

Union Calendar No. 412

116TH CONGRESS
2D SESSION

H. R. 5663

[Report No. 116–512]

To amend the Federal Food, Drug, and Cosmetic Act to give authority to the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to destroy counterfeit devices.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 21, 2020

Mr. GUTHRIE (for himself and Mr. ENGEL) introduced the following bill;
which was referred to the Committee on Energy and Commerce

SEPTEMBER 17, 2020

Additional sponsor: Mr. BALDERSON

SEPTEMBER 17, 2020

Reported with an amendment; committed to the Committee of the Whole
House on the State of the Union and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italie*]

[For text of introduced bill, see copy of bill as introduced on January 21, 2020]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to give authority to the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to destroy counterfeit devices.

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 “Safeguarding Thera-*
5 *peutics Act”.*

6 **SEC. 2. AUTHORITY TO DESTROY COUNTERFEIT DEVICES.**

7 *(a) IN GENERAL.—Section 801(a) of the Federal Food,*
8 *Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended—*

9 *(1) in the fourth sentence, by inserting “or coun-*
10 *terfeit device” after “counterfeit drug”; and*

11 *(2) by striking “The Secretary of the Treasury*
12 *shall cause the destruction of” and all that follows*
13 *through “liable for costs pursuant to subsection (c).”*
14 *and inserting the following: “The Secretary of the*
15 *Treasury shall cause the destruction of any such arti-*
16 *cle refused admission unless such article is exported,*
17 *under regulations prescribed by the Secretary of the*
18 *Treasury, within 90 days of the date of notice of such*
19 *refusal or within such additional time as may be per-*
20 *mitted pursuant to such regulations, except that the*
21 *Secretary of Health and Human Services may de-*
22 *stroy, without the opportunity for export, any drug or*
23 *device refused admission under this section, if such*
24 *drug or device is valued at an amount that is \$2,500*
25 *or less (or such higher amount as the Secretary of the*

1 *Treasury may set by regulation pursuant to section*
2 *498(a)(1) of the Tariff Act of 1930 (19 U.S.C.*
3 *1498(a)(1))) and was not brought into compliance as*
4 *described under subsection (b). The Secretary of*
5 *Health and Human Services shall issue regulations*
6 *providing for notice and an opportunity to appear*
7 *before the Secretary of Health and Human Services*
8 *and introduce testimony, as described in the first sen-*
9 *tence of this subsection, on destruction of a drug or*
10 *device under the seventh sentence of this subsection.*
11 *The regulations shall provide that prior to destruc-*
12 *tion, appropriate due process is available to the*
13 *owner or consignee seeking to challenge the decision to*
14 *destroy the drug or device. Where the Secretary of*
15 *Health and Human Services provides notice and an*
16 *opportunity to appear and introduce testimony on*
17 *the destruction of a drug or device, the Secretary of*
18 *Health and Human Services shall store and, as ap-*
19 *plicable, dispose of the drug or device after the*
20 *issuance of the notice, except that the owner and con-*
21 *signee shall remain liable for costs pursuant to sub-*
22 *section (c).”.*

23 *(b) DEFINITION.—Section 201(h) of the Federal Food,*
24 *Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended—*

1 (1) by redesignating subparagraphs (1), (2), and
2 (3) as clauses (A), (B), and (C), respectively; and

3 (2) after making such redesignations—

4 (A) by striking “(h) The term” and insert-
5 ing “(h)(1) The term”; and

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

7 “(2) The term ‘counterfeit device’ means a device
8 which, or the container, packaging, or labeling of
9 which, without authorization, bears a trademark,
10 trade name, or other identifying mark, imprint, or
11 symbol, or any likeness thereof, or is manufactured
12 using a design, of a device manufacturer, packer, or
13 distributor other than the person or persons who in
14 fact manufactured, packed, or distributed such device
15 and which thereby falsely purports or is represented
16 to be the product of, or to have been packed or distrib-
17 uted by, such other device manufacturer, packer, or
18 distributor.

19 “(3) For purposes of subparagraph (2)—

20 “(A) the term ‘manufactured’ refers to any
21 of the following activities: manufacture, prepara-
22 tion, propagation, compounding, assembly, or
23 processing; and

1 “(B) the term ‘manufacturer’ means a per-
2 son who is engaged in any of the activities listed
3 in clause (A).”.

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