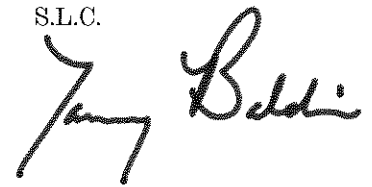


Baldwin #2



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

Purpose: To amend the Federal Food, Drug, and Cosmetic Act with respect to citizen petitions.

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 IX, insert the fol-  
2 lowing:

3 **SEC. 9 \_\_\_\_\_. ENSURING TIMELY ACCESS TO GENERICS.**

4 Section 505(q) of the Federal Food, Drug, and Cos-  
5 metic Act (21 U.S.C. 355(q)) is amended—

6 (1) in paragraph (1)—

7 (A) in subparagraph (A)(i), by inserting “,  
8 10.31,” after “10.30”;

9 (B) in subparagraph (E)—

10 (i) by striking “application and” and  
11 inserting “application or”;

1 (ii) by striking “If the Secretary” and  
2 inserting the following:

3 “(i) IN GENERAL.—If the Secretary”;  
4 and

5 (iii) by striking the second sentence  
6 and inserting the following:

7 “(ii) PRIMARY PURPOSE OF DELAY-  
8 ING.—

9 “(I) IN GENERAL.—In deter-  
10 mining whether a petition was sub-  
11 mitted with the primary purpose of  
12 delaying an application, the Secretary  
13 may consider the following factors:

14 “(aa) Whether the petition  
15 was submitted in accordance with  
16 paragraph (2)(B), based on when  
17 the petitioner knew or reasonably  
18 should have known the relevant  
19 information relied upon to form  
20 the basis of such petition.

21 “(bb) Whether the petitioner  
22 has submitted multiple or serial  
23 petitions or supplements to peti-  
24 tions raising issues that reason-  
25 ably could have been known to

1 the petitioner at the time of sub-  
2 mission of the earlier petition or  
3 petitions.

4 “(cc) Whether the petition  
5 was submitted close in time to a  
6 known, first date upon which an  
7 application under subsection  
8 (b)(2) or (j) of this section or  
9 section 351(k) of the Public  
10 Health Service Act could be ap-  
11 proved.

12 “(dd) Whether the petition  
13 was submitted without relevant  
14 data or information in support of  
15 the scientific positions forming  
16 the basis of such petition.

17 “(ee) Whether the petition  
18 raises the same or substantially  
19 similar issues as a prior petition  
20 to which the Secretary has re-  
21 sponded substantively already, in-  
22 cluding if the subsequent submis-  
23 sion follows such response from  
24 the Secretary closely in time.

1                   “(ff) Whether the petition  
2 requests changing the applicable  
3 standards that other applicants  
4 are required to meet, including  
5 requesting testing, data, or label-  
6 ing standards that are more on-  
7 erous or rigorous than the stand-  
8 ards the Secretary has deter-  
9 mined to be applicable to the list-  
10 ed drug, reference product, or pe-  
11 titioner’s version of the same  
12 drug.

13                   “(gg) The petitioner’s record  
14 of submitting petitions to the  
15 Food and Drug Administration  
16 that have been determined by the  
17 Secretary to have been submitted  
18 with the primary purpose of  
19 delay.

20                   “(hh) Other relevant and  
21 appropriate factors, which the  
22 Secretary shall describe in guid-  
23 ance.

24                   “(II) GUIDANCE.—The Secretary  
25 may issue or update guidance, as ap-

1 appropriate, to describe factors the Sec-  
2 retary considers in accordance with  
3 subclause (I).”;

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

5 “(iii) REFERRAL TO THE FEDERAL  
6 TRADE COMMISSION.—The Secretary shall  
7 establish procedures for referring to the  
8 Federal Trade Commission any petition or  
9 supplement to a petition that the Secretary  
10 determines was submitted with the primary  
11 purpose of delaying approval of an applica-  
12 tion. Such procedures shall include notifi-  
13 cation to the petitioner by the Secretary.”;

14 (D) by striking subparagraph (F);

15 (E) by redesignating subparagraphs (G)  
16 through (I) as subparagraphs (F) through (H),  
17 respectively; and

18 (F) in subparagraph (H), as so redesign-  
19 nated, by striking “submission of this petition”  
20 and inserting “submission of this document”;

21 (2) in paragraph (2)—

22 (A) by redesignating subparagraphs (A)  
23 through (C) as subparagraphs (C) through (E),  
24 respectively;

1 (B) by inserting before subparagraph (C),  
2 as so redesignated, the following:

3 “(A) IN GENERAL.—A person shall submit  
4 a petition to the Secretary under paragraph (1)  
5 before filing a civil action in which the person  
6 seeks to set aside, delay, rescind, withdraw, or  
7 prevent submission, review, or approval of an  
8 application submitted under subsection (b)(2)  
9 or (j) of this section or section 351(k) of the  
10 Public Health Service Act. Such petition and  
11 any supplement to such a petition shall describe  
12 all information and arguments that form the  
13 basis of the relief requested in any civil action  
14 described in the previous sentence.

15 “(B) TIMELY SUBMISSION OF CITIZEN PE-  
16 TITION.—A petition and any supplement to a  
17 petition shall be submitted within 60 days after  
18 the person knew, or reasonably should have  
19 known, the information that forms the basis of  
20 the request made in the petition or supple-  
21 ment.”;

22 (C) in subparagraph (C), as so redesign-  
23 nated—

24 (i) in the heading, by striking “WITH-  
25 IN 150 DAYS”;

1 (ii) in clause (i), by striking “during  
2 the 150-day period referred to in para-  
3 graph (1)(F),”; and

4 (iii) by amending clause (ii) to read as  
5 follows:

6 “(ii) on or after the date that is 151  
7 days after the date of submission of the  
8 petition, the Secretary approves or has ap-  
9 proved the application that is the subject  
10 of the petition without having made such a  
11 final decision.”;

12 (D) by amending subparagraph (D), as so  
13 redesignated, to read as follows:

14 “(D) DISMISSAL OF CERTAIN CIVIL AC-  
15 TIONS.—

16 “(i) PETITION.—If a person files a  
17 civil action against the Secretary in which  
18 a person seeks to set aside, delay, rescind,  
19 withdraw, or prevent submission, review, or  
20 approval of an application submitted under  
21 subsection (b)(2) or (j) of this section or  
22 section 351(k) of the Public Health Service  
23 Act without complying with the require-  
24 ments of subparagraph (A), the court shall

1 dismiss without prejudice the action for  
2 failure to exhaust administrative remedies.

3 “(ii) TIMELINESS.—If a person files a  
4 civil action against the Secretary in which  
5 a person seeks to set aside, delay, rescind,  
6 withdraw, or prevent submission, review, or  
7 approval of an application submitted under  
8 subsection (b)(2) or (j) of this section or  
9 section 351(k) of the Public Health Service  
10 Act without complying with the require-  
11 ments of subparagraph (B), the court shall  
12 dismiss with prejudice the action for fail-  
13 ure to timely file a petition.

14 “(iii) FINAL RESPONSE.—If a civil ac-  
15 tion is filed against the Secretary with re-  
16 spect to any issue raised in a petition time-  
17 ly filed under paragraph (1) in which the  
18 petitioner requests that the Secretary take  
19 any form of action that could, if taken, set  
20 aside, delay, rescind, withdraw, or prevent  
21 submission, review, or approval of an appli-  
22 cation submitted under subsection (b)(2)  
23 or (j) of this section or section 351(k) of  
24 the Public Health Service Act before the  
25 Secretary has taken final agency action on



1           the petition within the meaning of sub-  
2           paragraph (C), the court shall dismiss  
3           without prejudice the action for failure to  
4           exhaust administrative remedies.”; and

5           (E) in clause (iii) of subparagraph (E), as  
6           so redesignated, by striking “as defined under  
7           subparagraph (2)(A)” and inserting “within the  
8           meaning of subparagraph (C)”;

9           (3) in paragraph (4)—

10           (A) by striking “EXCEPTIONS” and all that  
11           follows through “This subsection does” and in-  
12           serting “EXCEPTIONS.—This subsection does”;

13           (B) by striking subparagraph (B); and

14           (C) by redesignating clauses (i) and (ii) as  
15           subparagraphs (A) and (B), respectively, and  
16           adjusting the margins accordingly.