

107TH CONGRESS  
1ST SESSION

# H. R. 58

To amend section 804 of the Federal Food, Drug, and Cosmetic Act to correct impediments in the implementation of the Medicine Equity and Drug Safety Act of 2000.

---

## IN THE HOUSE OF REPRESENTATIVES

JANUARY 3, 2001

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

---

## A BILL

To amend section 804 of the Federal Food, Drug, and Cosmetic Act to correct impediments in the implementation of the Medicine Equity and Drug Safety Act of 2000.

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 “Medicine Equity and  
5       Drug Safety Act Corrections of 2001”.

1 **SEC. 2. CORRECTION OF IMPEDIMENTS IN IMPLEMENTA-**  
2 **TION OF MEDICINE EQUITY AND DRUG SAFE-**  
3 **TY ACT OF 2000.**

4 (a) ACCESS TO LABELING TO PERMIT IMPORTA-  
5 TION.—Section 804 of the Federal Food, Drug, and Cos-  
6 metic Act (as added by section 745(c)(2) of Public Law  
7 106–387) is amended—

8 (1) in subsection (b)—

9 (A) in paragraph (2), by striking “and” at  
10 the end ;

11 (B) in paragraph (3), by striking the pe-  
12 riod at the end and inserting “; and”; and

13 (C) by adding at the end the following  
14 paragraph:

15 “(4) specify a fair and reasonable fee that a  
16 manufacturer may charge an importer for the use of  
17 labeling of a covered product.”;

18 (2) in subsection (e)(2), by inserting after  
19 “used only for purposes of testing” the following:  
20 “or the labeling of covered products”; and

21 (3) in subsection (h), by adding at the end the  
22 following sentence: “No manufacturer of a covered  
23 product may impose any condition for the privilege  
24 of an importer using labeling for a covered product,  
25 except a requirement that the importer pay a fee for

1 such use established by regulation under subsection  
 2 (a)(4).”.

3 (b) PREVENTING DISCRIMINATION AGAINST IMPORT-  
 4 ERS.—Section 804(h) of such Act is amended by inserting  
 5 before the period at the end of the first sentence the fol-  
 6 lowing: “or that discriminates against a person on the  
 7 basis of the person’s importation of covered products im-  
 8 ported pursuant to subsection (a) or the sale or distribu-  
 9 tion of such covered products”.

10 (c) CONDITIONS FOR TAKING EFFECT.—Section  
 11 804(l) of such Act is amended in the matter preceding  
 12 paragraph (1) by striking “This section shall become ef-  
 13 fective” and all that follows through “will” and inserting  
 14 the following: “This section shall become effective only if  
 15 the Secretary certifies to the Congress that, in the deter-  
 16 mination of the Secretary, there is a reasonable probability  
 17 that the implementation of this section will”.

18 (d) ELIMINATION OF SUNSET.—Section 804 of such  
 19 Act is amended by striking subsection (m).

20 (e) AUTHORIZATION OF APPROPRIATIONS.—Section  
 21 804 of such Act, as amended by subsection (d) of this  
 22 section, is amended by inserting after subsection (l) the  
 23 following subsection:

24 “(m) AUTHORIZATION OF APPROPRIATIONS.—There  
 25 are authorized to be appropriated for fiscal year 2002 and

- 1 each subsequent fiscal year such sums as may be nec-
- 2 essary to carry out this section.”.

