

Baldwin #1



AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To set forth limitations on exclusivity for orphan drugs.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

**S. 4348**

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

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. BALDWIN

Viz:

1 At the appropriate place in title V, insert the fol-  
2 lowing:

3 **SEC. 5 \_\_\_\_ . LIMITATIONS ON EXCLUSIVE APPROVAL OR**  
4 **LICENSURE OF ORPHAN DRUGS.**

5 (a) IN GENERAL.—Section 527 of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

7 (1) in subsection (a), in the matter following  
8 paragraph (2), by striking “same disease or condi-  
9 tion” and inserting “same approved use or indica-  
10 tion within such rare disease or condition”;

11 (2) in subsection (b)—

1 (A) in the matter preceding paragraph (1),  
2 by striking “same rare disease or condition”  
3 and inserting “same approved use or indication  
4 for which such 7-year period applies to such al-  
5 ready approved drug”; and

6 (B) in paragraph (1), by inserting “, relat-  
7 ing to the approved use or indication,” after  
8 “the needs”;

9 (3) in subsection (c)(1), by striking “same rare  
10 disease or condition as the already approved drug”  
11 and inserting “same use or indication for which the  
12 already approved or licensed drug was approved or  
13 licensed”; and

14 (4) by adding at the end the following:

15 “(f) APPROVED USE OR INDICATION DEFINED.—In  
16 this section, the term ‘approved use or indication’ means  
17 the use or indication approved under section 505 of this  
18 Act or licensed under section 351 of the Public Health  
19 Service Act for a drug designated under section 526 for  
20 a rare disease or condition.”.

21 (b) APPLICATION OF AMENDMENTS.—The amend-  
22 ments made by subsection (a) shall apply with respect to  
23 any drug designated under section 526 of the Federal  
24 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-  
25 less of the date on which the drug was so designated, and

1 regardless of the date on which the drug was approved  
2 under section 505 of such Act (21 U.S.C. 355) or licensed  
3 under section 351 of the Public Health Service Act (42  
4 U.S.C. 262).