

117<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 9011

To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish a process to allow the holders of abbreviated new drug applications to make labeling changes to include new or updated safety-related information, and for other purposes.

---

## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2022

Mr. MCEACHIN introduced the following bill; which was referred to the  
Committee on Energy and Commerce

---

## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish a process to allow the holders of abbreviated new drug applications to make labeling changes to include new or updated safety-related information, 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 “Updated Drug Label-  
5        ing for Patient Safety Act”.

1 **SEC. 2. SAFETY LABELING CHANGES INITIATED BY ANDA**  
2 **HOLDERS.**

3 (a) IN GENERAL.—Section 505(j) of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is  
5 amended by adding at the end the following:

6 “(14) Notwithstanding paragraphs (2)(A)(v), the  
7 Secretary shall establish a process to allow the holder of  
8 an abbreviated new drug application to change the labeling  
9 of the drug that is the subject of the application to include  
10 new or updated safety-related information, including a  
11 process to make such changes prior to being approved by  
12 the Secretary.”.

13 (b) REGULATIONS.—

14 (1) IN GENERAL.—Not later than 18 months  
15 after the date of enactment of this Act, the Sec-  
16 retary of Health and Human Services shall issue a  
17 final rule to implement paragraph (14) of section  
18 505(j) of the Federal Food, Drug, and Cosmetic Act  
19 (21 U.S.C. 355(j)), as added by subsection (a).

20 (2) CONTENTS.—The final rule issued under  
21 paragraph (1) shall include a process for conforming  
22 the labeling of a drug that is labeled pursuant to  
23 such paragraph (14), the listed drug (as such term  
24 is used in such section 505(j)), and other drugs ap-  
25 proved under such section 505(j) that reference such  
26 listed drug.

1           (3) EFFECTIVE DATE.—The final rule issued  
2           under paragraph (1) shall become effective not later  
3           than 180 days after the date on which such final  
4           rule is issued.

○