

116TH CONGRESS
1ST SESSION

S. _____

To establish a process for updating the labeling of certain drugs with outdated labeling.

IN THE SENATE OF THE UNITED STATES

Mr. BENNET (for himself and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on _____

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To establish a process for updating the labeling of certain drugs with outdated labeling.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4 **WITH OUTDATED LABELING.**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9 **WITH OUTDATED LABELING.**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7 tion has been withdrawn for reasons other than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.”.