

117TH CONGRESS
2D SESSION

S. 3516

To require the Secretary of Health and Human Services to provide emergency use authorization with respect to certain COVID–19 diagnostic tests approved for use in the European Union.

IN THE SENATE OF THE UNITED STATES

JANUARY 18, 2022

Mr. SASSE introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To require the Secretary of Health and Human Services to provide emergency use authorization with respect to certain COVID–19 diagnostic tests approved for use in the European Union.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Increase Access to
5 COVID Testing Act”.

1 **SEC. 2. EMERGENCY USE APPROVAL OF CERTAIN COVID-19**

2 **TESTS.**

3 (a) IN GENERAL.—For the duration of the public
4 health emergency declared under section 319 of the Public
5 Health Service Act (42 U.S.C. 247d) with respect to
6 COVID-19, the Secretary of Health and Human Services
7 shall authorize the introduction into interstate commerce,
8 pursuant to section 564 of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 360bbb-3), without regard for
10 any specific criteria under subsection (c)(2) of such sec-
11 tion, of any antigen diagnostic test to detect SARS-CoV-
12 2 that is described in subsection (b), upon request by the
13 manufacturer under such section 564.

14 (b) TESTS DESCRIBED.—An antigen diagnostic test
15 to detect SARS-CoV-2 described in this subsection is
16 such a test—

17 (1) that is included on the common list of
18 COVID-19 rapid antigen tests of the European
19 Commission Directorate-General for Health and
20 Food Safety; and

21 (2) for which the emergency use authorization
22 request is for an at-home, or other non-laboratory
23 site, use, without a prescription.

24 (c) TERMS OF AUTHORIZATION.—

25 (1) IN GENERAL.—A diagnostic test authorized
26 as described in subsection (a) shall be subject to the

1 same terms and requirements as other products au-
2 thorized under section 564 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 360bbb-3).

4 (2) CHANGE IN STATUS IN THE EU.—In the
5 case of an antigen diagnostic test authorized as de-
6 scribed in subsection (a), if the European Commis-
7 sion Directorate-General for Health and Food Safety
8 removes such test from the common list described in
9 subsection (b)(1), the Secretary of Health and
10 Human Services, not later than 30 days after such
11 removal from the common list, shall conduct a re-
12 view of the test to determine whether the emergency
13 use authorization under section 564 of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-
15 3) should continue.

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