

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

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

**March 2020
Compounding**

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	BACKGROUND	2
III.	DISCUSSION	2

Contains Nonbinding Recommendations

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 compounders⁴ 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).

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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.

⁵The 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](https://www.who.int/gpsc/5may/Guide%20to%20Local%20Production.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)).

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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.