

119TH CONGRESS
2D SESSION

S. _____

To require regulatory review of pharmaceutical products from Chinese entities,
and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. COTTON introduced the following bill; which was read twice and referred
to the Committee on _____

A BILL

To require regulatory review of pharmaceutical products from
Chinese entities, 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 “Securing America’s
5 Drug Supply from Communist China Act”.

6 **SEC. 2. REGULATORY REVIEW OF PHARMACEUTICAL PROD-**
7 **UCTS FROM CHINESE ENTITIES.**

8 (a) DEFINITIONS.—In this section:

9 (1) CHINESE ENTITY.—The term “Chinese en-
10 tity” means an entity organized under the laws of

1 the People’s Republic of China or otherwise subject
2 to the jurisdiction of the Government of the People’s
3 Republic of China.

4 (2) DRUG APPLICATION.—The term “drug ap-
5 plication” means an application submitted under
6 subsection (b) or (j) of section 505 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
8 subsection (a) or (k) of section 351 of the Public
9 Health Service Act (42 U.S.C. 262).

10 (3) PRC-, CCP-, OR PLA-AFFILIATED ENTITY.—

11 (A) IN GENERAL.—The term “PRC-, CCP-
12 , or PLA-affiliated entity” means any entity
13 that receives support directly or indirectly from
14 the Government of the People’s Republic of
15 China, the Chinese Communist Party, or the
16 People’s Liberation Army, including—

17 (i) an entity owned or controlled by
18 the Government of the People’s Republic of
19 China or an entity owned or controlled by
20 such an entity; and

21 (ii) an entity that has on its board of
22 directors one or more individuals described
23 in subparagraph (B) who collectively hold
24 an ownership interest in the entity.

1 (B) INDIVIDUALS DESCRIBED.—An indi-
2 vidual described in this subparagraph is—

3 (i) an official of the Government of
4 the People’s Republic of China, the Chi-
5 nese Communist Party, or the People’s
6 Liberation Army; or

7 (ii) an executive officer of an entity
8 owned or controlled by the Government of
9 the People’s Republic of China, including
10 the president or vice president of, or any
11 other executive officer who performs a pol-
12 icy-making function for, the entity.

13 (4) SECRETARY.—The term “Secretary” means
14 the Secretary of Health and Human Services, acting
15 through the Commissioner of Food and Drugs.

16 (b) REVIEW OF CERTAIN NEW DRUG APPLICATIONS
17 SUBMITTED ON OR AFTER ENACTMENT.—

18 (1) IN GENERAL.—The Secretary, in coordina-
19 tion with the Office of National Security of the De-
20 partment of Health and Human Services, shall re-
21 view each drug application submitted on or after the
22 date of enactment of this Act by a sponsor that is
23 a Chinese entity, or an entity licensing a product
24 owned by a Chinese entity, to determine whether
25 such sponsor is a PRC-, CCP-, or PLA-affiliated en-

1 tity. In carrying out this paragraph, the Secretary
2 may review any Drug Master File referenced by
3 such an application.

4 (2) DENIED APPROVAL OF CERTAIN APPLICA-
5 TIONS.—The Secretary shall not approve any drug
6 application submitted on or after the date of enact-
7 ment of this Act if the Secretary has determined
8 under paragraph (1) that the sponsor of such appli-
9 cation is a PRC-, CCP-, or PLA-affiliated entity.

10 (c) REVIEW OF CERTAIN NEW DRUG APPLICATIONS
11 SUBMITTED PRIOR TO ENACTMENT.—

12 (1) IN GENERAL.—The Secretary, in coordina-
13 tion with the Office of National Security of the De-
14 partment of Health and Human Services, shall re-
15 view each drug application submitted during the pe-
16 riod described in paragraph (2) to determine wheth-
17 er the sponsor of the application and, if applicable,
18 the holder of the approved application, is a PRC-,
19 CCP-, or PLA-affiliated entity. In carrying out this
20 paragraph, the Secretary may review any Drug Mas-
21 ter File referenced by such an application.

22 (2) PERIOD DESCRIBED.—The period described
23 in this paragraph is the period beginning on Janu-
24 ary 1, 2016, on ending on the day before the date
25 of enactment of this Act.

1 (d) REFUSAL OF CERTAIN DRUGS OFFERED FOR IM-
2 PORT.—

3 (1) IN GENERAL.—Section 801 of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 381) is
5 amended by adding at the end the following;

6 “(v) IMPORT OF DRUGS SPONSORED BY PRC-, CCP-
7 , AND PLA-AFFILIATED ENTITIES.—

8 “(1) IN GENERAL.—The Secretary shall furnish
9 to the Commissioner of U.S. Customs and Border
10 Protection a list of drugs for which the sponsor or
11 holder of an approved application is determined
12 under section 2(c) of the Securing America’s Drug
13 Supply from Communist China Act to be a PRC-,
14 CCP-, or PLA-affiliated entity.

15 “(2) REFUSAL.—If it appears that a drug im-
16 ported or offered for import into the United States
17 is a drug for which the sponsor or holder of an ap-
18 proved application is determined under section 2(c)
19 of the Securing America’s Drug Supply from Com-
20 munist China Act to be a PRC-, CCP-, or PLA-af-
21 filiated entity, then such drug shall be refused, ex-
22 cept as provided in paragraphs (3) and (4), and the
23 Commissioner of U.S. Customs and Border Protec-
24 tion shall destroy, without the opportunity for ex-
25 port, such drug.

1 “(3) COMPLIANCE.—

2 “(A) IN GENERAL.—The Secretary shall
3 establish a process under which the sponsor of
4 a drug described in paragraph (2) or the holder
5 of an approved application for such a drug, as
6 applicable, may—

7 “(i) demonstrate to the Secretary that
8 it is no longer a PRC-, CCP-, or PLA-af-
9 filiated entity; or

10 “(ii) within 180 days, sell the ap-
11 proved application for such drug to an en-
12 tity that is not a PRC-, CCP-, or PLA-af-
13 filiated entity.

14 “(B) REQUIREMENT.—The process estab-
15 lished under subparagraph (A) shall include the
16 opportunity to appear before the Secretary and
17 introduce testimony.

18 “(C) NOTIFICATION.—If the Secretary is
19 satisfied with the action taken under clause (i)
20 or (ii) of subparagraph (A), the Secretary shall
21 notify the Commissioner of U.S. Customs and
22 Border Protection.

23 “(4) WAIVER.—The Commissioner of U.S. Cus-
24 toms and Border Protection may waive the require-
25 ments of paragraph (2) and authorize the import of

1 a drug described in such paragraph if the Secretary
2 has determined that the refusal of the import would
3 create or exacerbate a drug shortage in the United
4 States.

5 “(5) DEFINITION OF PRC-, CCP-, OR PLA-AF-
6 FILLATED ENTITY.—In this subsection, the term
7 ‘PRC-, CCP-, or PLA-affiliated entity’ has the
8 meaning given such term in section 2(a) of the Se-
9 curing America’s Drug Supply from Communist
10 China Act.”.

11 (e) AUTHORIZATION OF APPROPRIATIONS.—There is
12 authorized to be appropriated to carry out this section and
13 the amendments made by this section \$5,000,000, to re-
14 main available until expended.