

117TH CONGRESS  
2D SESSION

# S. 3493

To require guidance on extending expiration dates for certain drugs, and  
for other purposes.

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## IN THE SENATE OF THE UNITED STATES

JANUARY 12 (legislative day, JANUARY 10), 2022

Mr. CARDIN (for himself and Ms. COLLINS) introduced the following bill;  
which was read twice and referred to the Committee on Health, Edu-  
cation, Labor, and Pensions

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## A BILL

To require guidance on extending expiration dates for certain  
drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Drug Shortages Shelf  
5 Life Extension Act”.

6 **SEC. 2. EXTENDING EXPIRATION DATES FOR CERTAIN**  
7 **DRUGS.**

8 (a) IN GENERAL.—Not later than 180 days after the  
9 date of enactment of this Act, the Secretary of Health and  
10 Human Services (referred to in this section as the “Sec-

1 retary”) shall issue draft guidance, or revise existing guid-  
2 ance, to address recommendations for sponsors of applica-  
3 tions under section 505 of the Federal Food, Drug, and  
4 Cosmetic Act (21 U.S.C. 355) or section 351 of the Public  
5 Health Service Act (42 U.S.C. 262) regarding—

6 (1) the submission of stability testing data in  
7 such applications; and

8 (2) establishing in the labeling of drugs the  
9 longest feasible expiration date supported by such  
10 data, taking into consideration how extended expira-  
11 tion dates may help prevent or mitigate drug short-  
12 ages.

13 (b) REPORT.—Not later than 2 years after the date  
14 of enactment of this Act, and again 2 years thereafter,  
15 the Secretary shall submit to the Committee on Health,  
16 Education, Labor, and Pensions of the Senate and the  
17 Committee on Energy and Commerce of the House of  
18 Representatives a report that includes—

19 (1) the number of drugs for which the Sec-  
20 retary has requested the manufacturer make a label-  
21 ing change regarding the expiration date; and

22 (2) for each drug for which the Secretary has  
23 requested a labeling change with respect to the expi-  
24 ration date, information regarding the circumstances  
25 of such request, including—

1 (A) the name and dose of such drug;

2 (B) the rationale for the request;

3 (C) whether the drug, at the time of the  
4 request, was listed on the drug shortage list  
5 under section 506E of the Federal Food, Drug,  
6 and Cosmetic Act (21 U.S.C. 356e), or was at  
7 risk of shortage;

8 (D) whether the request was made during  
9 a public health emergency declared under sec-  
10 tion 319 of the Public Health Service Act (42  
11 U.S.C. 247d); and

12 (E) whether the manufacturer made the  
13 requested change by the requested date, and for  
14 instances where the manufacturer does not  
15 make the requested change, the manufacturer's  
16 justification for not making the change, if the  
17 manufacturer agrees to provide such justifica-  
18 tion for inclusion in the report.

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