

115TH CONGRESS
2D SESSION

S. 3519

To establish a process for the Food and Drug Administration to determine whether to modify the labeling of drugs whose labeling may be outdated, including drugs with accepted uses that are not reflected in the approved labeling.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 27, 2018

Mr. HATCH (for himself and Mr. BENNET) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To establish a process for the Food and Drug Administration to determine whether to modify the labeling of drugs whose labeling may be outdated, including drugs with accepted uses that are not reflected in the approved labeling.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. SHORT TITLE.**

4 This Act may be cited as the “Making Objective Drug
5 Evidence Revisions for New Labeling Act” or the “MOD-
6 ERN Labeling Act”.

1 **SEC. 2. PROCESS TO UPDATE LABELING FOR DRUGS WITH**
2 **OUTDATED LABELING.**

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

6 **“SEC. 503D. PROCESS TO UPDATE LABELING FOR DRUGS**
7 **WITH OUTDATED LABELING.**

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

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

11 “(A) for which all patents and exclusivity
12 periods under this chapter have expired;

13 “(B) for which the approval of the label
14 has been withdrawn; and

15 “(C) whose labeling potentially should be
16 modified because—

17 “(i) some aspects of the labeling of
18 the drug may be outdated according to evi-
19 dence that, since the date on which the
20 drug was so approved, has become avail-
21 able regarding the conditions of use re-
22 flected in the approved labeling;

23 “(ii) there is a relevant accepted use
24 in clinical practice that is not reflected in
25 the approved labeling; or

1 “(iii) the labeling of such drug does
2 not reflect current legal and regulatory re-
3 quirements.

4 “(2) The term ‘exclusivity period’, with respect
5 to a drug approved under section 505(c), means the
6 period by which the effective date of the approval of
7 an application for a different drug product could be
8 delayed, or the different drug product could other-
9 wise be impacted, under clause (ii), (iii), or (iv) of
10 section 505(c)(3)(E), clause (ii), (iii), or (iv) of sec-
11 tion 505(j)(5)(F), or section 505A, 505E, or 527.

12 “(3) The term ‘generic version’ means a drug
13 approved under section 505(j), whose reference drug
14 is a covered drug.

15 “(4) The term ‘relevant accepted use’ means a
16 use for a drug in clinical practice that is supported
17 by evidence that could meet the standards for ap-
18 proval under section 505.

19 “(5) The term ‘selected drug’ means a covered
20 drug for which the Secretary has determined
21 through the process under subsection (c) that the la-
22 beling should be updated because aspects of such la-
23 beling are outdated according to evidence that has
24 become available regarding the conditions of use re-

1 flected in the approved labeling or to reflect one or
2 more relevant accepted uses.

3 “(b) IDENTIFICATION OF COVERED DRUG CAN-
4 DIDATES FOR REVISION.—The Secretary may consider re-
5 quiring changes to the labeling of drugs where such up-
6 dates would benefit the public health. To assist in deciding
7 whether to require labeling changes for covered drugs, the
8 Secretary may do one or both of the following:

9 “(1) Enter into cooperative agreements or con-
10 tracts with public or private entities to review the
11 available evidence concerning such drugs.

12 “(2) Seek public input concerning such drugs,
13 including input on whether there is a relevant ac-
14 cepted use in clinical practice that is not reflected in
15 the approved labeling of such drugs or whether as-
16 pects of the labeling of such drugs is outdated ac-
17 cording to evidence that has become available re-
18 garding the conditions of use reflected in the ap-
19 proved labeling by—

20 “(A) holding public meetings;

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

23 “(C) other means, as the Secretary deter-
24 mines appropriate.

1 “(c) SELECTION OF DRUGS FOR UPDATING.—If the
2 Secretary determines, with respect to a covered drug, that
3 the available evidence is sufficient to meet the standards
4 under section 505 for adding information to the labeling
5 or modifying information in the labeling regarding the use
6 of the covered drug, the Secretary may initiate the process
7 under subsection (d).

8 “(d) INITIATION OF THE PROCESS OF UPDATING.—
9 If the Secretary determines that labeling changes are ap-
10 propriate for a selected drug pursuant to subsection (c),
11 the Secretary shall provide notice to the holders of ap-
12 proved applications for a generic version of such drug
13 that—

14 “(1) summarizes the findings supporting the
15 determination of the Secretary that the available evi-
16 dence is sufficient to meet the standards under sec-
17 tion 505 for modifying the labeling of the drug pur-
18 suant to subsection (c);

19 “(2) states the modifications to the labeling
20 that should be made in order to reflect such deter-
21 mination (including, as applicable, modifications to
22 add the relevant accepted use to the labeling of the
23 drug as an additional indication for the drug); and

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

4 “(e) RESPONSE TO NOTIFICATION.—Within 30 days
5 of receipt of notification provided by the Secretary pursu-
6 ant to subsection (d), the holder of an approved applica-
7 tion shall—

8 “(1) agree to change the approved labeling to
9 reflect the modifications the Secretary has deter-
10 mined are appropriate; or

11 “(2) notify the Secretary that the holder of the
12 approved application does not agree that the re-
13 quested modifications are warranted and submit a
14 statement detailing the reasons why such modifica-
15 tions are not warranted.

16 “(f) REVIEW OF APPLICATION HOLDER’S RE-
17 SPONSE.—

18 “(1) IN GENERAL.—The Secretary shall
19 promptly review each statement received under sub-
20 section (e)(2) and determine which modifications to
21 the Secretary’s notice under subsection (d) are ap-
22 propriate, if any.

23 “(2) CHANGES TO LABELING.—After consid-
24 ering a response from a holder of an approved appli-
25 cation under paragraph (1) or (2) of subsection (e),

1 the Secretary may order such holder to make the la-
2 beling changes the Secretary determines are appro-
3 priate. Such holder of an approved application
4 shall—

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

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

9 “(C) submit the revised labeling through
10 the form, ‘Supplement—Changes Being Ef-
11 fected’.

12 “(g) VIOLATION.—If the holder of an approved appli-
13 cation for the generic version of the selected drug does
14 not comply with the requirements of subsection (f), such
15 generic version of the selected drug shall be deemed to
16 be misbranded under section 502.

17 “(h) LIMITATIONS; GENERIC DRUGS.—

18 “(1) IN GENERAL.—With respect to the modi-
19 fication of the labeling sought through a supple-
20 mental application pursuant to subsection (f)(2)(C)
21 the manufacturer of any generic version shall, by
22 reason of the statement of the Secretary under sub-
23 section (d)(2), be deemed to have the same condi-
24 tions of use and the same labeling as a reference
25 drug for purposes of clauses (i) and (v) of section

1 505(j)(2)(A). The approval of a supplemental appli-
2 cation shall not have any legal effects for the appli-
3 cant that are different than the legal effects that
4 would have resulted if the supplemental application
5 had been submitted to conform the labeling of the
6 generic version to a change in the labeling of the ref-
7 erence drug.

8 “(2) SUPPLEMENTAL APPLICATIONS.—Changes
9 to labeling made in accordance with this paragraph
10 shall not be eligible for an exclusivity period under
11 this Act.

12 “(i) DRUG PRODUCT CLASSES.—In the case of a se-
13 lected drug for which the statement of the Secretary under
14 subsection (d)(2) applies to the selected drug as a class
15 of drugs, a supplemental application pursuant to sub-
16 section (f)(2)(C) may be submitted for each such drug
17 product.

18 “(j) RULE OF CONSTRUCTION.—This section shall
19 not be construed as altering the applicability of any sub-
20 stantive approval standard under section 505.

21 “(k) REPORTS.—Not later than 4 years after the
22 date of the enactment of the Making Objective Drug Evi-
23 dence Revisions for New Labeling Act 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 describes
3 the actions of the Secretary under this section and that
4 provides any recommendations of the Secretary for modi-
5 fying the program under this section, including any rec-
6 ommendations on whether the program should apply to
7 a broader scope of drugs. Each report under this sub-
8 section shall be made publicly available on the Internet
9 website of the Food and Drug Administration.”.

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