

116TH CONGRESS
2^D SESSION

H. R. 5668

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Making Objective Drug
3 Evidence Revisions for New Labeling Act of 2020” or the
4 “MODERN Labeling Act of 2020”.

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

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

10 **“SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN**
11 **DRUGS.**

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

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

15 “(A) for which there are no unexpired pat-
16 ents included in the list under section 505(j)(7)
17 and no unexpired period of exclusivity;

18 “(B) for which the approval of the applica-
19 tion has been withdrawn for reasons other than
20 safety or effectiveness; and

21 “(C) for which—

22 “(i)(I) there is new scientific evidence
23 available pertaining to the existing condi-
24 tions of use that is not reflected in the la-
25 beling;

1 “(II) the approved labeling does not
2 reflect current legal and regulatory re-
3 quirements for content or format; or

4 “(III) there is a relevant accepted use
5 in clinical practice that is not reflected in
6 the approved labeling; and

7 “(ii) updating the labeling would ben-
8 efit the public health.

9 “(2) The term ‘period of exclusivity’, with re-
10 spect to a drug approved under section 505(c),
11 means any period of exclusivity under clause (ii),
12 (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii),
13 or (iv) of section 505(j)(5)(F), or section 505A,
14 505E, or 527.

15 “(3) The term ‘generic version’ means a drug
16 approved under section 505(j) whose reference listed
17 drug is a covered drug.

18 “(4) The term ‘relevant accepted use’ means a
19 use for a drug in clinical practice that is supported
20 by scientific evidence that appears to the Secretary
21 to meet the standards for approval under section
22 505.

23 “(5) The term ‘selected drug’ means a covered
24 drug for which the Secretary has determined

1 through the process under subsection (c) that the la-
2 beling should be changed.

3 “(b) IDENTIFICATION OF COVERED DRUGS.—The
4 Secretary may identify covered drugs for which labeling
5 updates would provide a public health benefit. To assist
6 in identifying covered drugs, the Secretary may do one or
7 both of the following:

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

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

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

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

20 “(C) other means, as the Secretary deter-
21 mines appropriate.

22 “(c) SELECTION OF DRUGS FOR UPDATING.—If the
23 Secretary determines, with respect to a covered drug, that
24 the available scientific evidence meets the standards under
25 section 505 for adding or modifying information to the

1 labeling or providing supplemental information to the la-
2 beling regarding the use of the covered drug, the Secretary
3 may initiate the process under subsection (d).

4 “(d) INITIATION OF THE PROCESS OF UPDATING.—

5 If the Secretary determines that labeling changes are ap-
6 propriate for a selected drug pursuant to subsection (c),
7 the Secretary shall provide notice to the holders of ap-
8 proved applications for a generic version of such drug
9 that—

10 “(1) summarizes the findings supporting the
11 determination of the Secretary that the available sci-
12 entific evidence meets the standards under section
13 505 for adding or modifying information or pro-
14 viding supplemental information to the labeling of
15 the covered drug pursuant to subsection (c);

16 “(2) provides a clear statement regarding the
17 additional, modified, or supplemental information for
18 such labeling, according to the determination by the
19 Secretary (including, as applicable, modifications to
20 add the relevant accepted use to the labeling of the
21 drug as an additional indication for the drug); and

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

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

5 “(1) agree to change the approved labeling to
6 reflect the additional, modified, or supplemental in-
7 formation the Secretary has determined to be appro-
8 priate; or

9 “(2) notify the Secretary that the holder of the
10 approved application does not believe that the re-
11 quested labeling changes are warranted and submit
12 a statement detailing the reasons why such changes
13 are not warranted.

14 “(f) REVIEW OF APPLICATION HOLDER’S RE-
15 SPONSE.—

16 “(1) IN GENERAL.—Upon receipt of the appli-
17 cation holder’s response, the Secretary shall prompt-
18 ly review each statement received under subsection
19 (e)(2) and determine which labeling changes pursu-
20 ant to the Secretary’s notice under subsection (d)
21 are appropriate, if any. If the Secretary disagrees
22 with the reasons why such labeling changes are not
23 warranted, the Secretary shall provide opportunity
24 for discussions with the application holders to reach
25 agreement on whether the labeling for the covered

1 drug should be updated to reflect available scientific
2 evidence, and if so, the content of such labeling
3 changes.

4 “(2) CHANGES TO LABELING.—After consid-
5 ering all responses from the holder of an approved
6 application under paragraph (1) or (2) of subsection
7 (e), and any discussion under paragraph (1), the
8 Secretary may order such holder to make the label-
9 ing changes the Secretary determines are appro-
10 priate. Such holder of an approved application
11 shall—

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

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

16 “(C) submit the revised labeling through
17 the form, ‘Supplement—Changes Being Ef-
18 fected’.

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

24 “(h) LIMITATIONS; GENERIC DRUGS.—

1 “(1) IN GENERAL.—With respect to any label-
2 ing change required under this section, the generic
3 version shall be deemed to have the same conditions
4 of use and the same labeling as its reference listed
5 drug for purposes of clauses (i) and (v) of section
6 505(j)(2)(A). Any labeling change so required shall
7 not have any legal effect for the applicant that is
8 different than the legal effect that would have re-
9 sulted if a supplemental application had been sub-
10 mitted and approved to conform the labeling of the
11 generic version to a change in the labeling of the ref-
12 erence drug.

13 “(2) SUPPLEMENTAL APPLICATIONS.—Changes
14 to labeling made in accordance with this section
15 shall not be eligible for an exclusivity period under
16 this Act.

17 “(3) SELECTION OF DRUGS.—Nothing in this
18 section shall be construed to give the Secretary the
19 authority to identify a drug as a covered drug or se-
20 lect a drug label for updating solely based on the
21 availability of new safety information. Upon identi-
22 fication of a drug as a covered drug, the Secretary
23 may then consider the availability of new, additional,
24 or different safety information in determining

1 whether the drug is a selected drug and in deter-
2 mining what labeling changes are appropriate.

3 “(4) MAINTENANCE OF LABELING.—Nothing in
4 this section shall be construed to affect the responsi-
5 bility of the holder of an approved application under
6 section 505(j) to maintain its labeling in accordance
7 with existing requirements, including subpart B of
8 part 201 and sections 314.70 and 314.97 of title 21,
9 Code of Federal Regulations (or any successor regu-
10 lations).

11 “(i) RULES OF CONSTRUCTION.—

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

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

24 “(j) REPORTS.—Not later than 4 years after the date
25 of the enactment of the Making Objective Drug Evidence

1 Revisions for New Labeling Act of 2020, and every 4 years
2 thereafter, the Secretary shall prepare and submit to the
3 Committee on Energy and Commerce of the House of
4 Representatives and the Committee on Health, Education,
5 Labor, and Pensions of the Senate, a report that—

6 “(1) describes the actions of the Secretary
7 under this section, including—

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

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

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

Passed the House of Representatives November 17,
2020.

Attest:

Clerk.

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