118TH CONGRESS
1ST SESSION

S. 1128

To establish special rules relating to information provided with respect to drug applications concerning method of use patents.

IN THE SENATE OF THE UNITED STATES

MARCH 30, 2023

Ms. HASSAN (for herself and Mr. BRAUN) 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 establish special rules relating to information provided with respect to drug applications concerning method of use patents.

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 ''Ensuring Access to Generic Medications Act''.

SEC. 2. SPECIAL RULES RELATING TO METHOD OF USE PATENTS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(z) CAUSE OF ACTION RELATING TO DRUG USE CODES.—

''(1) IN GENERAL.—In the case of an application under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act with respect to which the applicant seeking approval includes in the application a statement that a patent claiming a method of use does not claim a use for the drug that is the subject of such application, as described in subsection (b)(2)(B) or (j)(2)(A)(viii), or in the case of an application under such section 351(k), as otherwise required by the Secretary, the sponsor of the application under subsection (b)(2) or (j) or such section 351(k) described in paragraph (2) may file a civil action in an appropriate district court of the United States against the holder of the approved application for the applicable reference drug or reference product seeking a court order requiring the holder to correct or delete information relating to a use code submitted by the holder of the reference drug or reference product with respect to

such patent claiming a method of use, on the ground that such use code—

"(A) does not correspond to a patent that claims the reference drug or reference product for which the application was approved;

"(B) does not correspond to a patent that claims an approved method of using the reference drug or reference product; or

"(C) is overly broad or otherwise inaccurate or inappropriate.

"(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to affect the application of subsection (j)(5)(C)(ii).

"(3) DEFINITION.—For purposes of paragraph (1), the term 'use code' means the information relating to a patent claiming a method of using a drug that is approved under section 505 of this Act or under section 351 of the Public Health Service Act, as applicable, based upon information submitted by the drug sponsor or holder of the approved application or licensure pursuant to section 314.53(c)(2)(ii)(P)(3) of title 21, Code of Federal Regulations (or any successor regulations).".

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