

116TH CONGRESS
2D SESSION

H. R. 5663

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

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 Section 801(a) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 381(a)) is amended—

1 (1) in the fourth sentence insert “or counterfeit
2 device” after “counterfeit drug”; and

3 (2) by striking “The Secretary of the Treasury
4 shall cause the destruction of” and all that follows
5 through “liable for costs pursuant to subsection
6 (c).” and inserting the following: “The Secretary of
7 the Treasury shall cause the destruction of any such
8 article refused admission unless such article is ex-
9 ported, under regulations prescribed by the Sec-
10 retary of the Treasury, within ninety days of the
11 date of notice of such refusal or within such addi-
12 tional time as may be permitted pursuant to such
13 regulations, except that the Secretary of Health and
14 Human Services may destroy, without the oppor-
15 tunity for export, any drug or device refused admis-
16 sion under this section, if such drug or device is val-
17 ued at an amount that is \$2,500 or less (or such
18 higher amount as the Secretary of the Treasury may
19 set by regulation pursuant to section 498(a)(1) of
20 the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))) and
21 was not brought into compliance as described under
22 subsection (b). The Secretary of Health and Human
23 Services shall issue regulations providing for notice
24 and an opportunity to appear before the Secretary
25 of Health and Human Services and introduce testi-

1 mony, as described in the first sentence of this sub-
2 section, on destruction of a drug or device under the
3 seventh sentence of this subsection. The regulations
4 shall provide that prior to destruction, appropriate
5 due process is available to the owner or consignee
6 seeking to challenge the decision to destroy the drug
7 or device. Where the Secretary of Health and
8 Human Services provides notice and an opportunity
9 to appear and introduce testimony on the destruc-
10 tion of a drug or device, the Secretary of Health and
11 Human Services shall store and, as applicable, dis-
12 pose of the drug or device after the issuance of the
13 notice, except that the owner and consignee shall re-
14 main liable for costs pursuant to subsection (c).”.

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