

# Union Calendar No. 471

116<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5668

**[Report No. 116-573]**

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

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## 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

NOVEMBER 16, 2020

Additional sponsor: Mr. TAYLOR

NOVEMBER 16, 2020

Reported with an amendment; committed to the Committee of the Whole  
House on the State of the Union and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italie*]

[For text of introduced bill, see copy of bill as introduced on January 24, 2020]

# **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”.*

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

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

12 **“SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN**  
13 **DRUGS.**

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

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

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

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21 *tion has been withdrawn for reasons other than*  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

23 *“(C) for which—*

24 *“(i)(I) there is new scientific evidence*  
25 *available pertaining to the existing condi-*

1            *tions of use that is not reflected in the label-*  
2            *ing;*

3            *“(II) the approved labeling does not re-*  
4            *fect current legal and regulatory require-*  
5            *ments for content or format; or*

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

9            *“(ii) updating the labeling would ben-*  
10           *efit the public health.*

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

16           *“(3) The term ‘generic version’ means a drug ap-*  
17           *proved under section 505(j) whose reference listed*  
18           *drug is a covered drug.*

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

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

1        *the process under subsection (c) that the labeling*  
2        *should be changed.*

3        “(b) *IDENTIFICATION OF COVERED DRUGS.—The Sec-*  
4        *retary may identify covered drugs for which labeling up-*  
5        *dates would provide a public health benefit. To assist in*  
6        *identifying covered drugs, the Secretary may do one or both*  
7        *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 accept-*  
13               *ed use in clinical practice that is not reflected in the*  
14               *approved labeling of such drugs or whether new sci-*  
15               *entific evidence is available regarding the conditions*  
16               *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 la-*

1 *belonging or providing supplemental information to the label-*  
2 *ing regarding the use of the covered drug, the Secretary may*  
3 *initiate the process under subsection (d).*

4       “(d) *INITIATION OF THE PROCESS OF UPDATING.—If*  
5 *the Secretary determines that labeling changes are appro-*  
6 *priate for a selected drug pursuant to subsection (c), the*  
7 *Secretary shall provide notice to the holders of approved*  
8 *applications for a generic version of such drug that—*

9               “(1) *summarizes the findings supporting the de-*  
10 *termination of the Secretary that the available sci-*  
11 *entific evidence meets the standards under section 505*  
12 *for adding or modifying information or providing*  
13 *supplemental information to the labeling of the cov-*  
14 *ered drug pursuant to subsection (c);*

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

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

24       “(e) *RESPONSE TO NOTIFICATION.—Within 30 days of*  
25 *receipt of notification provided by the Secretary pursuant*

1 to subsection (d), the holder of an approved application for  
2 a generic version of the selected drug shall—

3 “(1) agree to change the approved labeling to re-  
4 flect the additional, modified, or supplemental infor-  
5 mation the Secretary has determined to be appro-  
6 priate; or

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

12 “(f) REVIEW OF APPLICATION HOLDER’S RE-  
13 SPONSE.—

14 “(1) IN GENERAL.—Upon receipt of the applica-  
15 tion holder’s response, the Secretary shall promptly  
16 review each statement received under subsection (e)(2)  
17 and determine which labeling changes pursuant to the  
18 Secretary’s notice under subsection (d) are appro-  
19 priate, if any. If the Secretary disagrees with the rea-  
20 sons why such labeling changes are not warranted, the  
21 Secretary shall provide opportunity for discussions  
22 with the application holders to reach agreement on  
23 whether the labeling for the covered drug should be  
24 updated to reflect available scientific evidence, and if  
25 so, the content of such labeling changes.

1           “(2) *CHANGES TO LABELING.*—After considering  
2           all responses from the holder of an approved applica-  
3           tion under paragraph (1) or (2) of subsection (e), and  
4           any discussion under paragraph (1), the Secretary  
5           may order such holder to make the labeling changes  
6           the Secretary determines are appropriate. 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 the  
13                   form, ‘Supplement—Changes Being Effected’.

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

19           “(h) *LIMITATIONS; GENERIC DRUGS.*—

20                   “(1) *IN GENERAL.*—With respect to any labeling  
21                   change required under this section, the generic version  
22                   shall be deemed to have the same conditions of use  
23                   and the same labeling as its reference listed drug for  
24                   purposes of clauses (i) and (v) of section 505(j)(2)(A).  
25                   Any labeling change so required shall not have any



1       *legal effect for the applicant that is different than the*  
2       *legal effect that would have resulted if a supplemental*  
3       *application had been submitted and approved to con-*  
4       *form the labeling of the generic version to a change*  
5       *in the labeling of the reference drug.*

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

10              “(3) *SELECTION OF DRUGS.*—*Nothing in this*  
11       *section shall be construed to give the Secretary the au-*  
12       *thority to identify a drug as a covered drug or select*  
13       *a drug label for updating solely based on the avail-*  
14       *ability of new safety information. Upon identification*  
15       *of a drug as a covered drug, the Secretary may then*  
16       *consider the availability of new, additional, or dif-*  
17       *ferent safety information in determining whether the*  
18       *drug is a selected drug and in determining what la-*  
19       *beling changes are appropriate.*

20              “(4) *MAINTENANCE OF LABELING.*—*Nothing in*  
21       *this section shall be construed to affect the responsi-*  
22       *bility of the holder of an approved application under*  
23       *section 505(j) to maintain its labeling in accordance*  
24       *with existing requirements, including subpart B of*  
25       *part 201 and sections 314.70 and 314.97 of title 21,*

1       *Code of Federal Regulations (or any successor regula-*  
2       *tions).*

3       “(i) *RULES OF CONSTRUCTION.*—

4               “(1) *APPROVAL STANDARDS.*—*This section shall*  
5       *not be construed as altering the applicability of the*  
6       *standards for approval of an application under sec-*  
7       *tion 505. No order shall be issued under this sub-*  
8       *section unless the scientific evidence supporting the*  
9       *changed labeling meets the standards for approval ap-*  
10       *licable to any change to labeling under section 505.*

11              “(2) *SECRETARY AUTHORITY.*—*Nothing in this*  
12       *section shall be construed to limit the authority of the*  
13       *Secretary to require labeling changes under section*  
14       *505(o).*

15              “(j) *REPORTS.*—*Not later than 4 years after the date*  
16       *of the enactment of the Making Objective Drug Evidence*  
17       *Revisions for New Labeling Act of 2020, and every 4 years*  
18       *thereafter, the Secretary shall prepare and submit to the*  
19       *Committee on Energy and Commerce of the House of Rep-*  
20       *resentatives and the Committee on Health, Education,*  
21       *Labor, and Pensions of the Senate, a report that—*

22                      “(1) *describes the actions of the Secretary under*  
23       *this section, including—*

24                              “(A) *the number of covered drugs and de-*  
25       *scription of the types of drugs the Secretary has*

1           *selected for labeling changes and the rationale for*  
2           *such recommended changes; and*

3                     *“(B) the number of times the Secretary en-*  
4                     *tered into discussions concerning a disagreement*  
5                     *with an application holder or holders and a*  
6                     *summary of the decision regarding a labeling*  
7                     *change, if any; and*

8                     *“(2) includes any recommendations of the Sec-*  
9                     *retary for modifying the program under this sec-*  
10                    *tion.”.*

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