

117TH CONGRESS H.R. 7669

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

IN THE HOUSE OF REPRESENTATIVES

May 6, 2022

Ms. Matsui introduced the following bill; which was referred to the Committee on Energy and Commerce

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 1 year 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- 1 retary") shall issue draft guidance, or revise existing guid-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 submitted under section 505 of the Federal Food,
- 4 Drug, and Cosmetic Act (21 U.S.C. 355) or section 351
- 5 of the Public Health Service Act (42 U.S.C. 262) regard-
- 6 ing—
- 7 (1) the submission of stability testing data in
- 8 such applications, including considerations for data
- 9 requirements that could be streamlined or reduced
- to facilitate faster review of longer proposed expira-
- 11 tion dates;
- 12 (2) establishing in the labeling of drugs the
- longest feasible expiration date scientifically sup-
- ported by such data, taking into consideration how
- extended expiration dates may—
- 16 (A) help prevent or mitigate drug short-
- 17 ages; and
- (B) affect product quality; and
- 19 (3) the use of innovative approaches for drug
- and combination product stability modeling to sup-
- 21 port initial product expiration dates and expiration
- date extensions.
- 23 (b) Report.—Not later than 2 years after the date
- 24 of enactment of this Act, and again 2 years thereafter,
- 25 the Secretary shall submit to the Committee on Health,

1	Education, Labor, and Pensions of the Senate and the
2	Committee on Energy and Commerce of the House of
3	Representatives a report that includes—
4	(1) the number of drugs for which the Sec-
5	retary has requested the manufacturer make a label-
6	ing change regarding the expiration date; and
7	(2) for each drug for which the Secretary has
8	requested a labeling change with respect to the expi-
9	ration date, information regarding the circumstances
10	of such request, including—
11	(A) the name and dose of such drug;
12	(B) the rationale for the request;
13	(C) whether the drug, at the time of the
14	request, was listed on the drug shortage list
15	under section 506E of the Federal Food, Drug,
16	and Cosmetic Act (21 U.S.C. 356e), or was at
17	risk of shortage;
18	(D) whether the request was made during
19	a public health emergency declared under sec-
20	tion 319 of the Public Health Service Act (42
21	U.S.C. 247d); and
22	(E) whether the manufacturer made the
23	requested change by the requested date, and for
24	instances where the manufacturer does not
25	make the requested change, the manufacturer's

justification for not making the change, if the manufacturer agrees to provide such justification for inclusion in the report.

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