

115TH CONGRESS
2D SESSION

H. R. 5811

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, 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. POSTAPPROVAL STUDY REQUIREMENTS.**

2 (a) PURPOSES OF STUDY.—Section 505(o)(3)(B) of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(o)(3)(B)) is amended by adding at the end the fol-
5 lowing:

6 “(iv) To assess a potential reduction
7 in effectiveness of the drug for the condi-
8 tions of use prescribed, recommended, or
9 suggested in the labeling thereof if—

10 “(I) the drug involved—

11 “(aa) is or contains a sub-
12 stance for which a listing in any
13 schedule is in effect (on a tem-
14 porary or permanent basis) under
15 section 201 of the Controlled
16 Substances Act; or

17 “(bb) is a drug that has not
18 been approved under this section
19 or licensed under section 351 of
20 the Public Health Service Act,
21 for which an application for such
22 approval or licensure is pending
23 or anticipated, and for which the
24 Secretary provides notice to the
25 sponsor that the Secretary in-
26 tends to issue a scientific and

1 medical evaluation and rec-
2 ommend controls under the Con-
3 trolled Substances Act; and

4 “(II) the potential reduction in
5 effectiveness could result in the bene-
6 fits of the drug no longer outweighing
7 the risks.”.

8 (b) ESTABLISHMENT OF REQUIREMENT.—Section
9 505(o)(3)(C) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 355(o)(3)(C)) is amended by striking
11 “such requirement” and all that follows through “safety
12 information.” and inserting the following: “such require-
13 ment—

14 “(i) in the case of a purpose described
15 in clause (i), (ii), or (iii) of subparagraph
16 (B), only if the Secretary becomes aware of
17 new safety information; and

18 “(ii) in the case of a purpose de-
19 scribed in clause (iv) of such subpara-
20 graph, if the Secretary determines that
21 new effectiveness information exists.”.

22 (c) APPLICABILITY.—Section 505(o)(3) of the Fed-
23 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3))
24 is amended by adding at the end the following new sub-
25 paragraph:

1 “(G) APPLICABILITY.—The conduct of a
2 study or clinical trial required pursuant to this
3 paragraph for the purpose specified in subpara-
4 graph (B)(iv) shall not be considered a new
5 clinical investigation for the purpose of a period
6 of exclusivity under clause (iii) or (iv) of sub-
7 section (c)(3)(E) or clause (iii) or (iv) of sub-
8 section (j)(5)(F).”.

9 (d) NEW EFFECTIVENESS INFORMATION DE-
10 FINED.—Section 505(o)(2) of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 355(o)(2)) is amended by
12 adding at the end the following new subparagraph:

13 “(D) NEW EFFECTIVENESS INFORMA-
14 TION.—The term ‘new effectiveness informa-
15 tion’, with respect to a drug that is or contains
16 a controlled substance for which a listing in any
17 schedule is in effect (on a temporary or perma-
18 nent basis) under section 201 of the Controlled
19 Substances Act, means new information about
20 the effectiveness of the drug, including a new
21 analysis of existing information, derived from—

22 “(i) a clinical trial; an adverse event
23 report; a postapproval study or clinical
24 trial (including a study or clinical trial
25 under paragraph (3));

1 “(ii) peer-reviewed biomedical lit-
2 erature;

3 “(iii) data derived from the
4 postmarket risk identification and analysis
5 system under subsection (k); or

6 “(iv) other scientific data determined
7 to be appropriate by the Secretary.”.

8 (e) CONFORMING AMENDMENTS WITH RESPECT TO
9 LABELING CHANGES.—Section 505(o)(4) of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(4)) is
11 amended—

12 (1) in subparagraph (A)—

13 (A) in the heading, by inserting “OR NEW
14 EFFECTIVENESS” after “SAFETY”;

15 (B) by striking “safety information” and
16 inserting “new safety information or new effec-
17 tiveness information such”; and

18 (C) by striking “believes should be” and
19 inserting “believes changes should be made to”;

20 (2) in subparagraph (B)(i)—

21 (A) by striking “new safety information”
22 and by inserting “new safety information or
23 new effectiveness information”; and

24 (B) by inserting “indications,” after
25 “boxed warnings,”;

1 (3) in subparagraph (C), by inserting “or new
2 effectiveness information” after “safety informa-
3 tion”; and

4 (4) in subparagraph (E), by inserting “or new
5 effectiveness information” after “safety informa-
6 tion”.

7 (f) **RULE OF CONSTRUCTION.**—Nothing in the
8 amendments made by this section shall be construed to
9 alter, in any manner, the meaning or application of the
10 provisions of paragraph (3) of section 505(o) of the Fed-
11 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(o))
12 with respect to the authority of the Secretary of Health
13 and Human Services to require a postapproval study or
14 clinical trial for a purpose specified in clauses (i) through
15 (iii) of subparagraph (B) of such paragraph (3) or para-
16 graph (4) of such section 505(o) with respect to the Sec-
17 retary’s authority to require safety labeling changes.

 Passed the House of Representatives June 19, 2018.

 Attest:

Clerk.

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