

116TH CONGRESS
2D SESSION

S. 3938

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

JUNE 11, 2020

Mr. THUNE (for himself, Mr. BRAUN, Mr. GRASSLEY, Mr. ROUNDS, and Ms. ERNST) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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-

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

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

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

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

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

20(3) Hydrogen peroxide.

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

23(c) ETHANOL PRODUCED IN CERTAIN FACILITIES.—
 24Ethanol 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.

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