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98TH CONGRESS
1ST SESSION

H. R. 3605

To amend the Federal Food, Drug, and Cosmetic Act to authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs.

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 1983

Mr. WAXMAN (for himself, Mr. MADIGAN, Mr. WYDEN, Mr. SIKORSKI, Mr. WIRTH, Mr. LELAND, Mr. MARKEY, Mr. SWIFT, Mr. BRYANT, and Mr. WEISS) 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 authorize an abbreviated new drug application under section 505 of that Act for generic new drugs equivalent to approved new drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Drug Price Competition Act of 1983".

SEC. 2. Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following new sentence: "Clause (1) of the previous

sentence shall not apply in the case of an application for a drug for which a previous application has been approved in accordance with subsection (c), if the drug with respect to which such subsequent application is filed meets appropriate standards of identity, strength, quality, purity, stability, bioavailability, and bioequivalence in relation to the drug approved in the previous application.".

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