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109TH CONGRESS
1ST SESSION

H. R. 2299

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

MAY 11, 2005

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

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 ''Generic Drugs Access Act of 2005''.

SEC. 2. THERAPEUTIC EQUIVALENCE.

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

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

plication submitted under paragraph (1), the Secretary shall include in such approval a finding that the drug for which the application is approved is or is not the therapeutic equivalent of the listed drug involved.'';

(2) by inserting ''(i)'' after ''(A)'' and by adding at the end of subparagraph (A) the following:

''(ii) For purposes of clause (i), a drug is the therapeutic equivalent of a listed drug when, with respect to the listed drug—

''(I) all of its active ingredients are the same, it is of the same dosage form, it has the same route of administration, it is identical in strength or concentration, and it meets the same compendial or other applicable standard, except that it may differ in shape, scoring, configuration, packaging, excipients, expiration time, or (within the limits established by paragraph (2)(A)(v)) labeling;

''(II) it is expected to have the same clinical effect and safety profile when administered to patients under conditions specified in the labeling; and

''(III) it either does not present a known or potential bioequivalence problem and meets an acceptable in vitro standard or if it does present such a

problem, is shown to meet an appropriate bioequivalence standard.

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

(3) in paragraph (7)(A)(i) by striking in subclause (II) ''and the number of the application which was approved'' and inserting '', the number of the application which was approved, and, in the case of a drug that is the subject of an application approved under paragraph (5)(A) after the date of the enactment of the Generic Drugs Access Act of 2005, the finding of the Secretary that the drug is or is not the therapeutic equivalent of the listed drug involved''.

SEC. 3. STATE LAWS.

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:

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

to, any requirement related to therapeutic equivalence applicable under paragraph (5)(A)(ii) to the drug.''.

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