

111TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act with respect to generic drugs, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

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Mrs. SHAHEEN (for herself and Mr. VITTER) introduced the following bill; which was read twice and referred to the Committee on

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## **A BILL**

To amend the Federal Food, Drug, and Cosmetic Act with respect to generic 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 “Access to Affordable  
5 Medicines Act”.

6 **SEC. 2. LABELING CHANGES.**

7 Section 505(j) of the Federal Food, Drug, and Cos-  
8 metic Act (21 U.S.C. 355(j)) is amended by adding at the  
9 end the following:

1           “(10) If the proposed labeling of a drug that is the  
2 subject of an application under this subsection is different  
3 from the labeling of the listed drug at the time the Sec-  
4 retary evaluates the application under this subsection, the  
5 drug that is the subject of such application shall, notwith-  
6 standing any other provision of this Act, be eligible for  
7 approval and shall not be considered misbranded under  
8 section 502 if—

9           “(A) a revision to the labeling of the listed drug  
10 has been approved by the Secretary within 60 days  
11 of the expiration of the patent or exclusivity period  
12 that otherwise prohibited the approval of the drug  
13 under this subsection;

14           “(B) the Secretary has not determined the ap-  
15 plicable text of the labeling for the drug that is the  
16 subject the application under this subsection at the  
17 time of expiration of such patent or exclusivity pe-  
18 riod;

19           “(C) the labeling revision described under sub-  
20 paragraph (A) does not include a change to the  
21 ‘Warnings’ section of the labeling;

22           “(D) the Secretary does not deem that the con-  
23 tinued presence in commerce of the labeling of the  
24 listed drug (as in effect before the revision described

1 under subparagraph (A)) adversely impacts the safe  
2 use of the drug;

3 “(E) the sponsor of the application under this  
4 subsection agrees to submit revised labeling of the  
5 drug that is the subject of such application not later  
6 than 60 days after the notification of any changes  
7 to such labeling required by the Secretary; and

8 “(F) such application otherwise meets the ap-  
9 plicable requirements for approval under this sub-  
10 section.”.