

Union Calendar No. 24

116TH CONGRESS
1ST SESSION

H. R. 938

[Report No. 116-46]

To amend the Federal Food, Drug, and Cosmetic Act, with respect to eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 31, 2019

Mr. SCHRADER (for himself and Mr. CARTER of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce

MAY 2, 2019

Additional sponsors: Mrs. CRAIG, Mrs. DINGELL, Mr. RUIZ, Mr. PALLONE, Ms. ESHOO, Mr. KENNEDY, Ms. MATSUI, Mr. RUSH, Mr. VAN DREW, Ms. CLARKE of New York, Mr. WALDEN, Ms. SCHAKOWSKY, Mr. MCADAMS, Ms. MUCARSEL-POWELL, and Mr. MEADOWS

MAY 2, 2019

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

A BILL

To amend the Federal Food, Drug, and Cosmetic Act, with respect to eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, 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 “Bringing Low-cost Op-
 5 tions and Competition while Keeping Incentives for New
 6 Generics Act of 2019” or the “BLOCKING Act of 2019”.

7 **SEC. 2. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-**
 8 **SIVITY TO SPUR ACCESS AND COMPETITION.**

9 Section 505(j)(5)(B)(iv) of the Federal Food, Drug,
 10 and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amend-
 11 ed—

12 (1) in subclause (I), by striking “180 days
 13 after” and all that follows through the period at the
 14 end and inserting the following: “180 days after the
 15 earlier of—

16 “(aa) the date of the first com-
 17 mercial marketing of the drug (includ-
 18 ing the commercial marketing of the
 19 listed drug) by any first applicant; or

20 “(bb) the applicable date speci-
 21 fied in subclause (III).”; and

22 (2) by adding at the end the following new sub-
 23 clause:

24 “(III) APPLICABLE DATE.—The appli-
 25 cable date specified in this subclause, with

1 respect to an application for a drug de-
2 scribed in subclause (I), is the date on
3 which each of the following conditions is
4 first met:

5 “(aa) The approval of such an
6 application could be made effective,
7 but for the eligibility of a first appli-
8 cant for 180-day exclusivity under
9 this clause.

10 “(bb) At least 30 months have
11 passed since the date of submission of
12 an application for the drug by at least
13 one first applicant.

14 “(cc) Approval of an application
15 for the drug submitted by at least one
16 first applicant is not precluded under
17 clause (iii).

18 “(dd) No application for the drug
19 submitted by any first applicant is ap-
20 proved at the time the conditions
21 under items (aa), (bb), and (cc) are
22 all met, regardless of whether such an
23 application is subsequently ap-
24 proved.”.

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