

*Bob Casey*

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

Purpose: To prevent food shortages, including shortages of infant formula and certain medical foods.

**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 Mr. CASEY

Viz:

1        On page 477, lines 22 and 23, strike “or other condi-  
2        tions requiring a medical food”.

3        On page 479, line 19, strike “2012” and insert  
4        “2017”.

5        On page 480, line 1, strike “what” and insert “a  
6        summary of”.

7        On page 480, strike lines 4 through 6.

1       On page 483, between lines 17 and 18, insert the fol-  
2       lowing:

3               “(3) SUNSET.—This subsection shall cease to  
4       have force or effect on September 30, 2026.”.

5       On page 483, strike line 22 and all that follows  
6       through line 11 on page 484 and insert the following:

7               “(1) MARKETING SUBMISSIONS.—Subject to para-  
8       graph (2), the Secretary shall provide an interim response  
9       on a submission under subsection (d) not later than 65  
10      days after receiving such submission.”.

11      On page 486, lines 16 and 17, strike “and the Com-  
12      mittee on Energy and Commerce of the House of Rep-  
13      resentatives” and insert “, the Committee on Energy and  
14      Commerce of the House of Representatives, and the Sec-  
15      retary of Agriculture”.

16      On page 487, line 22, strike “2026” and insert  
17      “2027”.

18      On page 491, line 21, strike “5 business days after”  
19      and insert “6 months prior to the date of”.

1       On page 493, lines 2 and 3, strike “and implement,  
2 as appropriate,” and insert “and, as appropriate, imple-  
3 ment”.

4       At the end of section 910, insert the following:

5       (k) PROHIBITED ACTS.—Section 301 of the Federal  
6 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as  
7 amended by section 824(a)(5), is further amended by add-  
8 ing at the end the following:

9       “(mmm) The failure to provide information as re-  
10 quired under section 424 after receipt of a letter from the  
11 Secretary under subsection (c) of such section.”.

12       (l) REMOTE RECORDS ASSESSMENT FOR CRITICAL  
13 FOODS.—

14           (1)       FACTORY       INSPECTION.—Section  
15       704(a)(4)(A) of the Federal Food, Drug, and Cos-  
16       metic Act (21 U.S.C. 374(a)(4)(A)) is amended in  
17       the first sentence by inserting “or the manufac-  
18       turing, processing, packing, or holding of a critical  
19       food (as defined in section 201(tt))” after “proc-  
20       essing of a drug”.

21           (2) REGULATIONS.—Not later than 1 year after  
22       the date of enactment of this Act, the Secretary  
23       shall promulgate regulations describing cir-  
24       cumstances in which the Secretary may issue re-

1       quests for records or other information in advance  
2       of, or in lieu of, an inspection pursuant to section  
3       704(a)(4)(A) of the Federal Food, Drug, and Cos-  
4       metic Act, as amended by paragraph (1), processes  
5       for responding to such requests electronically or in  
6       physical form, and factors the Secretary may con-  
7       sider in evaluating whether such records are pro-  
8       vided within a reasonable timeframe, within reason-  
9       able limits, and in a reasonable manner, accounting  
10      for resource and other limitations that may exist, in-  
11      cluding for small businesses.

12      (m) AUTHORIZATION OF APPROPRIATIONS.—For  
13      purposes of carrying out this section, including the amend-  
14      ments made by this section, there are authorized to be  
15      appropriated such sums as may be necessary for each of  
16      fiscal years 2023 through 2027.