this title,*
8 *part 8 of subchapter C of chapter VII of the Federal Food,*
9 *Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), as in*
10 *effect on the day before the date of the enactment of this*
11 *title, shall continue to be in effect with respect to biosimilar*
12 *biological product applications and supplements (as defined*
13 *in such part as of such day) that were accepted by the Food*
14 *and Drug Administration for filing on or after October 1,*
15 *2017, but before October 1, 2022, with respect to assessing*
16 *and collecting any fee required by such part for a fiscal*
17 *year prior to fiscal year 2023.*

18 **TITLE V—REAUTHORIZATION OF**
19 **OTHER PROVISIONS**

20 **SEC. 5001. REAUTHORIZATION OF THE BEST PHARMA-**
21 **CEUTICALS FOR CHILDREN PROGRAM.**

22 *Section 409I(d)(1) of the Public Health Service Act*
23 *(42 U.S.C. 284m(d)(1)) is amended by striking*
24 *“\$25,000,000 for each of fiscal years 2018 through 2022”*

1 *and inserting “\$5,273,973 for the period beginning on Octo-*
2 *ber 1, 2022 and ending on December 16, 2022”.*

3 **SEC. 5002. REAUTHORIZATION OF THE HUMANITARIAN DE-**
4 **VICE EXEMPTION INCENTIVE.**

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

8 **SEC. 5003. REAUTHORIZATION OF THE PEDIATRIC DEVICE**
9 **CONSORTIA PROGRAM.**

10 *Section 305(e) of the Food and Drug Administration*
11 *Amendments Act of 2007 (Public Law 110–85; 42 U.S.C.*
12 *282 note) is amended by striking “\$5,250,000 for each of*
13 *fiscal years 2018 through 2022” and inserting “\$1,107,534*
14 *for the period beginning on October 1, 2022, and ending*
15 *on December 16, 2022”.*

16 **SEC. 5004. REAUTHORIZATION OF PROVISION PERTAINING**
17 **TO DRUGS CONTAINING SINGLE**
18 **ENANTIOMERS.**

19 *Section 505(u)(4) of the Federal Food, Drug, and Cos-*
20 *metic Act (21 U.S.C. 355(u)(4)) is amended by striking*
21 *“October 1” and inserting “December 17”.*

22 **SEC. 5005. REAUTHORIZATION OF THE CRITICAL PATH PUB-**
23 **LIC-PRIVATE PARTNERSHIP.**

24 *Section 566(f) of the Federal Food, Drug, and Cos-*
25 *metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking*

1 “\$6,000,000 for each of fiscal years 2018 through 2022” and
2 inserting “\$1,265,753 for the period beginning on October
3 1, 2022 and ending on December 16, 2022”.

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

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

10 **SEC. 5007. REAUTHORIZATION OF CERTAIN DEVICE INSPEC-**
11 **TIONS.**

12 Section 704(g)(11) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 374(g)(11)) is amended by striking
14 “October 1” and inserting “December 17”.

15 **SEC. 5008. REAUTHORIZATION OF REPORTING REQUIRE-**
16 **MENTS RELATED TO PENDING GENERIC**
17 **DRUG APPLICATIONS AND PRIORITY REVIEW**
18 **APPLICATIONS.**

19 Section 807 of the FDA Reauthorization Act of 2017
20 (Public Law 115–52) is amended, in the matter preceding
21 paragraph (1), by striking “October 1” and inserting “De-
22 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/Calf*
6 *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 initiated*
10 *the Las Dispensas-Gallinas prescribed burn on Fed-*
11 *eral land in the Santa Fe National Forest in San*
12 *Miguel County, New Mexico, when erratic winds were*
13 *prevalent in the area that was also suffering from se-*
14 *vere drought after many years of insufficient precipi-*
15 *tation;*

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

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

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

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

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

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

19 (8) the U.S. Forest Service has assumed respon-
20 sibility for the Hermit’s Peak/Calf Canyon Fire;

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

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

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

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

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

6 **SEC. 103. DEFINITIONS.**

7 *In this Act:*

8 (1) *ADMINISTRATOR.*—*The term “Adminis-*
9 *trator” means—*

10 (A) *the Administrator of the Federal Emer-*
11 *gency Management Agency; or*

12 (B) *if a Manager is appointed under section*
13 *104(a)(3), the Manager.*

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

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

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

23 (C) *the merger of the two fires described in*
24 *subparagraphs (A) and (B), reported as the Her-*

1 *mit's Peak Fire or the Hermit's Peak Fire/Calf*
2 *Canyon Fire.*

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

12 (4) *INJURED PERSON.*—*The term “injured per-*
13 *son” means—*

14 (A) *an individual, regardless of the citizen-*
15 *ship or alien status of the individual; or*

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

22 (5) *INJURY.*—*The term “injury” has the same*
23 *meaning as the term “injury or loss of property, or*
24 *personal injury or death” as used in section*
25 *1346(b)(1) of title 28, United States Code.*

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

4 (7) *OFFICE*.—*The term “Office” means the Office*
5 *of Hermit’s Peak/Calf Canyon Fire Claims established*
6 *by section 104(a)(2).*

7 (8) *TRIBAL ENTITY*.—*The term “Tribal entity”*
8 *includes any Indian Tribe, tribal organization, In-*
9 *dian-controlled organization serving Indians, Native*
10 *Hawaiian organization, or Alaska Native entity, as*
11 *such terms are defined or used in section 166 of the*
12 *Workforce Innovation and Opportunity Act (29*
13 *U.S.C. 3221).*

14 **SEC. 104. COMPENSATION FOR VICTIMS OF HERMIT’S PEAK/**
15 **CALF CANYON FIRE.**

16 (a) *IN GENERAL*.—

17 (1) *COMPENSATION*.—*Each injured person shall*
18 *be eligible to receive from the United States com-*
19 *penensation for injury suffered by the injured person as*
20 *a result of the Hermit’s Peak/Calf Canyon Fire, sub-*
21 *ject to the availability of appropriations and subject*
22 *to the Administrator making the determinations re-*
23 *quired under subsection (d).*

24 (2) *OFFICE OF HERMIT’S PEAK/CALF CANYON*
25 *FIRE CLAIMS*.—

1 (A) *IN GENERAL.*—*There is established*
2 *within the Federal Emergency Management*
3 *Agency an Office of Hermit’s Peak/Calf Canyon*
4 *Fire Claims.*

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

8 (C) *FUNDING.*—*The Office—*

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

12 (ii) *may appoint and fix the com-*
13 *ensation of such temporary personnel as*
14 *may be necessary, without regard to the*
15 *provisions of title 5, United States Code,*
16 *governing appointments in competitive*
17 *service; and*

18 (iii) *may reimburse other Federal*
19 *agencies for claims processing support and*
20 *assistance.*

21 (3) *OPTION TO APPOINT INDEPENDENT CLAIMS*
22 *MANAGER.*—*The Administrator may appoint an Inde-*
23 *pendent Claims Manager to—*

24 (A) *head the Office; and*

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

3 (4) *DETAIL.*—Upon the request of the Adminis-
4 trator, the head of any Federal department or agency
5 may detail, on a reimbursable basis, any of the per-
6 sonnel of that department or agency to the Federal
7 Emergency Management Agency to assist the Agency
8 in carrying out the duties under this Act.

9 (b) *SUBMISSION OF CLAIMS.*—Not later than 2 years
10 after the date on which regulations are first promulgated
11 under subsection (f), an injured person may submit to the
12 Administrator a written claim for 1 or more injuries suf-
13 fered by the injured person in accordance with such require-
14 ments as the Administrator determines to be appropriate.

15 (c) *INVESTIGATION OF CLAIMS.*—

16 (1) *IN GENERAL.*—In accordance with subsection
17 (d), the Administrator shall, on behalf of the United
18 States, investigate, consider, ascertain, adjust, deter-
19 mine, grant, deny, or settle any claim for money
20 damages asserted under subsection (b).

21 (2) *APPLICABILITY OF STATE LAW.*—Except as
22 otherwise provided in this Act, the laws of the State
23 of New Mexico shall apply to the calculation of dam-
24 ages under subsection (d)(4).

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

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

5 (B) shall not include—

6 (i) interest before settlement or pay-
7 ment of a claim; or

8 (ii) punitive damages.

9 (d) *PAYMENT OF CLAIMS.*—

10 (1) *DETERMINATION AND PAYMENT OF*
11 *AMOUNT.*—

12 (A) *IN GENERAL.*—

13 (i) *PAYMENT.*—Not later than 180
14 days after the date on which a claim is sub-
15 mitted under this Act, the Administrator
16 shall determine and fix the amount, if any,
17 to be paid for the claim.

18 (ii) *PRIORITY.*—The Administrator, to
19 the maximum extent practicable, shall pay
20 subrogation claims submitted under this Act
21 only after paying claims submitted by in-
22 jured parties that are not insurance compa-
23 nies seeking payment as subrogees.

1 (B) *PARAMETERS OF DETERMINATION.*—*In*
2 *determining and settling a claim under this Act,*
3 *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 Hermit’s*
8 *Peak/Calf Canyon Fire;*

9 (iii) *whether the person or persons are*
10 *otherwise eligible to receive any amount de-*
11 *termined 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, the*
20 *Administrator shall reduce the amount to be*
21 *paid for the claim by an amount that is*
22 *equal to the total of insurance benefits (ex-*
23 *cluding 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 the*
11 *determination required under paragraph (1)(B),*
12 *before the final settlement of a claim, including*
13 *final settlement on any portion or aspect of a*
14 *claim that is determined to be severable.*

15 (B) *JUDICIAL DECISION.*—*If a claimant re-*
16 *ceives a partial payment on a claim under this*
17 *Act, but further payment on the claim is subse-*
18 *quently denied by the Administrator, the claim-*
19 *ant may—*

20 (i) *seek judicial review under sub-*
21 *section (i); and*

22 (ii) *keep any partial payment that the*
23 *claimant received, unless the Administrator*
24 *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 de-
8 scribed in subsection (a), the insurer or other third
9 party shall be subrogated to any right that the claim-
10 ant has to receive any payment under this Act or any
11 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 infrastructure,
23 including irrigation infrastructure such as
24 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 the
5 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 inven-
20 tory, 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 paid
5 for injury under this Act may include damages
6 resulting from the Hermit’s Peak/Calf Canyon
7 Fire for the following types of otherwise uncom-
8 pensated 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 de-
18 termined 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 lev-
22 els prevailing in those counties before the
23 Hermit’s Peak/Calf Canyon Fire, that are
24 incurred not later than the date that is 3
25 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 May*
5 *31, 2024, if, as a result of the Hermit’s*
6 *Peak/Calf Canyon Fire, a person that was*
7 *not required to purchase flood insurance be-*
8 *fore the Hermit’s Peak/Calf Canyon Fire is*
9 *required to purchase flood insurance.*

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

12 *(x) Any other loss that the Adminis-*
13 *trator determines to be appropriate for in-*
14 *clusion as financial loss.*

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

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

21 *(2) constitute a complete release of all claims*
22 *against the United States (including any agency or*
23 *employee of the United States) under chapter 171 of*
24 *title 28, United States Code (commonly known as the*
25 *“Federal Tort Claims Act”), or any other Federal or*

1 *State law, arising out of or relating to the same sub-*
2 *ject matter.*

3 *(f) REGULATIONS AND PUBLIC INFORMATION.—*

4 *(1) REGULATIONS.—Notwithstanding any other*
5 *provision of law, not later than 45 days after the date*
6 *of enactment of this Act, the Administrator shall pro-*
7 *mulgate and publish in the Federal Register interim*
8 *final regulations for the processing and payment of*
9 *claims under this Act.*

10 *(2) PUBLIC INFORMATION.—*

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

18 *(i) the rights conferred under this Act;*

19 *and*

20 *(ii) the procedural and other require-*
21 *ments of the regulations promulgated under*
22 *paragraph (1).*

23 *(B) DISSEMINATION THROUGH OTHER*
24 *MEDIA.—The Administrator shall disseminate*
25 *the explanation published under subparagraph*

1 (A) through websites, blogs, social media, bro-
2 chures, pamphlets, radio, television, and other
3 media that the Administrator determines are
4 likely to reach prospective claimants.

5 (g) CONSULTATION.—In administering this Act, the
6 Administrator shall consult with the Secretary of the Inte-
7 rior, the Secretary of Energy, the Secretary of Agriculture,
8 the Administrator of the Small Business Administration,
9 other Federal agencies, and State, local, and Tribal authori-
10 ties, as determined to be necessary by the Administrator,
11 to—

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

14 (2) provide for local concerns.

15 (h) ELECTION OF REMEDY.—

16 (1) IN GENERAL.—An injured person may elect
17 to seek compensation from the United States for 1 or
18 more injuries resulting from the Hermit's Peak/Calf
19 Canyon Fire by—

20 (A) submitting a claim under this Act;

21 (B) filing a claim or bringing a civil action
22 under chapter 171 of title 28, United States Code
23 (commonly known as the “Federal Tort Claims
24 Act”); or

1 (C) *bringing an authorized civil action*
2 *under any other provision of law.*

3 (2) *EFFECT OF ELECTION.*—*In accordance with*
4 *subsection (e), an election by an injured person to*
5 *seek compensation in any manner described in para-*
6 *graph (1) shall be final and conclusive on the claim-*
7 *ant with respect to all injuries resulting from the*
8 *Hermit's Peak/Calf Canyon Fire that are suffered by*
9 *the claimant upon acceptance of an award.*

10 (3) *ARBITRATION.*—

11 (A) *IN GENERAL.*—*Not later than 45 days*
12 *after the date of enactment of this Act, the Ad-*
13 *ministrator shall establish by regulation proce-*
14 *dures under which a dispute regarding a claim*
15 *submitted under this Act may be settled by arbi-*
16 *tration.*

17 (B) *ARBITRATION AS REMEDY.*—*On estab-*
18 *lishment of arbitration procedures under sub-*
19 *paragraph (A), an injured person that submits*
20 *a disputed claim under this Act may elect to set-*
21 *tle the claim through arbitration.*

22 (C) *BINDING EFFECT.*—*An election by an*
23 *injured person to settle a claim through arbitra-*
24 *tion under this paragraph shall—*

25 (i) *be binding; and*

1 (ii) preclude any exercise by the in-
2 jured person of the right to judicial review
3 of a claim described in subsection (i).

4 (4) *NO EFFECT ON ENTITLEMENTS.*—*The value*
5 *of compensation that may be provided under this Act*
6 *shall not be considered income or resources for any*
7 *purpose under any Federal, State, or local laws, in-*
8 *cluding laws relating to taxation, welfare, and public*
9 *assistance programs, and no State or political sub-*
10 *division thereof shall decrease any assistance other-*
11 *wise provided to an injured person because of the re-*
12 *ceipt of benefits under this Act.*

13 (i) *JUDICIAL REVIEW.*—

14 (1) *IN GENERAL.*—*Any claimant aggrieved by a*
15 *final decision of the Administrator under this Act*
16 *may, not later than 60 days after the date on which*
17 *the decision is issued, bring a civil action in the*
18 *United States District Court for the District of New*
19 *Mexico, to modify or set aside the decision, in whole*
20 *or in part.*

21 (2) *RECORD.*—*The court shall hear a civil action*
22 *under paragraph (1) on the record made before the*
23 *Administrator.*

24 (3) *STANDARD.*—*The decision of the Adminis-*
25 *trator incorporating the findings of the Administrator*

1 *shall be upheld if the decision is supported by sub-*
2 *stantial evidence on the record considered as a whole.*

3 *(j) ATTORNEY'S AND AGENT'S FEES.—*

4 *(1) IN GENERAL.—No attorney or agent, acting*
5 *alone or in combination with any other attorney or*
6 *agent, shall charge, demand, receive, or collect, for*
7 *services rendered in connection with a claim sub-*
8 *mitted under this Act, fees in excess of the limitations*
9 *established under section 2678 of title 28, United*
10 *States Code.*

11 *(2) VIOLATION.—An attorney or agent who vio-*
12 *lates paragraph (1) shall be fined not more than*
13 *\$10,000.*

14 *(k) WAIVER OF REQUIREMENT FOR MATCHING*
15 *FUNDS.—*

16 *(1) STATE AND LOCAL PROJECT.—*

17 *(A) IN GENERAL.—Notwithstanding any*
18 *other provision of law, a State or local project*
19 *that is determined by the Administrator to be*
20 *carried out in response to the Hermit's Peak/Calf*
21 *Canyon Fire under any Federal program that*
22 *applies to an area affected by the Hermit's Peak/*
23 *Calf Canyon Fire shall not be subject to any re-*
24 *quirement for State or local matching funds to*

1 *pay the cost of the project under the Federal pro-*
2 *gram.*

3 *(B) FEDERAL SHARE.—The Federal share*
4 *of the costs of a project described in subpara-*
5 *graph (A) shall be 100 percent.*

6 *(2) OTHER NEEDS PROGRAM ASSISTANCE.—Not-*
7 *withstanding section 408(g)(2) of the Robert T. Staf-*
8 *ford Disaster Relief and Emergency Assistance Act*
9 *(42 U.S.C. 5174(g)(2)), for any emergency or major*
10 *disaster declared by the President under that Act for*
11 *the Hermit's Peak/Calf Canyon Fire, the Federal*
12 *share of assistance provided under that section shall*
13 *be 100 percent.*

14 *(3) AGRICULTURAL PROGRAM ASSISTANCE.—*

15 *(A) IN GENERAL.—Notwithstanding any*
16 *other provision of law, a State, local, or indi-*
17 *vidual project that is determined by the Sec-*
18 *retary of Agriculture to be carried out in re-*
19 *sponse to the Hermit's Peak/Calf Canyon Fire*
20 *under any Federal program that applies to an*
21 *area affected by the Hermit's Peak/Calf Canyon*
22 *Fire shall not be subject to any requirement for*
23 *State, local, or individual matching funds to pay*
24 *the cost of the project under the Federal pro-*
25 *gram.*

1 (B) *FEDERAL SHARE.*—*The Federal share*
2 *of the costs of a project described in subpara-*
3 *graph (A) shall be 100 percent.*

4 (l) *APPLICABILITY OF DEBT COLLECTION REQUIRE-*
5 *MENTS.*—*Section 3711(a) of title 31, United States Code,*
6 *shall not apply to any payment under this Act, unless—*
7 (1) *there is evidence of civil or criminal fraud,*
8 *misrepresentation, presentation of a false claim; or*
9 (2) *a claimant was not eligible under subsection*
10 *(d)(2) of this Act to any partial payment.*

11 (m) *INDIAN COMPENSATION.*—*Notwithstanding any*
12 *other provision of law, in the case of an Indian Tribe, a*
13 *Tribal entity, or a member of an Indian Tribe that submits*
14 *a claim under this Act—*

15 (1) *the Bureau of Indian Affairs shall have no*
16 *authority over, or any trust obligation regarding, any*
17 *aspect of the submission of, or any payment received*
18 *for, the claim;*

19 (2) *the Indian Tribe, Tribal entity, or member*
20 *of an Indian Tribe shall be entitled to proceed under*
21 *this Act in the same manner and to the same extent*
22 *as any other injured person; and*

23 (3) *except with respect to land damaged by the*
24 *Hermit's Peak/Calf Canyon Fire that is the subject of*
25 *the claim, the Bureau of Indian Affairs shall have no*

1 *responsibility to restore land damaged by the Her-*
2 *mit's Peak/Calf Canyon Fire.*

3 *(n) REPORT.—Not later than 1 year after the date of*
4 *promulgation of regulations under subsection (f)(1), and*
5 *annually thereafter, the Administrator shall submit to Con-*
6 *gress a report that describes the claims submitted under this*
7 *Act during the year preceding the date of submission of the*
8 *report, including, for each claim—*

9 *(1) the amount claimed;*

10 *(2) a brief description of the nature of the claim;*

11 *and*

12 *(3) the status or disposition of the claim, includ-*
13 *ing the amount of any payment under this Act.*

14 *(o) AUTHORIZATION OF APPROPRIATIONS.—There are*
15 *authorized to be appropriated such sums as are necessary*
16 *to carry out this Act.*

Attest:

Secretary.

117TH CONGRESS
2^D SESSION

H.R. 6833

AMENDMENT