[117H9011]

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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

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

Mr. SCHIFF introduced the following bill; which was referred to the Committee on _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Updated Drug Labeling for Patient Safety Act''.

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

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

''(14) Notwithstanding paragraph (2)(A)(v), the Secretary shall establish a process to allow the holder of an abbreviated new drug application to change the labeling of the drug that is the subject of the application to include new or updated safety-related information, including a process to make such changes prior to being approved by the Secretary.''.

(b) REGULATIONS.—

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

(2) CONTENTS.—The final rule issued under paragraph (1) shall include a process for conforming the labeling of a drug that is labeled pursuant to such paragraph (14), the listed drug (as such term

is used in such section 505(j)), and other drugs approved under such section 505(j) that reference such listed drug.

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