I

106TH CONGRESS
2D SESSION

H. R. 5231

To amend the Federal Food, Drug, and Cosmetic Act and title 35, United States Code, with respect to abbreviated applications for the approval of new drugs.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 20, 2000

Mr. MOLLOHAN (for himself and Mr. CALVERT) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and title 35, United States Code, with respect to abbreviated applications for the approval of new drugs.

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 ''Pharmaceutical Reform Act of 2000''.

SEC. 2. AMENDMENTS REGARDING ABBREVIATED APPLICATIONS FOR APPROVAL OF NEW DRUGS.

(a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) in section 306(f), by adding at the end the following paragraph:

"(4) LIMITATION.—The Secretary shall cease consideration of a petition under paragraph (1), and shall terminate any order under such paragraph issued in response to the petition, if the Secretary determines that the person submitting the petition received, as an inducement for submitting the petition, valuable consideration provided directly or indirectly by an entity any of whose financial interests are served by the issuance of an order under such paragraph."; and

(2) in section 505(j)—

(A) in paragraph (2), by adding at the end the following subparagraph:

"(D) For purposes of subparagraph (A)(vii), a patent may not be considered to claim a listed drug unless with respect to such drug the patent claims an active ingredient.";

(B) in paragraph (5)(B)(iii), in the second sentence, in the matter preceding subclause (I), by striking ''If such an action'' and all that follows through '', except that'' and inserting the following: ''If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of such period as the court may designate, consistent with chapters 28 and 29 of title 35, United States Code, and taking into account whether the parties to the action reasonably cooperate in expediting the action (which period shall begin on the date of the receipt of the notice provided under paragraph (2)(B)(i)), except that'';

(C) in paragraph (5)(B)(iv)—

(i) in the matter preceding subclause (I), by striking ''a certification,'' and inserting ''a certification and has been approved,''; and

(ii) by amending subclause (I) to read as follows:

''(I) the date on which the Secretary approved the previous application,'';

(D) in paragraph (7)(A)(i), in the matter preceding subclause (I), by striking ''the Sec-

retary shall publish'' and inserting the following: ''the Secretary, in consultation with the Commissioner of Patents and Trademarks, shall publish''; and

(E) by adding at the end the following paragraph:

''(10)(A) No State or political subdivision of a State may establish or continue in effect with respect to a drug approved under this subsection any requirement that is different from, or in addition to, any requirement applicable under this Act to the drug.

''(B) Pursuant to subparagraph (A), no State or political subdivision of a State may establish or continue in effect with respect to a drug approved under this subsection any prohibition against the use of the drug as a substitute for any listed drug to which the drug is therapeutically equivalent as determined by the Secretary, including therapeutic equivalence evaluated by the Secretary as having an AB code (relating to actual or potential bioequivalence problems that have been resolved with adequate evidence that supports bioequivalence).''.

(b) TITLE 35, UNITED STATES CODE.—Section 271(e)(1) of title 35, United States Code, is amended by striking ''a Federal law which regulates'' and inserting the

following: ''a Federal law, or a law of a foreign country, which regulates''.

(c) SENSE OF CONGRESS.—It is the sense of the Congress that section 351(j) of the Public Health Service Act (as added by section 123(g) of the Food and Drug Administration Modernization Act of 1997; 111 Stat. 2324) authorizes the submission, under section 505(j) of the Federal Food, Drug, and Cosmetic Act, of an abbreviated application for the approval of a new drug that is a biological product.

○