

#1



AMENDMENT NO. _____ Calendar No. _____

Purpose: To change conditions of first generic exclusivity
to spur access and competition.

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 Mr. SCOTT of South
Carolina

Viz:

1 Strike section 205 and insert the following:

2 **SEC. 205. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-**
3 **SIVITY TO SPUR ACCESS AND COMPETITION.**

4 (a) IN GENERAL.—Section 505(j)(5)(B)(iv) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 355(j)(5)(B)(iv)) is amended—

7 (1) in subclause (I) by striking “180 days after
8 the date” and inserting “180 days after the earlier
9 of the following:

10 “(aa) “The date”; and

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

“(bb) The date on which all of the following conditions are first met:

“(AA) An application for the drug submitted by an applicant other than a first applicant could receive approval, if no first applicant were eligible for 180-day exclusivity under this clause.

“(BB) Thirty months have passed since the date of submission of an application for the drug by at least one first applicant.

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

“(DD) No application for the drug submitted by any first applicant is approved at the time the con-

1 ditions under items (AA),
2 (BB), and (CC) are all met,
3 regardless of whether such
4 an application is subse-
5 quently approved.”; and

6 (3) by adding at the end the following:

7 “(III) EXCEPTION.—

8 “ (aa) IN GENERAL.—The
9 date in paragraph (I)(bb) shall
10 not apply if In the case that any
11 first applicant is actively pur-
12 suing final approval of an appli-
13 cation for the relevant drug, then
14 the applicable date under sub-
15 clause (I) shall be the date de-
16 scribed in item (aa).

17 “(bb) DEFINITION.—For the
18 purposes of this subclause, the
19 term ‘actively pursuing final ap-
20 proval’ means an applicant’s
21 good faith effort to pursue mar-
22 keting approval in a timely man-
23 ner, based on a consideration of
24 all relevant factors, such as the
25 applicant’s compliance with regu-

1
2
3
4
5

lations and the timeliness of its
responses to the Secretary's
questions or application defi-
ciencies during the review pe-
riod.”.