

119TH CONGRESS  
2D SESSION

# S. 5043

To direct the Food and Drug Administration to prevent the importation of counterfeit, unapproved, misbranded, or adulterated drugs from the People’s Republic of China or other foreign countries, to establish enhanced safeguards for imported drug products, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

JULY 21, 2026

Mr. BUDD introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To direct the Food and Drug Administration to prevent the importation of counterfeit, unapproved, misbranded, or adulterated drugs from the People’s Republic of China or other foreign countries, to establish enhanced safeguards for imported drug products, 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 “Secure Drug Supply  
5 Chain Act of 2026”.

1 **SEC. 2. PURPOSE.**

2 The purposes of this Act are—

3 (1) to prevent the unlawful importation of coun-  
4 terfeit, unapproved, misbranded, or adulterated  
5 drugs from the People’s Republic of China and other  
6 countries that are known to engage in intellectual  
7 property theft, forced labor, or the distribution of  
8 counterfeit and illicit pharmaceutical products that  
9 undermine the public health and economic interests  
10 of the United States;

11 (2) to increase visibility into the United States  
12 pharmaceutical supply chain; and

13 (3) to reduce the direct and indirect dependence  
14 of the United States on active pharmaceutical ingre-  
15 dients and key starting materials sourced from the  
16 People’s Republic of China or that are of Chinese  
17 origin and sourced through third countries, in order  
18 to strengthen the resilience of the United States  
19 drug supply and protect public health and national  
20 security.

21 **SEC. 3. PREVENTION OF IMPORTATION OF UNLAWFUL**  
22 **COUNTERFEIT PRESCRIPTION AND OVER-**  
23 **THE-COUNTER DRUGS.**

24 (a) IN GENERAL.—The Secretary of Health and  
25 Human Services (referred to in this Act as the “Sec-  
26 retary”) shall utilize authorities under the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to prevent  
2 the importation of drugs, including active pharmaceutical  
3 ingredients and key starting materials, that are counter-  
4 feit, unapproved, misbranded, or adulterated and manu-  
5 factured, prepared, propagated, compounded, and proc-  
6 essed in a foreign establishment, with particular emphasis  
7 on preventing importation of such drugs, including active  
8 pharmaceutical ingredients and key starting materials,  
9 from the People's Republic of China and other countries  
10 that are designated as adversarial by the Secretary of  
11 State.

12 (b) ENFORCEMENT ACTIONS.—In carrying out sub-  
13 section (a), the Secretary shall—

14 (1) conduct compliance and enforcement actions  
15 directed at entities involved in the manufacture,  
16 preparation, propagation, compounding, processing,  
17 or distribution of unapproved, adulterated, or mis-  
18 branded drugs, including active pharmaceutical in-  
19 gredients and key starting materials, that are of-  
20 fered for import;

21 (2) in cooperation with the Attorney General,  
22 initiate civil and criminal enforcement actions, in-  
23 cluding injunctions and seizures, under sections 301,  
24 302, 303, 304, and 801 of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 331, 332, 333, 334,  
2 381);

3 (3) refuse entry into the United States of such  
4 drugs, including active pharmaceutical ingredients or  
5 key starting materials; and

6 (4) conduct inspections of, or use alternative  
7 tools with respect to, as appropriate, facilities en-  
8 gaged in compounding to monitor for unauthorized  
9 receipt, use, or handling of drugs from the People's  
10 Republic of China and other countries designated as  
11 adversarial by the Secretary of State that were im-  
12 ported into the United States in violation of applica-  
13 ble laws and regulations.

14 (c) ANNUAL REPORTING.—Beginning with fiscal year  
15 2027, not later than 180 days after the end of each fiscal  
16 year, the Secretary shall submit a report to the Committee  
17 on Health, Education, Labor, and Pensions of the Senate  
18 and the Committee on Energy and Commerce of the  
19 House of Representatives, detailing enforcement actions  
20 described in subsection (b) that were taken in the previous  
21 fiscal year, including information on the number and type  
22 of drugs, active pharmaceutical ingredients, and key start-  
23 ing materials that were the subjects of such actions during  
24 the previous fiscal year.

1 (d) GUIDANCE; RECOMMENDATIONS.—Not later than  
 2 180 days after the submission of each report under sub-  
 3 section (c), based on the information compiled in the re-  
 4 port, the Secretary shall—

5 (1) issue or update guidance for importers of  
 6 drugs to comply with the requirements of this Act,  
 7 including the amendments made by this Act; and

8 (2) submit to Congress legislative proposals re-  
 9 lating to resources and policies that would facilitate  
 10 carrying out this Act, including the amendments  
 11 made by this Act.

12 **SEC. 4. SUPPLY CHAIN TRANSPARENCY AND RESILIENCE.**

13 (a) REPORTING REQUIREMENTS FOR ACTIVE PHAR-  
 14 MACEUTICAL INGREDIENTS AND KEY STARTING MATE-  
 15 RIALS.—

16 (1) IN GENERAL.—Section 510(j)(3) of the  
 17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
 18 360(j)(3)) is amended—

19 (A) in the first sentence of subparagraph

20 (A)—

21 (i) by striking “annually” and insert-  
 22 ing “quarterly”; and

23 (ii) by inserting “and the information  
 24 described in subparagraph (C)” before the  
 25 period at the end; and

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

2 “(C)(i) The annual report required under sub-  
3 paragraph (A) shall include the information de-  
4 scribed in clause (ii) with respect to drugs, in ac-  
5 cordance with the following:

6 “(I) In the 1-year period beginning on the  
7 effective date of the final regulations described  
8 in section 4(c) of the Secure Drug Supply  
9 Chain Act of 2026, the information described in  
10 clause (ii) shall be included in the report under  
11 subparagraph (A) with respect to any drug  
12 that—

13 “(aa) is included on the Essential  
14 Medicines List maintained by the Food  
15 and Drug Administration pursuant to Ex-  
16 ecutive Order 13944 (85 Fed. Reg.  
17 49929); and

18 “(bb) is a drug for which any active  
19 pharmaceutical ingredient, key starting  
20 material, or acquired intermediate is  
21 sourced from the People’s Republic of  
22 China or another foreign country of con-  
23 cern.

24 “(II) Beginning on the day after the last  
25 day of the 1-year period described in subclause

1 (I), the information described in clause (ii) shall  
2 be included in the report under subparagraph  
3 (A) if it is a drug for which any active pharma-  
4 ceutical ingredient, key starting material, or ac-  
5 quired intermediate is sourced from the Peo-  
6 ple's Republic of China or another foreign coun-  
7 try of concern.

8 “(ii) The information described in this clause is  
9 the following, as applicable:

10 “(I) The identity of each active pharma-  
11 ceutical ingredient, key starting material, and  
12 acquired intermediate used by the registrant to  
13 manufacture the listed drug.

14 “(II) The total amount of each such active  
15 pharmaceutical ingredient, key starting mate-  
16 rial, and acquired intermediate used by the reg-  
17 istrant to manufacture the listed drug during  
18 the reporting period, expressed in such units as  
19 the Secretary shall specify.

20 “(III) The country of origin of each such  
21 active pharmaceutical ingredient, key starting  
22 material, and acquired intermediate, including  
23 the name, address, and unique facility identifier  
24 (as applicable) of each establishment at which  
25 such active pharmaceutical ingredient, key

1 starting material, or acquired intermediate was  
2 manufactured.

3 “(iii) Information reported under this subpara-  
4 graph shall include the country of origin without re-  
5 gard to any distribution or shipment through a  
6 country other than the country of origin.

7 “(iv) A person required to report information  
8 under this subparagraph shall maintain such records  
9 and supporting documentation as the Secretary shall  
10 require to verify the accuracy and completeness of  
11 information submitted under this paragraph, for a  
12 period of not less than 5 years, and shall make such  
13 records available to the Secretary upon request.

14 “(D) Not later than 18 months after the 1-year  
15 period described in subparagraph (C)(i)(I) ends, and  
16 annually thereafter, the Secretary shall, based on  
17 the reports submitted under subparagraph (A), issue  
18 a confidential report to Congress that—

19 “(i) analyzes United States vulnerabilities  
20 arising from dependence on active pharma-  
21 ceutical ingredients and key starting materials  
22 sourced from the People’s Republic of China or  
23 other foreign countries of concern, including  
24 any such ingredients or materials with origins  
25 in the People’s Republic of China or another



1 foreign country of concern that are sourced  
2 through third countries;

3 “(ii) identifies the proportion of drugs  
4 manufactured, prepared, propagated, com-  
5 pounded, or processed for commercial distribu-  
6 tion in the United States that depend on active  
7 pharmaceutical ingredients and key starting  
8 materials sourced from the People’s Republic of  
9 China or other foreign countries of concern,  
10 disaggregated by country of origin to the extent  
11 practicable;

12 “(iii) determines specific supply chain  
13 vulnerabilities, including drug classes or thera-  
14 peutic categories for which dependence on ac-  
15 tive pharmaceutical ingredients and key start-  
16 ing materials sourced from the People’s Repub-  
17 lic of China or another foreign country of con-  
18 cern, poses a risk to public health or national  
19 security; and

20 “(iv) tracks trends over time in dependence  
21 on active pharmaceutical ingredients and key  
22 starting materials sourced from the People’s  
23 Republic of China or another foreign country of  
24 concern, including anonymized aggregate data

1 reflecting increases or decreases in such de-  
2 pendence.

3 “(E) In this paragraph:

4 “(i) The term ‘acquired intermediate’  
5 means a material produced during steps in the  
6 manufacture of an active pharmaceutical ingre-  
7 dient that undergoes further molecular change  
8 or purification before it becomes an active phar-  
9 maceutical ingredient and is manufactured at  
10 an establishment other than the establishment  
11 at which the active pharmaceutical ingredient is  
12 manufactured.

13 “(ii) The term ‘country of origin’ means,  
14 with respect to an active pharmaceutical ingre-  
15 dient, key starting material, or acquired inter-  
16 mediate, each country in which such ingredient,  
17 intermediate, or material was manufactured  
18 into its chemical identity through chemical syn-  
19 thesis, fermentation, extraction, purification, or  
20 other manufacturing process including each  
21 country at which such active pharmaceutical in-  
22 gredient, key starting material, or acquired in-  
23 termediate was repackaged, relabeled, finished,  
24 blended, or tested.

1                   “(iii) The term ‘foreign country of concern’  
2                   has the meaning given such term in section  
3                   10612(a) of the Research and Development,  
4                   Competition, and Innovation Act.”.

5                   (2) CONFIDENTIALITY.—Nothing in the amend-  
6                   ment made by paragraph (1) shall be construed as  
7                   authorizing the Secretary to disclose any information  
8                   that is a trade secret or confidential information  
9                   subject to section 552(b)(4) of title 5, United States  
10                  Code, or section 1905 of title 18, United States  
11                  Code.

12                  (b) REGULATORY GAP ANALYSIS.—Not later than  
13                  180 days after the date of enactment of this Act, the Sec-  
14                  retary shall identify and submit to Congress a report de-  
15                  scribing—

16                   (1) existing regulatory authorities available to  
17                   the Secretary to support or incentivize the sourcing  
18                   of active pharmaceutical ingredients and key start-  
19                   ing materials from countries other than the People’s  
20                   Republic of China, or from sources with no People’s  
21                   Republic of China origin content; and

22                   (2) any deficiencies in existing regulatory au-  
23                   thorities that limit the ability of the Secretary to  
24                   support or incentivize such sourcing, together with

1 recommendations for legislative or administrative ac-  
 2 tion to address such deficiencies.

3 (c) REGULATIONS.—The Secretary of Health and  
 4 Human Services shall—

5 (1) not later than 90 days after the date of en-  
 6 actment of this Act, issue proposed regulations im-  
 7 plementing the amendments made by subsection (a);  
 8 and

9 (2) not later than 180 days after issuance of  
 10 the proposed regulations described in paragraph (1),  
 11 finalize such regulations.

12 **SEC. 5. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**  
 13 **COSMETIC ACT.**

14 (a) BAN ON IMPORTS OF DRUGS FROM ESTABLISH-  
 15 MENTS USING FORCED LABOR OR VIOLATING SANC-  
 16 TIONS.—Section 801(a) of the Federal Food, Drug, and  
 17 Cosmetic Act (21 U.S.C. 381(a)) is amended, in the third  
 18 sentence—

19 (1) by inserting “or (6) such article is a drug  
 20 and the safety of such drug is based solely on infor-  
 21 mation or certifications provided by a foreign gov-  
 22 ernment, including any inspection described in sec-  
 23 tion 704(i), without routine inspections conducted by  
 24 United States inspectors to verify compliance with  
 25 this Act, or (7) such article is a drug and was manu-

1       factured, prepared, propagated, compounded, proc-  
 2       essed in an establishment known to have used forced  
 3       labor (as defined in section 307 of the Tariff Act of  
 4       1930) or to have been in violation of sanctions im-  
 5       posed by the Federal Government under the Inter-  
 6       national Emergency Economic Powers Act or other  
 7       applicable law, as determined by the Secretary in  
 8       consultation with the Secretary of Homeland Secu-  
 9       rity,” after “301(cc),”; and

10               (2) by striking “clauses (1) through (5)” and  
 11       inserting “clauses (1) through (7)”.

12       (b) DESTRUCTION OF REFUSED ARTICLES PRE-  
 13       SENTING SIGNIFICANT PUBLIC HEALTH CONCERNS.—  
 14       Section 801 of the Federal Food, Drug, and Cosmetic Act  
 15       (21 U.S.C. 381) is amended by adding at the end the fol-  
 16       lowing:

17       “(v) DESTRUCTION OF REFUSED ARTICLES PRE-  
 18       SENTING SIGNIFICANT PUBLIC HEALTH CONCERNS.—

19               “(1) IN GENERAL.—If the Secretary determines  
 20       that an article that has been refused admission  
 21       under subsection (a) presents a significant public  
 22       health concern, the Secretary may issue to the owner  
 23       or consignee of the article an order to destroy the  
 24       article, without the opportunity for export.

1           “(2) DEADLINE; COSTS.—Not later than 90  
2       days after the issuance of an order under paragraph  
3       (1), the owner or consignee shall destroy the article.  
4       The owner or consignee shall be responsible for the  
5       costs of such destruction.

6           “(3) DUE PROCESS.—The Secretary shall pro-  
7       vide to the owner or consignee of an article subject  
8       to an order under paragraph (1) appropriate due  
9       process prior to the destruction of the article. Such  
10      due process shall include notice and an opportunity  
11      to appear before the Secretary and introduce testi-  
12      mony on the destruction, in combination with the  
13      notice and opportunity to appear and introduce tes-  
14      timony on the refusal of admission of the article  
15      under subsection (a) or separately.”.

16       (c) PROHIBITION ON REGISTRATION OF CERTAIN  
17      FOREIGN ESTABLISHMENTS.—Section 510(i) of the Fed-  
18      eral Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is  
19      amended by adding at the end the following:

20       “(6) Notwithstanding any other provision of this sec-  
21      tion, any establishment that knowingly used, or partnered  
22      with, contracted with, or purchased from an entity that  
23      has used, forced labor (as defined in section 307 of the  
24      Tariff Act of 1930) or that knowingly violated sanctions  
25      imposed by the Federal Government under the Inter-

1 national Emergency Economic Powers Act or other appli-  
2 cable law, as determined by the Secretary in consultation  
3 with the Secretary of Homeland Security, shall not be eli-  
4 gible for registration under this section, and the Secretary  
5 shall revoke any registration of such an establishment that  
6 was accepted prior to the date of enactment of the Secure  
7 Drug Supply Chain Act of 2026.”.

8 (d) PROHIBITED ACTS.—Section 301 of the Federal  
9 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
10 ed by adding at the end the following:

11 “(jjj) The unauthorized movement, or introduction or  
12 delivery for introduction into interstate commerce, includ-  
13 ing export, of an article that is subject to an order for  
14 destruction under section 801(v).

15 “(kkk) The knowing provision of a materially false,  
16 fictitious, or fraudulent statement or representation to the  
17 Secretary that accompanies or relates to a drug imported  
18 or offered for import into the United States.

19 “(lll) The import or offering for import into the  
20 United States of a drug that previously has been refused  
21 admission under section 801(a) or exported during the  
22 pendency of a detention, unless the person reimporting or  
23 reoffering the drug affirmatively makes reference to the  
24 original refusal or detention and establishes that the drug

1 complies with the applicable requirements of this Act, as  
2 determined by the Secretary.”.

3 (e) MISBRANDED DRUGS.—Section 502 of the Fed-  
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 352) is  
5 amended by adding at the end the following:

6 “(hh) If it is a drug, including an active pharma-  
7 ceutical ingredient and key starting material, imported or  
8 offered for import and the drug is accompanied by a mate-  
9 rially false, fictitious, or fraudulent statement or represen-  
10 tation knowingly made by the person importing the drug  
11 or offering the drug for import.”.

12 (f) ADULTERATED DRUGS.—Section 501 of the Fed-  
13 eral Food, Drug, and Cosmetic Act (21 U.S.C. 351) is  
14 amended by adding at the end the following:

15 “(k) If it is an active pharmaceutical ingredient that  
16 has not been approved as part of an application under sec-  
17 tion 505 of this Act or 351 of the Public Health Service  
18 Act, or otherwise approved or authorized for use in a drug  
19 or device, and it was manufactured, prepared, propagated,  
20 compounded, or processed in—

21 “(1) an establishment that was not inspected  
22 within the immediately preceding 3-year period; or

23 “(2) in the case of an establishment located in  
24 a foreign country with which the Secretary has an  
25 arrangement or agreement under section 809 to rec-



1       ognize the inspection of establishments by the gov-  
2       ernment or an agency of the government of such  
3       country, within the immediately preceding 5-year pe-  
4       riod.

5       “(1) If it is a drug that was manufactured, prepared,  
6       propagated, compounded, or processed in an establishment  
7       that the Secretary, in consultation with the Secretary of  
8       Homeland Security, determines—

9               “(1) knowingly utilizes forced labor (as defined  
10       in section 307 of the Tariff Act of 1930); or

11               “(2) is in violation of sanctions imposed by the  
12       Federal Government under the International Emer-  
13       gency Economic Powers Act or other applicable law,  
14       including an establishment that is designated to the  
15       list of specially designated nationals and blocked  
16       persons maintained by the Office of Foreign Assets  
17       Control of the Department of the Treasury or owned  
18       50 percent more or more, directly or indirectly, by  
19       one or more such designated persons.”.

20       (g) REGULATIONS.—The Secretary of Health and  
21       Human Services shall—

22               (1) not later than 90 days after the date of en-  
23       actment of this Act, issue proposed regulations im-  
24       plementing the amendments made by this section;  
25       and

1           (2) not later than 180 days after issuance of  
2           the draft guidance described in paragraph (1), final-  
3           ize such guidance.

4           (h) APPLICABILITY.—The amendments made by this  
5           section shall apply beginning on the date that is 180 days  
6           after the final guidance under section 6(2) is issued.

7   **SEC. 6. DEFINING KEY STARTING MATERIAL.**

8           The Secretary of Health and Human Services shall—

9           (1) not later than 90 days after the date of en-  
10          actment of this Act, issue draft guidance defining  
11          the term “key starting material” for purposes of this  
12          Act and the amendments made by this Act; and

13          (2) not later than 180 days after the date of  
14          enactment of this Act, issue final guidance defining  
15          such term for such purposes.

○