Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency

Immediately in Effect Guidance for Industry

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(2). Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact FDA's human drug compounding team (CDER) at compounding@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2020
Compounding

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Contains Nonbinding Recommendations

Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency Immediately in Effect Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

Due to the Coronavirus Disease 2019 (COVID-19) pandemic, the Food and Drug Administration (FDA or Agency) has received a number of queries concerning compounding of alcohol-based hand sanitizers. The Agency is issuing this guidance to communicate its policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in State-licensed pharmacies or Federal facilities and registered outsourcing facilities (referred to collectively in this guidance as compounders) for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020.[2]

In light of the public health emergency posed by COVID-19, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)(i)) and 21 CFR 10.115(g)(2)). This guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research at the Food and Drug Administration.

[2] The HHS Public Health Emergency Declaration is available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

II. BACKGROUND

There is currently an outbreak of respiratory disease caused by a novel coronavirus that was first detected in Wuhan City, Hubei Province, China, and that has now been detected in many locations internationally, including cases in the United States. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). SARS-CoV-2 has demonstrated the capability to rapidly spread, leading to significant impacts on healthcare systems and causing societal disruption. The potential public health threat posed by COVID-19 is high, both globally and to the United States. On January 31, 2020, the Secretary of HHS determined that a public health emergency exists.

Hand hygiene is an important part of the U.S. response to COVID-19. Washing hands often with soap and water for at least 20 seconds is essential, especially after going to the bathroom, before eating, and after coughing, sneezing or blowing one's nose. If soap and water are not readily available, the Centers for Disease Control and Prevention (CDC) recommends an alcohol-based hand sanitizer that contains at least 60 percent alcohol.[3]

III. DISCUSSION

We understand that some consumers are currently experiencing difficulties accessing alcohol-based hand sanitizers containing at least 60 percent alcohol. We are also aware of reports that some consumers are producing hand sanitizers for personal use; the Agency lacks information on the methods being used to prepare such products and whether they are safe for use on human skin. We further recognize that compounders, relative to untrained consumers, are more familiar with standards and methods for producing drug products.

Because of the public health emergency posed by COVID-19, FDA does not intend to take action against compounders[4] that prepare alcohol-based hand sanitizers for consumer use for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, provided the following circumstances are present:

[3] Isopropyl alcohol and ethyl alcohol are two of the active ingredients currently being evaluated by FDA as part of its review of over-the-counter (OTC) monographs for hand sanitizers for use in reducing bacteria on the skin that potentially can cause disease or decreasing bacteria on the skin. See "Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use," Final Rule, 84 FR 14847 (April 12, 2019); Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use Final Rule, 82 FR 60474 (December 20, 2017); "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM).

[4] Specifically, FDA does not intend to take action against pharmacists in State-licensed pharmacies or Federal facilities, for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, for violations of sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355), or against outsourcing facilities for violations of sections 502(f)(1), 505, or 582 of the FD&C Act (21 U.S.C. 352(f)(1), 355, and 360eee-1).

1. The hand sanitizer is compounded using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:[5]
    a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; **or** Isopropyl Alcohol (75%, v/v) in an aqueous solution.[6]
    b. Glycerol (1.45% v/v).[7]
    c. Hydrogen peroxide (0.125% v/v).
    d. Sterile distilled water or boiled cold water.

    The compounder does not add other active or inactive ingredients. Different or additional ingredients may reduce the safety and effectiveness of the product.

2. The compounder pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used.

3. The hand sanitizer is prepared under conditions routinely used by your facility to compound similar nonsterile drugs.[8]

4. The hand sanitizer is labeled consistent with the attached labeling in Appendix A (Labeling for Ethyl Alcohol Formulation) or Appendix B (Labeling for Isopropyl Alcohol Formulation).

This policy does not extend to other types of products, such as products that use different active ingredients, whose potency falls above or below the formulation described above, that are marketed with claims that do not conform to the "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (e.g., pathogen-specific disease claims), or whose advertising or promotion is false or misleading in any particular.

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[5]The 1994 TFM is available at https://www.gpo.gov/fdsys/pkg/FR-1994-06-17/html/94-14503 htm. WHO's recommendations, titled "Guide to Local Production: WHO-recommended Handrub Formulations," are available at https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf.

[6] Consistent with the 1994 TFM, alcohol should be used in a final product concentration between 60-95% (v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; isopropyl alcohol should be used in a concentration between 70-91.3% (v/v). This guidance is consistent with WHO's recommended formulation specifications of 80% alcohol and 75% isopropyl alcohol.

[7] Although WHO's recommended formulation includes glycerol 1.45% (v/v), reports indicate that glycerol negatively impacts effectiveness of isopropyl alcohol (https://www.ncbi.nlm.nih.gov/pubmed/28670452), and reports studying the effectiveness of WHO's formulation have suggested a reduction from 1.45% to 0.725% (https://www ncbi.nlm.nih.gov/pubmed/23388358/).

[8] In particular, outsourcing facilities compound drugs subject to current Good Manufacturing Practice requirements, and other pharmacy compounders generally prepare nonsterile drug products from bulk drug substances in compliance with United States Pharmacopoeia chapter 795. Both outsourcing facilities and other pharmacy compounders must also avoid insanitary conditions as set forth in section 501(a)(2)(A) of the FD&C Act (21 U.S.C. 351(a)(2)(A)).

FDA encourages consumers and health care professionals to report adverse events experienced with the use of hand sanitizers to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

Outsourcing facilities can see Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act for more information.

Appendix A. Labeling for Ethyl Alcohol Formulation

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s] ***Purpose***
Alcohol 80% v/v..... Antiseptic

Use[s]
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings
For external use only. Flammable. Keep away from heat or flame

Do not use
- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Appendix B. Labeling for Isopropyl Alcohol Formulation

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Isopropyl Alcohol Antiseptic 75%
Topical Solution

Hand Sanitizer
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s] ***Purpose***

Isopropyl alcohol 75% v/v.....Antiseptic

Use[s]

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP