

108TH CONGRESS
1ST SESSION

H. R. 3401

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 29, 2003

Mr. PALLONE 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 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 2003”.

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—

9 (1) by adding at the end of subparagraph (A)
10 the following: “When the Secretary approves an ap-

1 plication submitted under paragraph (1), the Sec-
2 retary shall include in such approval a finding that
3 the drug for which the application is approved is or
4 is not the therapeutic equivalent of the listed drug
5 involved.”;

6 (2) by inserting “(i)” after “(A)” and by add-
7 ing at the end of subparagraph (A) the following:

8 “(ii) For purposes of clause (i), a drug is the thera-
9 peutic equivalent of a listed drug when, with respect to
10 the listed drug—

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

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

22 “(III) it either does not present a known or po-
23 tential bioequivalence problem and meets an accept-
24 able in vitro standard or if it does present such a

1 problem, is shown to meet an appropriate bioequiva-
2 lence standard.

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

8 (3) in paragraph (7)(A)(i) by striking in sub-
9 clause (II) “and the number of the application which
10 was approved” and inserting “, the number of the
11 application which was approved, and, in the case of
12 a drug that is the subject of an application approved
13 under paragraph (5)(A) after the date of the enact-
14 ment of the Generic Drugs Access Act of 2003, the
15 finding of the Secretary that the drug is or is not
16 the therapeutic equivalent of the listed drug in-
17 volved”.

18 **SEC. 3. STATE LAWS.**

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

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

1 to, any requirement related to therapeutic equivalence ap-
2 plicable under paragraph (5)(A)(ii) to the drug.”.

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