

119TH CONGRESS
1ST SESSION

H. R. 5158

To amend the Federal Food, Drug, and Cosmetic Act regarding the approval of combination products consisting of a generic drug and a device, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 4, 2025

Ms. SCHOLTEN 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 regarding the approval of combination products consisting of a generic drug and a device, 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 “Fair Price Device
5 Act”.

6 **SEC. 2. GENERIC DRUGS FOR USE WITH DEVICES.**

7 Section 505(j) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 355(j)) is amended—

9 (1) in paragraph (2)(A)—

1 (A) in clause (v)—

2 (i) by striking “except for changes re-
3 quired because of differences” and insert-
4 ing “except for changes required or appro-
5 priate, as determined by the Secretary, be-
6 cause of differences”; and

7 (ii) by inserting “, including changes
8 as a result of differences that are other-
9 wise permitted under this subsection, such
10 as changes as a result of appropriate dif-
11 ferences in the device for use with the new
12 drug” before the semicolon;

13 (B) in clause (vii), by striking the “and”
14 at the end;

15 (C) in clause (viii) by striking the period at
16 the end and inserting “; and”;

17 (D) by inserting after clause (viii) the fol-
18 lowing new clause:

19 “(ix) if the listed drug referred to in clause (i)
20 is intended for use with a device, relevant informa-
21 tion as determined by the Secretary to support that
22 the new drug for use with the device can be expected
23 to have the same clinical effect and safety profile as
24 the listed drug for use with the device when adminis-

1 tered to patients under the conditions specified in
2 the labeling of the drug, which information—

3 “(I) shall be in addition to information
4 under clauses (i) through (viii) that is relevant,
5 as determined by the Secretary, to the evalua-
6 tion of the new drug for use with the device and
7 the device proposed for use with the new drug;
8 and

9 “(II) may include—

10 “(aa) information (comparative and
11 non-comparative) regarding the device and
12 its performance, including information
13 about the compatibility of the new drug
14 with the device and information regarding
15 the delivery of the new drug when used
16 with the device;

17 “(bb) comparative analyses of the new
18 drug for use with the device and the listed
19 drug for use with its device, including in-
20 formation identifying any differences be-
21 tween the user interface of the new drug
22 and listed drug; information identifying
23 any differences between the user interface
24 of the device proposed for use with the new
25 drug and the device used with the listed

1 drug; and information to show that, de-
2 spite any such differences, the new drug
3 when used with the device can be expected
4 to have the same clinical effect and safety
5 profile as the listed drug when used with
6 the device when administered to patients
7 under the conditions specified in the label-
8 ing of the drug; and

9 “(cc) comparative and non-compara-
10 tive human factors studies.”; and

11 (E) in the matter following clause (ix), as
12 inserted by subparagraph (D), by striking
13 “through (viii)” and inserting “through (ix)”;
14 and

15 (2) in paragraph (4)—

16 (A) in subparagraph (G)—

17 (i) by striking “except for changes re-
18 quired because of differences” and insert-
19 ing “except for changes required or appro-
20 priate, as determined by the Secretary, be-
21 cause of differences”; and

22 (ii) by inserting “, including changes
23 as a result of differences that are other-
24 wise permitted under this subsection, such
25 as changes as a result of appropriate dif-

1 ferences in the device for use with the new
2 drug’’ before the semicolon;

3 (B) by redesignating subparagraphs (J)
4 through (K) as subparagraphs (K) through (L);
5 and

6 (C) by inserting after subparagraph (I) the
7 following:

8 “(J) if the listed drug is intended for use with
9 a device, information submitted in the application is
10 insufficient to show that the new drug for use with
11 the device can be expected to have the same clinical
12 effect and safety profile as the listed drug for use
13 with the device when administered to patients under
14 the conditions specified in the labeling of the drug;”.

○