

118TH CONGRESS
1ST SESSION

H. R. 4134

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

JUNE 14, 2023

Mr. SCHIFF (for himself and Ms. KUSTER) 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 paragraph (2)(A)(v), the Sec-
7 retary shall establish a process to allow the holder of an
8 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.

○