109TH CONGRESS
1ST SESSION

S. 511

To provide that the approved application under the Federal Food, Drug, and Cosmetic Act for the drug commonly known as RU–486 is deemed to have been withdrawn, to provide for the review by the Comptroller General of the United States of the process by which the Food and Drug Administration approved such drug, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 3, 2005

Mr. DEMINT (for himself, Mr. ALLEN, Mr. BROWNBACK, Mr. COBURN, Mr. ENSIGN, Mr. ENZI, Mr. INHOFE, Mr. SANTORUM, and Mr. VITTER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide that the approved application under the Federal Food, Drug, and Cosmetic Act for the drug commonly known as RU–486 is deemed to have been withdrawn, to provide for the review by the Comptroller General of the United States of the process by which the Food and Drug Administration approved such drug, and for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 ''RU–486 Suspension and Review Act of 2005''.

SEC. 2. FINDING.

Congress finds that the use of the drug mifepristone (marketed as Mifeprex, and commonly known as RU–486) in conjunction with the off-label use of misoprostol to chemically induce abortion has caused a significant number of deaths, near deaths, and adverse reactions.

SEC. 3. SUSPENSION OF APPROVAL OF DRUG COMMONLY KNOWN AS RU–486; REVIEW AND REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.

(a) IN GENERAL.—Effective on the date that is 15 days after the date of the enactment of this Act:

(1) The approved application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) for the drug mifepristone (marketed as Mifeprex, and commonly known as RU–486) is deemed to have been withdrawn under section 505(e) of such Act (21 U.S.C. 355(e)).

(2) For purposes of sections 301(d) and 304 of such Act (21 U.S.C. 331(d) and 334), the introduction or delivery for introduction of such drug into interstate commerce shall be considered a violation of section 505 of such Act.

(3) The drug misoprostol shall be considered misbranded for purposes of sections 301 and 304 of such Act if the drug bears labeling providing that the drug may be used for the medical termination of intrauterine pregnancy or that the drug may be used in conjunction with another drug for the medical termination of intrauterine pregnancy.

(b) REVIEW AND REPORT BY GOVERNMENT ACCOUNTABILITY OFFICE.—

(1) IN GENERAL.—The Comptroller General of the United States shall review the process by which the Food and Drug Administration approved mifepristone under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and shall determine whether such approval was provided in accordance with such section. The Secretary of Health and Human Services shall ensure that the Comptroller General has full access to all information possessed by the Department of Health and Human Services that relates to such process.

(2) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Comptroller General of the United States shall complete the review under paragraph (1) and submit to Con-

gress and the Secretary of Health and Human Services a report that provides the findings of the review.

(c) CONTINGENT REINSTATEMENT OF APPROVAL OF DRUG.—If the report under subsection (b) includes a determination by the Comptroller General of the United States that the approval by the Food and Drug Administration of mifepristone was provided in accordance with section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), the Secretary of Health and Human Services shall publish such statement in the Federal Register. Effective upon the expiration of 30 days after such publication, subsection (a) shall cease to have any legal effect.

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