

*Tim Smith*

AMENDMENT NO. 2

Calendar No. \_\_\_\_\_

Purpose: To amend the Federal Food, Drug, and Cosmetic Act with respect to the 180-day exclusivity period.

**IN THE SENATE OF THE UNITED STATES—116th Cong., 1st Sess.**

**S. 1895**

To lower health care costs.

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Ms. SMITH (for herself and  
Mr. Braun)

Viz:

- 1 Strike section 205 and insert the following:
- 2 **SEC. 205. 180-DAY EXCLUSIVITY PERIOD.**
- 3 (a) IN GENERAL.—Section 505(j)(5)(B)(iv) of the
- 4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
- 5 355(j)(5)(B)(iv)) is amended—
- 6 (1) in subclause (I), by striking “effective on
- 7 the date that is 180 days after” and all that follows
- 8 through the period at the end and inserting the fol-
- 9 lowing: “effective—
- 10 “(aa) subject to item (bb), on the date
- 11 that is 180 days after the date of the first
- 12 commercial marketing of the drug (includ-

1 ing the commercial marketing of the listed  
2 drug) by any first applicant; or

3 “(bb) if, in an infringement action  
4 brought solely against the applicant or an  
5 action for a declaratory judgment brought  
6 by that applicant with respect to each pat-  
7 ent to which a first applicant submitted  
8 and lawfully maintained a certification  
9 under paragraph (2)(A)(vii)(IV), the court  
10 has entered a final decision, from which no  
11 appeal other than a petition to the Su-  
12 preme Court for a writ of certiorari has  
13 been or can be taken, that the patent is in-  
14 valid or not infringed, and the applicant  
15 meets the requirements under subclause  
16 (III), immediately upon the court entering  
17 such final decision.”; and

18 (2) by adding at the end the following:

19 “(III) APPLICANT REQUIREMENTS.—The  
20 requirements under this subclause are that the  
21 applicant for the application described in sub-  
22 clause (I)—

23 “(aa) does not stay the action de-  
24 scribed in such subclause;

1                   “(bb) does not agree to be bound by  
2                   a judgment as to another applicant; and

3                   “(cc) does not request joinder under  
4                   section 42.122 of title 37, Code of Federal  
5                   Regulations (or any corresponding similar  
6                   regulation or ruling), for any petition that  
7                   the applicant may have filed with respect  
8                   to the application.”.

9           (b) APPLICABILITY.—The amendments made by sub-  
10          section (a) shall apply only with respect to an application  
11          filed under section 505(j) of the Federal Food, Drug, and  
12          Cosmetic Act (21 U.S.C. 355(j)) after the date of enact-  
13          ment of this Act that identifies a listed drug for which  
14          no certification under paragraph (2)(A)(vii)(IV) of such  
15          section was made before such date of enactment.