

106TH CONGRESS  
1ST SESSION

# H. R. 805

To amend the Federal Food, Drug, and Cosmetic Act to establish therapeutic equivalence requirements for generic drugs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 23, 1999

Mr. PALLONE (for himself, Mr. BERRY, Mrs. CLAYTON, Mr. SHOWS, Ms. KILPATRICK, Ms. JACKSON-LEE of Texas, Mr. STARK, Ms. NORTON, Ms. SCHAKOWSKY, Mr. RANGEL, Mr. WEINER, Mr. WAXMAN, Mr. BROWN of Ohio, Mr. MOAKLEY, Mr. LUTHER, Mr. NADLER, Mr. HINCHEY, and Mr. ALLEN) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish therapeutic equivalence requirements for generic drugs, 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 “Generic Drugs Access  
5 Act of 1999”.

6 **SEC. 2. THERAPEUTIC EQUIVALENCE.**

7 Section 505(j)(5) of the Federal Food, Drug, and  
8 Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

1           (1) by adding at the end of subparagraph (A)  
2           the following: “When the Secretary approves an ap-  
3           plication submitted under paragraph (1), the Sec-  
4           retary shall include in such approval a finding that  
5           the drug for which the application is approved is or  
6           is not the therapeutic equivalent of the listed drug  
7           involved.”;

8           (2) by inserting “(i)” after “(A)” and by add-  
9           ing at the end of subparagraph (A) the following:  
10          “(ii) For purposes of clause (i), a drug is the thera-  
11          peutic equivalent of a listed drug when, with respect to  
12          the listed drug—

13               “(I) all of its active ingredients are the same,  
14               it is of the same dosage form, it has the same route  
15               of administration, it is identical in strength or con-  
16               centration, and it meets the same compendial or  
17               other applicable standard, except that it may differ  
18               in shape, scoring, configuration, packaging,  
19               excipients, expiration time, or (within the limits es-  
20               tablished by paragraph (2)(A)(v)) labeling;

21               “(II) it is expected to have the same clinical ef-  
22               fect and safety profile when administered to patients  
23               under conditions specified in the labeling; and

24               “(III) it either does not present a known or po-  
25               tential bioequivalence problem and meets an accept-

1       able in vitro standard or if it does present such a  
2       problem, is shown to meet an appropriate bioequiva-  
3       lence standard.

4       “(iii) If a drug meets the requirements of clause (ii)  
5       with respect to a listed drug, the Secretary shall include  
6       in the approval of the application for the drug that it is  
7       the therapeutic equivalent of the listed drug involved.”;  
8       and

9               (3) in paragraph (7)(A)(i) by striking in sub-  
10       clause (II) “and the number of the application which  
11       was approved” and inserting “, the number of the  
12       application which was approved, and, in the case of  
13       a drug that is the subject of an application approved  
14       under paragraph (5)(A) after the date of the enact-  
15       ment of the Generic Drugs Access Act of 1999, the  
16       finding of the Secretary that the drug is or is not  
17       the therapeutic equivalent of the listed drug in-  
18       volved”.

19   **SEC. 3. STATE LAWS.**

20       Section 505(j) of the Federal Food, Drug, and Cos-  
21       metic Act (21 U.S.C. 355(j)) is amended by adding at the  
22       end the following:

23       “(10) No State or political subdivision of a State may  
24       establish or continue in effect with respect to a drug that  
25       is the subject of an application under paragraph (5)(A)

1 any requirement which is different from, or in addition  
2 to, any requirement related to therapeutic equivalence ap-  
3 plicable under paragraph (5)(A)(ii) to the drug.”.

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