

107TH CONGRESS
2^D SESSION

H. R. 5534

To amend the Federal Food, Drug, and Cosmetic Act to provide for the implementation of the program under section 804 of such Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 2, 2002

Mr. BERRY (for himself, Mrs. EMERSON, Mr. SHOWS, Mr. ALLEN, and Mr. BROWN of Ohio) 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 provide for the implementation of the program under section 804 of such Act, 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 “Prescription Drug
5 Price Reduction Act”.

6 **SEC. 2. IMPLEMENTATION OF SECTION 804 OF FEDERAL**
7 **FOOD, DRUG, AND COSMETIC ACT.**

8 (a) IN GENERAL.—Section 804 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 384) is amended—

1 (1) by striking subsection (l); and

2 (2) by redesignating subsection (m) as sub-
3 section (l).

4 (b) REGULATIONS.—The Secretary of Health and
5 Human Services shall promulgate a final rule for carrying
6 out section 804 of the Federal Food, Drug, and Cosmetic
7 Act not later than one year after the date of the enactment
8 of this Act. The effective date for such final rule may not
9 be later than 30 days after the date on which the final
10 rule is promulgated.

11 (c) LABELING.—Section 502 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 352) is amended by
13 adding at the end the following:

14 “(u) If it is a covered product imported into the
15 United States pursuant to section 804, unless, upon com-
16 mercial distribution of such product in the United States,
17 the product bears labeling that identifies the country from
18 which the product was imported, that provides the name
19 and address of the importer of the product, and that pro-
20 vides the name and address of the person who exported
21 the product to the United States.”.

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