

119TH CONGRESS
1ST SESSION

H. R. 1396

To amend the Internal Revenue Code of 1986 to establish the generic drugs and biosimilars production credit, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 14, 2025

Ms. TENNEY introduced the following bill; which was referred to the Committee on Ways and Means

A BILL

To amend the Internal Revenue Code of 1986 to establish the generic drugs and biosimilars production credit, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Producing Incentives
5 for Long-term production of Lifesaving Supply of medi-
6 cine Act” or the “PILLS Act”.

7 **SEC. 2. GENERIC DRUGS AND BIOSIMILARS PRODUCTION**
8 **CREDIT.**

9 (a) IN GENERAL.—Subpart D of part IV of sub-
10 chapter A of chapter 1 of the Internal Revenue Code of

1 1986 is amended by adding at the end the following new
2 section:

3 **“SEC. 45BB. GENERIC DRUGS AND BIOSIMILARS PRODUC-**
4 **TION CREDIT.**

5 “(a) IN GENERAL.—

6 “(1) ALLOWANCE OF CREDIT.—For purposes of
7 section 38, the generic drugs and biosimilars produc-
8 tion credit for any taxable year is an amount equal
9 to the credit amount determined under subsection
10 (b) with respect to each eligible component which
11 is—

12 “(A) produced by the taxpayer in the
13 United States, and

14 “(B) sold by such taxpayer to an unrelated
15 person (as determined by the Secretary) during
16 the taxable year.

17 “(2) PRODUCTION AND SALE MUST BE IN
18 TRADE OR BUSINESS.—Rules similar to the rules of
19 section 45X(a)(2) shall apply.

20 “(3) DISALLOWANCE OF CREDIT.—The credit
21 under this subsection shall not be allowed to any
22 taxpayer which, at any time during the taxable year,
23 was a foreign entity of concern (as defined in section
24 9901(8) of the William M. (Mac) Thornberry Na-

1 tional Defense Authorization Act for Fiscal Year
2 2021 (15 U.S.C. 4651)).

3 “(b) CREDIT AMOUNT.—For purposes of this sec-
4 tion—

5 “(1) IN GENERAL.—Subject to paragraph (4),
6 the amount determined under this subsection with
7 respect to any eligible component is an amount equal
8 to the base credit percentage of the value added to
9 such component by the taxpayer.

10 “(2) VALUE ADDED.—The value added to a
11 component by a taxpayer is an amount equal to—

12 “(A) the gross receipts received by the tax-
13 payer from the sale of the eligible component,
14 minus

15 “(B) the cost of eligible components pur-
16 chased from an unrelated person in connection
17 with the production of the component by the
18 taxpayer.

19 “(3) BASE CREDIT PERCENTAGE.—

20 “(A) IN GENERAL.—Except as provided in
21 subparagraphs (B) and (C), the base credit per-
22 centage is 30 percent.

23 “(B) INCREASED BASE CREDIT PERCENT-
24 AGE FOR CERTAIN ELIGIBLE COMPONENTS.—

1 The base credit percentage is 35 percent in the
2 case of the final production of—

3 “(i) a drug substance,

4 “(ii) a drug product, or

5 “(iii) a biological product.

6 “(C) DOMESTIC CONTENT BONUS CRED-
7 IT.—

8 “(i) IN GENERAL.—In the case of an
9 eligible component which contains domestic
10 content, the base credit percentage deter-
11 mined under this paragraph (determined
12 without regard to this subparagraph) shall
13 be increased by an amount equal to—

14 “(I) the domestic content per-
15 centage, multiplied by

16 “(II) 0.20.

17 “(ii) DOMESTIC CONTENT PERCENT-
18 AGE.—For purposes of this subparagraph,
19 the term ‘domestic content percentage’
20 means the percentage of the total cost of
21 the eligible components taken into account
22 for purposes of paragraph (2) which is at-
23 tributable to materials and components
24 that were produced in the United States.

25 “(iii) DOCUMENTATION RULES.—

1 “(I) RECORD KEEPING.—No do-
2 mestic content bonus credit shall be
3 determined under this subparagraph
4 unless the taxpayer provides docu-
5 mentation supporting the domestic
6 content percentage (in such form and
7 manner as the Secretary shall pre-
8 scribe).

9 “(II) CERTIFICATION BY UNRE-
10 LATED PARTY.—In the case of mate-
11 rials or components provided to the
12 taxpayer by an unrelated party, the
13 Secretary shall accept certification (in
14 such form and manner as the Sec-
15 retary shall prescribe) by such unre-
16 lated party that the materials or com-
17 ponents were produced in the United
18 States.

19 “(4) PHASE OUT.—

20 “(A) IN GENERAL.—In the case of any eli-
21 gible component sold after December 31, 2030,
22 the amount determined under this subsection
23 with respect to such component shall be equal
24 to the product of—

1 “(i) the amount determined under
2 paragraph (1) with respect to such compo-
3 nent (determined without regard to this
4 paragraph and after the application of
5 paragraphs (2) and (3)), and

6 “(ii) the phase out percentage.

7 “(B) PHASE OUT PERCENTAGE.—For pur-
8 poses of subparagraph (A), the phase out per-
9 centage is—

10 “(i) in the case of an eligible compo-
11 nent sold during calendar year 2031, 75
12 percent,

13 “(ii) in the case of an eligible compo-
14 nent sold during calendar year 2032, 50
15 percent,

16 “(iii) in the case of an eligible compo-
17 nent sold during calendar year 2033, 25
18 percent, and

19 “(iv) in the case of an eligible compo-
20 nent sold after December 31, 2033, 0 per-
21 cent.

22 “(c) DEFINITIONS.—For purposes of this section—

23 “(1) ELIGIBLE COMPONENT.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraphs (B) and (C), the term ‘eligible
3 component’ means—

4 “(i) an approved generic drug,

5 “(ii) a licensed biosimilar, and

6 “(iii) any drug substance, inter-
7 mediate raw material, starting material,
8 reagent, component, in-process material,
9 inactive ingredient, container closure sys-
10 tem, packaging, quality testing, or other
11 material or service used, or sold with in-
12 tention for use, in the production of an ap-
13 proved generic drug or a licensed bio-
14 similar.

15 “(B) EXCLUSION OF CERTAIN COMPO-
16 NENTS.—The term ‘eligible component’ shall
17 not include a component any portion of the pro-
18 duction of which occurred at a facility which is
19 the subject of a warning letter—

20 “(i) which was issued by the Food
21 and Drug Administration on or after Sep-
22 tember 1, 2009, and

23 “(ii) with respect to which the Food
24 and Drug Administration has not issued a
25 close-out letter.

1 “(C) APPLICATION WITH OTHER CRED-
 2 ITS.—The term ‘eligible component’ shall not
 3 include any property which is produced at a fa-
 4 cility if the basis of any property which is part
 5 of such facility is taken into account for pur-
 6 poses of the credit allowed under section 48F
 7 after the date of the enactment of this section.

8 “(2) APPROVED GENERIC DRUG.—The term
 9 ‘approved generic drug’ means—

10 “(A) a drug for which an approval of an
 11 application filed under section 505(j) of the
 12 Federal Food, Drug, and Cosmetic Act (21
 13 U.S.C. 355(j)) is in effect, or

14 “(B) an authorized generic drug (as de-
 15 fined in section 314.3 of title 21, Code of Fed-
 16 eral Regulations (or any successor regulation)).

17 “(3) LICENSED BIOSIMILAR.—

18 “(A) IN GENERAL.—The term ‘licensed
 19 biosimilar’ means a biological product for which
 20 a biologics license has been issued under section
 21 351(k) of the Public Health Service Act (42
 22 U.S.C. 262(k)).

23 “(B) BIOLOGICAL PRODUCT.—The term
 24 ‘biological product’ has the meaning given such

1 term in section 351(i)(1) of the Public Health
2 Service Act (42 U.S.C. 262(i)(1)).

3 “(4) OTHER TERMS.—The terms ‘drug sub-
4 stance’ and ‘drug product’ have the respective mean-
5 ings given such terms in section 314.3 of title 21,
6 Code of Federal Regulations (or any successor regu-
7 lation).

8 “(5) PRODUCED IN THE UNITED STATES.—The
9 term ‘produced in the United States’ means that all
10 the production of the material or component takes
11 place in the United States, regardless of the origin
12 of the subcomponents of such material or compo-
13 nent.

14 “(6) PRODUCTION.—The term ‘production’
15 means all steps in the manufacture, propagation,
16 and preparation of an eligible component, including
17 synthesis, mixing, granulating, milling, molding,
18 lyophilizing, tableting, encapsulating, coating, steri-
19 lizing, testing, filling, labeling, packaging, and stor-
20 age prior to release by the manufacturer.

21 “(d) SPECIAL RULES.—Rules similar to the rules of
22 paragraphs (1), (3), and (4) of section 45X(d) shall apply.

23 “(e) REGULATORY AUTHORITY.—The Secretary shall
24 prescribe such regulations and other guidance as are ap-

1 appropriate or necessary to carry out the purposes of this
2 section.”.

3 (b) ELECTIVE PAYMENT.—

4 (1) IN GENERAL.—Section 6417(b) of the In-
5 ternal Revenue Code of 1986 is amended by adding
6 at the end the following new paragraph:

7 “(13) The generic drugs and biosimilars pro-
8 duction credit determined under section 45BB.”.

9 (2) ELECTION WITH RESPECT TO OTHER ENTI-
10 TIES.—Paragraph (1) of section 6417(d) is amend-
11 ed—

12 (A) by redesignating subparagraph (E) as
13 subparagraph (F),

14 (B) by striking “or (D)” each place it ap-
15 pears in subparagraph (F), as so redesignated,
16 and inserting “(D), or (E)”, and

17 (C) by inserting after subparagraph (D)
18 the following new subparagraph:

19 “(E) ELECTION WITH RESPECT TO GE-
20 NERIC DRUGS AND BIOSIMILARS PRODUCTION
21 CREDIT.—

22 “(i) IN GENERAL.—If a taxpayer
23 other than an entity described in subpara-
24 graph (A) makes an election under this
25 subparagraph with respect to any taxable

1 year in which such taxpayer has, after De-
2 cember 31, 2024, produced eligible compo-
3 nents (as defined in section 45BB(c)(1)),
4 such taxpayer shall be treated as an appli-
5 cable entity for purposes of this section for
6 such taxable year, but only with respect to
7 the credit described in subsection (b)(13).

8 “(ii) OTHER RULES.—The rules of
9 clauses (ii) and (iii) of subparagraph (D)
10 shall apply for purposes of this subpara-
11 graph.”.

12 (c) TRANSFER OF CREDITS.—Section 6418(f)(1)(A)
13 of the Internal Revenue Code of 1986 is amended by add-
14 ing at the end the following new clause:

15 “(xii) The generic drugs and
16 biosimilars production credit determined
17 under section 45BB.”.

18 (d) CONFORMING AMENDMENTS.—

19 (1) Section 38(b) of the Internal Revenue Code
20 of 1986 is amended—

21 (A) by striking “plus” at the end of para-
22 graph (40),

23 (B) by striking the period at the end of
24 paragraph (41) and inserting “, plus”, and

1 (C) by adding at the end the following new
2 paragraph:

3 “(42) the generic drugs and biosimilars produc-
4 tion credit determined under section 45BB(a).”.

5 (2) The table of sections for subpart D of part
6 IV of subchapter A of chapter 1 of the Internal Rev-
7 enue Code of 1986 is amended by adding at the end
8 the following new item:

“Sec. 45BB. Generic drugs and biosimilars production credit.”.

9 (e) EFFECTIVE DATE.—The amendments made by
10 this section shall apply to generic drugs and biologics pro-
11 duced after the date of enactment of this Act.

12 **SEC. 3. GENERIC DRUGS AND BIOSIMILARS INVESTMENT**
13 **CREDIT.**

14 (a) IN GENERAL.—Subpart E of part IV of sub-
15 chapter A of chapter 1 of the Internal Revenue Code of
16 1986 is amended by inserting after section 48E the fol-
17 lowing new section:

18 **“SEC. 48F. GENERIC DRUGS AND BIOSIMILARS INVEST-**
19 **MENT CREDIT.**

20 “(a) ESTABLISHMENT OF CREDIT.—For purposes of
21 section 46, the generic drugs and biosimilars investment
22 credit for any taxable year is an amount equal to 25 per-
23 cent of the qualified investment for such taxable year with
24 respect to any qualified facility of an eligible taxpayer.

1 “(b) QUALIFIED INVESTMENT.—For purposes of this
2 section—

3 “(1) IN GENERAL.—The qualified investment
4 for any taxable year is the basis of any qualified
5 property placed in service by the taxpayer during
6 such taxable year which is part of a qualified facil-
7 ity.

8 “(2) QUALIFIED PROPERTY.—

9 “(A) IN GENERAL.—The term ‘qualified
10 property’ means property—

11 “(i) which is tangible property,

12 “(ii) with respect to which deprecia-
13 tion (or amortization in lieu of deprecia-
14 tion) is allowable,

15 “(iii) which is—

16 “(I) constructed, reconstructed,
17 or erected by the taxpayer, or

18 “(II) acquired by the taxpayer if
19 the original use of such property com-
20 mences with the taxpayer, and

21 “(iv) which is used as an integral part
22 of the qualified facility to produce eligible
23 components.

24 “(B) BUILDINGS AND STRUCTURAL COM-
25 PONENTS.—

1 “(i) IN GENERAL.—The term ‘quali-
2 fied property’ includes any building or its
3 structural components which otherwise sat-
4 isfies the requirements of subparagraph
5 (A).

6 “(ii) EXCEPTION.—Clause (i) shall
7 not apply with respect to a building or por-
8 tion of a building used for offices, adminis-
9 trative services, or other functions unre-
10 lated to the production of eligible compo-
11 nents.

12 “(3) QUALIFIED FACILITY.—The term ‘quali-
13 fied facility’ means a facility—

14 “(A) which is owned (in whole or in part)
15 by the taxpayer,

16 “(B) which is located in the United States
17 or any territory of the United States, and

18 “(C) the primary purpose of which is the
19 production of eligible components.

20 “(4) COORDINATION WITH REHABILITATION
21 CREDIT.—The qualified investment with respect to
22 any qualified facility for any taxable year shall not
23 include that portion of the basis of any property
24 which is attributable to qualified rehabilitation ex-
25 penditures (as defined in section 47(c)(2)).

1 “(5) CERTAIN PROGRESS EXPENDITURE RULES
2 MADE APPLICABLE.—Rules similar to the rules of
3 subsections (c)(4) and (d) of section 46 (as in effect
4 on the day before the date of the enactment of the
5 Revenue Reconciliation Act of 1990) shall apply.

6 “(c) DEFINITIONS.—For purposes of this section—

7 “(1) ELIGIBLE TAXPAYER.—The term ‘eligible
8 taxpayer’ means any taxpayer which is not a foreign
9 entity of concern (as defined in section 9901(8) of
10 the William M. (Mac) Thornberry National Defense
11 Authorization Act for Fiscal Year 2021 (15 U.S.C.
12 4651)).

13 “(2) ELIGIBLE COMPONENT.—The term ‘eligi-
14 ble component’ has the meaning given such term in
15 section 45BB(c)(1).

16 “(3) PRODUCTION.—The term ‘production’ has
17 the meaning given such term in section 45BB(c)(6).

18 “(d) TERMINATION OF CREDIT.—The credit allowed
19 under this section shall not apply to property the construc-
20 tion of which begins after December 31, 2028.

21 “(e) REGULATORY AUTHORITY.—The Secretary shall
22 prescribe such regulations and other guidance as are ap-
23 propriate or necessary to carry out the purposes of this
24 section.”.

25 (b) ELECTIVE PAYMENT.—

1 (1) IN GENERAL.—Section 6417(b) of the In-
 2 ternal Revenue Code of 1986, as amended by section
 3 2(b) of this Act, is further amended by adding at
 4 the end the following new paragraph:

5 “(14) The generic drugs and biosimilars invest-
 6 ment credit determined under section 48F.”.

7 (2) ELECTION WITH RESPECT TO OTHER ENTI-
 8 TIES.—Paragraph (1) of section 6417(d) of such
 9 Code, as amended by this Act, is further amended—

10 (A) by redesignating subparagraph (F) as
 11 subparagraph (G),

12 (B) by striking “or (E)” each place it ap-
 13 pears in subparagraph (G), as so redesignated,
 14 and inserting “(E), or (F)”, and

15 (C) by inserting after subparagraph (E)
 16 the following new subparagraph:

17 “(F) ELECTION WITH RESPECT TO GE-
 18 NERIC DRUGS AND BIOSIMILARS INVESTMENT
 19 CREDIT.—If a taxpayer other than an entity de-
 20 scribed in subparagraph (A) makes an election
 21 under this subparagraph with respect to any
 22 taxable year in which such taxpayer has placed
 23 in service a qualified facility (as defined in sec-
 24 tion 48F(b)(3)), such taxpayer shall be treated
 25 as an applicable entity for purposes of this sec-

1 tion for such taxable year, but only with respect
2 to the credit described in subsection (b)(14).”.

3 (c) TRANSFER OF CREDITS.—Section 6418(f)(1)(A)
4 of the Internal Revenue Code of 1986, as amended by this
5 Act, is further amended by adding at the end the following
6 new clause:

7 “(xiii) The generic drugs and
8 biosimilars investment credit determined
9 under section 48F.”.

10 (d) CONFORMING AMENDMENTS.—

11 (1) Section 46 of the Internal Revenue Code of
12 1986 is amended—

13 (A) by striking “and” at the end of para-
14 graph (6),

15 (B) by striking the period at the end of
16 paragraph (7) and inserting “, and”, and

17 (C) by adding at the end the following new
18 paragraph:

19 “(8) the generic drugs and biosimilars invest-
20 ment credit.”.

21 (2) Section 49(a)(1)(C) of such Code is amend-
22 ed—

23 (A) by striking “and” at the end of clause
24 (vii),

1 (B) by striking the period at the end of
2 clause (viii) and inserting “, and”, and

3 (C) by adding at the end the following new
4 clause:

5 “(ix) the basis of any qualified prop-
6 erty which is part of a qualified facility
7 under section 48F.”.

8 (3) The table of sections for subpart E of part
9 IV of subchapter A of chapter 1 is amended by in-
10 serting after the item relating to section 48E the fol-
11 lowing new item:

“48F. Generic drugs and biosimilars investment credit.”.

12 (e) EFFECTIVE DATE.—The amendments made by
13 this section shall apply to property placed in service after
14 December 31, 2026.

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