II

117TH CONGRESS
2D SESSION

S. 4638

To allow women greater access to safe and effective oral contraceptive drugs intended for routine use.

IN THE SENATE OF THE UNITED STATES

JULY 27, 2022

Ms. ERNST (for herself and Mr. GRASSLEY) 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 allow women greater access to safe and effective oral contraceptive drugs intended for routine use.

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 ''Allowing Greater Access to Safe and Effective Contraception Act''.

SEC. 2. SUPPLEMENTAL APPLICATIONS FOR OVER-THE-COUNTER CONTRACEPTIVE DRUGS.

(a) PRIORITY REVIEW OF APPLICATION.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall give priority review to

any supplemental application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) if—

(1) the supplemental application is with respect to an oral contraceptive drug intended for routine use;

(2) the supplemental application is not with respect to any emergency contraceptive drug;

(3) the supplemental application is not with respect to any drug that is also approved for induced abortion; and

(4) if the supplemental application is approved, with respect to individuals aged 18 and older, such drug would not be subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(b) FEE WAIVER.—The Secretary shall waive the fee under section 736(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(1)) with respect to a supplemental application that receives priority review under subsection (a).

(c) OVER-THE-COUNTER AVAILABILITY.—Notwithstanding any other provision of law, with respect to individuals under age 18, a contraceptive drug that is eligible for priority review under subsection (a) shall be subject

to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)), including after approval of the supplemental application as described in subsection (a)(3).

(d) APPLICABILITY.—This section applies with respect to a supplemental application described in subsection (a) that—

(1) is submitted before the date of enactment of this Act and remains pending as of such date of enactment; or

(2) is submitted after such date of enactment.

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