

116TH CONGRESS  
1ST SESSION

# S. 1897

To establish a process for updating the labeling of certain drugs with outdated labeling.

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IN THE SENATE OF THE UNITED STATES

JUNE 19, 2019

Mr. BENNET (for himself and Mr. ENZI) 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To establish a process for updating the labeling of certain drugs with outdated labeling.

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. PROCESS TO UPDATE LABELING FOR DRUGS**

4 **WITH OUTDATED LABELING.**

5 Chapter V of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
7 section 503C the following:

8 **“SEC. 503D. PROCESS TO UPDATE LABELING FOR DRUGS**

9 **WITH OUTDATED LABELING.**

10 **“(a) DEFINITIONS.—**For purposes of this section:

1           “(1) The term ‘covered drug’ means a drug ap-  
2           proved under section 505(c)—

3                   “(A) for which there are no unexpired pat-  
4                   ents included in the list under section 505(j)(7)  
5                   and no unexpired period of market exclusivity;

6                   “(B) for which the approval of the applica-  
7                   tion has been withdrawn for reasons other than  
8                   safety or effectiveness; and

9                   “(C) for which, with respect to the label-  
10                  ing—

11                           “(i) new scientific evidence is available  
12                           regarding the conditions of use of the  
13                           drug;

14                           “(ii) there is a relevant accepted use  
15                           in clinical practice that is not reflected in  
16                           the approved labeling; or

17                           “(iii) the labeling of such drug does  
18                           not reflect current legal and regulatory re-  
19                           quirements.

20           “(2) The term ‘period of market exclusivity’,  
21           with respect to a drug approved under section  
22           505(c), means any period of market exclusivity  
23           under clause (ii), (iii), or (iv) of section  
24           505(c)(3)(E), clause (ii), (iii), or (iv) of section  
25           505(j)(5)(F), or section 505A, 505E, or 527.

1           “(3) The term ‘generic version’ means a drug  
2 approved under section 505(j) whose reference drug  
3 is a covered drug.

4           “(4) The term ‘relevant accepted use’ means a  
5 use for a drug in clinical practice that is supported  
6 by scientific evidence that appears to the Secretary  
7 to meet the standards for approval under section  
8 505.

9           “(5) The term ‘selected drug’ means a covered  
10 drug for which the Secretary has determined  
11 through the process under subsection (c) that the la-  
12 beling should be changed.

13           “(b) IDENTIFICATION OF COVERED DRUGS.—The  
14 Secretary may identify covered drugs for which labeling  
15 updates would provide a public health benefit. To assist  
16 in identifying covered drugs, the Secretary may do one or  
17 both of the following:

18           “(1) Enter into cooperative agreements or con-  
19 tracts with public or private entities to review the  
20 available scientific evidence concerning such drugs.

21           “(2) Seek public input concerning such drugs,  
22 including input on whether there is a relevant ac-  
23 cepted use in clinical practice that is not reflected in  
24 the approved labeling of such drugs or whether new

1 scientific evidence is available regarding the condi-  
2 tions of use for such drug, by—

3 “(A) holding one or more public meetings;

4 “(B) opening a public docket for the sub-  
5 mission of public comments; or

6 “(C) other means, as the Secretary deter-  
7 mines appropriate.

8 “(c) SELECTION OF DRUGS FOR UPDATING.—If the  
9 Secretary determines, with respect to a covered drug, that  
10 the available scientific evidence meets the standards under  
11 section 505 for adding or modifying information to the  
12 labeling or providing supplemental information to the la-  
13 beling regarding the use of the covered drug, the Secretary  
14 may initiate the process under subsection (d).

15 “(d) INITIATION OF THE PROCESS OF UPDATING.—  
16 If the Secretary determines that labeling changes are ap-  
17 propriate for a selected drug pursuant to subsection (c),  
18 the Secretary shall provide notice to the holders of ap-  
19 proved applications for a generic version of such drug  
20 that—

21 “(1) summarizes the findings supporting the  
22 determination of the Secretary that the available sci-  
23 entific evidence meets the standards under section  
24 505 for adding or modifying information or pro-

1       viding supplemental information to the labeling of  
2       the covered drug pursuant to subsection (c);

3               “(2) provides a clear statement regarding the  
4       additional, modified, or supplemental information for  
5       such labeling, according to the determination by the  
6       Secretary (including, as applicable, modifications to  
7       add the relevant accepted use to the labeling of the  
8       drug as an additional indication for the drug); and

9               “(3) states whether the statement under para-  
10       graph (2) applies to the selected drug as a class of  
11       covered drugs or only as to a specific drug product.

12       “(e) RESPONSE TO NOTIFICATION.—Within 30 days  
13       of receipt of notification provided by the Secretary pursu-  
14       ant to subsection (d), the holder of an approved applica-  
15       tion for a generic version of the selected drug shall—

16               “(1) agree to change the approved labeling to  
17       reflect the additional, modified, or supplemental in-  
18       formation the Secretary has determined to be appro-  
19       priate; or

20               “(2) notify the Secretary that the holder of the  
21       approved application does not believe that the re-  
22       quested labeling changes are warranted and submit  
23       a statement detailing the reasons why such changes  
24       are not warranted.

1       “(f) REVIEW OF APPLICATION HOLDER’S RE-  
2 SPONSE.—

3           “(1) IN GENERAL.—Upon receipt of the appli-  
4 cation holder’s response, the Secretary shall prompt-  
5 ly review each statement received under subsection  
6 (e)(2) and determine which labeling changes pursu-  
7 ant to the Secretary’s notice under subsection (d)  
8 are appropriate, if any. If the Secretary disagrees  
9 with the reasons why such labeling changes are not  
10 warranted, the Secretary shall provide opportunity  
11 for discussions with the application holders to reach  
12 agreement on whether the labeling for the covered  
13 drug should be updated to reflect current scientific  
14 evidence, and if so, the content of such labeling  
15 changes.

16           “(2) CHANGES TO LABELING.—After consid-  
17 ering all responses from the holder of an approved  
18 application under paragraph (1) or (2) of subsection  
19 (e), and any discussion under paragraph (1), the  
20 Secretary may order such holder to make the label-  
21 ing changes the Secretary determines are appro-  
22 priate. Such holder of an approved application  
23 shall—

24                   “(A) update its paper labeling for the drug  
25                   at the next printing of that labeling;

1           “(B) update any electronic labeling for the  
2           drug within 30 days; and

3           “(C) submit the revised labeling through  
4           the form, ‘Supplement—Changes Being Ef-  
5           fected’.

6           “(g) VIOLATION.—If the holder of an approved appli-  
7           cation for the generic version of the selected drug does  
8           not comply with the requirements of subsection (f)(2),  
9           such generic version of the selected drug shall be deemed  
10          to be misbranded under section 502.

11          “(h) LIMITATIONS; GENERIC DRUGS.—

12           “(1) IN GENERAL.—With respect to any label-  
13           ing change required under this section, the generic  
14           version shall be deemed to have the same conditions  
15           of use and the same labeling as a reference drug for  
16           purposes of clauses (i) and (v) of section  
17           505(j)(2)(A). Any labeling change so required shall  
18           not have any legal effect for the applicant that is  
19           different than the legal effect that would have re-  
20           sulted if a supplemental application had been sub-  
21           mitted and approved to conform the labeling of the  
22           generic version to a change in the labeling of the ref-  
23           erence drug.

24           “(2) SUPPLEMENTAL APPLICATIONS.—Changes  
25           to labeling made in accordance with this paragraph

1 shall not be eligible for an exclusivity period under  
2 this Act.

3 “(i) DRUG PRODUCT CLASSES.—In the case of a se-  
4 lected drug for which the labeling changes ordered by the  
5 Secretary under subsection (d)(2) are required for a class  
6 of covered drugs, such labeling changes shall be made for  
7 generic versions of such drug in that class.

8 “(j) RULES OF CONSTRUCTION.—

9 “(1) APPROVAL STANDARDS.—This section  
10 shall not be construed as altering the applicability of  
11 the standards for approval of an application under  
12 section 505. No order shall be issued under this sub-  
13 section unless the evidence supporting the changed  
14 labeling meets the standards for approval applicable  
15 to any change to labeling under section 505.

16 “(2) REMOVAL OF INFORMATION.—Nothing in  
17 this section shall be construed to give the Secretary  
18 additional authority to remove approved indications  
19 for drugs, other than the authority to remove certain  
20 indications from the labels of certain covered drugs,  
21 as described in this section.

22 “(k) REPORTS.—Not later than 4 years after the  
23 date of the enactment of this section and every 4 years  
24 thereafter, the Secretary shall prepare and submit to the  
25 Committee on Health, Education, Labor, and Pensions of



1 the Senate and the Committee on Energy and Commerce  
2 of the House of Representatives, a report that—

3 “(1) describes the actions of the Secretary  
4 under this section, including—

5 “(A) the number of covered drugs and de-  
6 scription of the types of drugs the Secretary  
7 has selected for labeling changes and the ra-  
8 tionale for such recommended changes; and

9 “(B) the number of times the Secretary  
10 entered into discussions concerning a disagree-  
11 ment with an application holder or holders and  
12 a summary of the decision regarding a labeling  
13 change, if any; and

14 “(2) includes any recommendations of the Sec-  
15 retary for modifying the program under this sec-  
16 tion.”.

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