

116TH CONGRESS
2D SESSION

S. _____

To extend Federal guidance concerning the use of certain alcohol-based hand sanitizer during the coronavirus public health emergency, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. THUNE introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To extend Federal guidance concerning the use of certain alcohol-based hand sanitizer during the coronavirus public health emergency, and for other purposes.

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 “Hand Sanitizer Guid-
5 ance Extension Act of 2020”.

6 **SEC. 2. FEDERAL GUIDANCE ON HAND SANITIZER.**

7 (a) EXTENSION OF FEDERAL GUIDANCE.—The Food
8 and Drug Administration guidance entitled “Guidance for
9 Industry: Temporary Policy for Preparation of Certain Al-

1 cohol-Based Hand Sanitizer Products During the Public
2 Health Emergency (COVID–19)”, initially released on
3 March 23, 2020, and updated on April 15, 2020, and on
4 June 1, 2020, shall remain in effect until the date that
5 is 2 years after the date of enactment of this Act.

6 (b) EFFECT OF EXTENSION.—During the 2-year pe-
7 riod described in subsection (a), the Food and Drug Ad-
8 ministration shall permit the production, sale, and use of
9 hand sanitizer, consistent with the guidance described in
10 subsection (a), provided that such hand sanitizer is manu-
11 factured using only the following ingredients in the prepa-
12 ration of the product:

13 (1)(A) Subject to subsection (c), alcohol (eth-
14 anol) that is not less than 94.9 percent ethanol by
15 volume; or

16 (B) United States Pharmacopeia grade iso-
17 propyl alcohol.

18 (2) United States Pharmacopeia grade or Food
19 Chemical Codex grade glycerin (glycerol).

20 (3) Hydrogen peroxide.

21 (4) Sterile water meeting United States Phar-
22 macopeia specifications for purified water.

23 (c) ETHANOL PRODUCED IN CERTAIN FACILITIES.—
24 Ethanol produced in facilities normally producing fuel or

1 technical ethanol may be used as described in subsection
2 (b)(1)(A) only if such ethanol—

3 (1) meets United States Pharmacopeia or Food
4 Chemical Codex grade requirements;

5 (2) has been screened for any other potentially
6 harmful impurities not specified in the United States
7 Pharmacopeia or Food Chemical Codex require-
8 ments; or

9 (3) has otherwise been approved for use by the
10 Food and Drug Administration.

11 (d) AUTOMATIC EXTENSION.—The effective period of
12 the guidance described in subsection (a) shall automati-
13 cally be extended for 1 additional year if the Secretary
14 of Health and Human Services determines that a public
15 health emergency exists at the time that the 2-year period
16 described in subsection (a) expires.

17 (e) EXEMPTION.—If the Commissioner of Food and
18 Drugs determines that a public health emergency requires
19 that the requirement for the use of denatured alcohol be
20 reduced, or requires a waiver of any other requirement
21 with respect to hand sanitizer under the guidance, the
22 Commissioner of Food and Drugs may waive or reduce
23 such requirement, as applicable.