

116TH CONGRESS
2D SESSION

H. R. 5668

To amend the Federal Food, Drug, and Cosmetic Act to modernize the labeling of certain generic drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 24, 2020

Ms. MATSUI (for herself and Mr. GUTHRIE) 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 modernize the labeling of certain generic drugs, 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 “Making Objective Drug
5 Evidence Revisions for New Labeling Act of 2020” or the
6 “MODERN Labeling Act of 2020”.

1 **SEC. 2. MODERNIZING THE LABELING OF CERTAIN GE-**
2 **NERIC DRUGS.**

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 CERTAIN**
7 **DRUGS.**

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 there are no unexpired pat-
12 ents included in the list under section 505(j)(7)
13 and no unexpired period of exclusivity;

14 “(B) for which the approval of the applica-
15 tion has been withdrawn for reasons other than
16 safety or effectiveness; and

17 “(C) for which, with respect to the label-
18 ing—

19 “(i) new scientific evidence is available
20 regarding the conditions of use of the
21 drug;

22 “(ii) there is a relevant accepted use
23 in clinical practice that is not reflected in
24 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 ‘period of exclusivity’, with re-
5 spect to a drug approved under section 505(c),
6 means any period of exclusivity under clause (ii),
7 (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii),
8 or (iv) of section 505(j)(5)(F), or section 505A,
9 505E, or 527.

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

13 “(4) The term ‘relevant accepted use’ means a
14 use for a drug in clinical practice that is supported
15 by scientific evidence that appears to the Secretary
16 to meet the standards for approval under section
17 505.

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

22 “(b) IDENTIFICATION OF COVERED DRUGS.—The
23 Secretary may identify covered drugs for which labeling
24 updates would provide a public health benefit. To assist

1 in identifying covered drugs, the Secretary may do one or
2 both of the following:

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

6 “(2) Seek public input concerning such drugs,
7 including input on whether there is a relevant ac-
8 cepted use in clinical practice that is not reflected in
9 the approved labeling of such drugs or whether new
10 scientific evidence is available regarding the condi-
11 tions of use for such drug, by—

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

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

15 “(C) other means, as the Secretary deter-
16 mines appropriate.

17 “(c) SELECTION OF DRUGS FOR UPDATING.—If the
18 Secretary determines, with respect to a covered drug, that
19 the available scientific evidence meets the standards under
20 section 505 for adding or modifying information to the
21 labeling or providing supplemental information to the la-
22 beling regarding the use of the covered drug, the Secretary
23 may initiate the process under subsection (d).

24 “(d) INITIATION OF THE PROCESS OF UPDATING.—
25 If the Secretary determines that labeling changes are ap-

1 appropriate for a selected drug pursuant to subsection (c),
2 the Secretary shall provide notice to the holders of ap-
3 proved applications for a generic version of such drug
4 that—

5 “(1) summarizes the findings supporting the
6 determination of the Secretary that the available sci-
7 entific evidence meets the standards under section
8 505 for adding or modifying information or pro-
9 viding supplemental information to the labeling of
10 the covered drug pursuant to subsection (c);

11 “(2) provides a clear statement regarding the
12 additional, modified, or supplemental information for
13 such labeling, according to the determination by the
14 Secretary (including, as applicable, modifications to
15 add the relevant accepted use to the labeling of the
16 drug as an additional indication for the drug); and

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

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

24 “(1) agree to change the approved labeling to
25 reflect the additional, modified, or supplemental in-

1 formation the Secretary has determined to be appro-
2 priate; or

3 “(2) notify the Secretary that the holder of the
4 approved application does not believe that the re-
5 quested labeling changes are warranted and submit
6 a statement detailing the reasons why such changes
7 are not warranted.

8 “(f) REVIEW OF APPLICATION HOLDER’S RE-
9 SPONSE.—

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

23 “(2) CHANGES TO LABELING.—After consid-
24 ering all responses from the holder of an approved
25 application under paragraph (1) or (2) of subsection

1 (e), and any discussion under paragraph (1), the
2 Secretary may order such holder to make the label-
3 ing changes the Secretary determines are appro-
4 priate and meet the standards under section 505 for
5 adding or modifying information or providing sup-
6 plemental information to such labeling. Such holder
7 of an approved application shall—

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

10 “(B) update any electronic labeling for the
11 drug within 30 days of such order; and

12 “(C) submit the revised labeling through
13 the form, ‘Supplement—Changes Being Ef-
14 fected’.

15 “(g) VIOLATION.—If the holder of an approved appli-
16 cation for the generic version of the selected drug does
17 not comply with the requirements of subsection (f)(2),
18 such generic version of the selected drug shall be deemed
19 to be misbranded under section 502.

20 “(h) LIMITATIONS; GENERIC DRUGS.—

21 “(1) IN GENERAL.—With respect to any label-
22 ing change required under this section, the generic
23 version shall be deemed to have the same conditions
24 of use and the same labeling as a reference drug for
25 purposes of clauses (i) and (v) of section

1 505(j)(2)(A). Any labeling change so required shall
2 not have any legal effect for the applicant that is
3 different than the legal effect that would have re-
4 sulted if a supplemental application had been sub-
5 mitted and approved 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 section
10 shall not be eligible for an exclusivity period under
11 this Act.

12 “(i) RULES OF CONSTRUCTION.—

13 “(1) APPROVAL STANDARDS.—This section
14 shall not be construed as altering the applicability of
15 the standards for approval of an application under
16 section 505. No order shall be issued under this sub-
17 section unless the scientific evidence supporting the
18 changed labeling meets the standards for approval
19 applicable to any change to labeling under section
20 505.

21 “(2) SECRETARY AUTHORITY.—Nothing in this
22 section shall be construed to limit the authority of
23 the Secretary to require labeling changes under sec-
24 tion 505(o).

1 “(j) REPORTS.—Not later than 4 years after the date
2 of the enactment of the Making Objective Drug Evidence
3 Revisions for New Labeling Act of 2020, and every 4 years
4 thereafter, the Secretary shall prepare and submit to the
5 Committee on Health, Education, Labor, and Pensions of
6 the Senate and the Committee on Energy and Commerce
7 of the House of Representatives, a report that—

8 “(1) describes the actions of the Secretary
9 under this section, including—

10 “(A) the number of covered drugs and de-
11 scription of the types of drugs the Secretary
12 has selected for labeling changes and the ra-
13 tionale for such recommended changes; and

14 “(B) the number of times the Secretary
15 entered into discussions concerning a disagree-
16 ment with an application holder or holders and
17 a summary of the decision regarding a labeling
18 change, if any; and

19 “(2) includes any recommendations of the Sec-
20 retary for modifying the program under this sec-
21 tion.”.

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