



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1106]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency." Due to the Coronavirus Disease 2019 (COVID-19) pandemic, FDA 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 notice and the guidance as *compounders*) for the duration of the public health emergency declared by the Secretary of Health and Human Services on January 31, 2020. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2020-D-1106 for "Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document. FOR FURTHER INFORMATION CONTACT: Rosilend Lawson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-6223.

SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is announcing the availability of a guidance entitled "Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency." Due to the COVID-19 pandemic and the resulting public health concerns, FDA has received a number of queries concerning compounding of alcohol-based hand sanitizers. We understand that some consumers and healthcare professionals are currently experiencing

difficulties accessing alcohol-based hand sanitizers containing at least 60 percent alcohol or 70 percent isopropyl 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 pharmacists in State-licensed pharmacies or Federal facilities and registered outsourcing facilities (referred to collectively in this notice and the guidance as *compounders*), relative to untrained consumers, are more familiar with appropriate standards and methods for producing drug products.

The Agency is issuing this guidance to communicate a policy for the temporary compounding of certain alcohol-based hand sanitizer products by compounders for consumer use and for use as healthcare personnel hand rubs for the duration of the public health emergency declared by the Secretary of Health and Human Services on January 31, 2020. In light of the public health emergency posed by COVID-19, FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i)) and 21 CFR 10.115(g)(2)). Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency." 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.

### III. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collection of information for "Current Good Manufacturing Practices for Finished Pharmaceuticals and Medical Gases" has been approved under OMB control number 0910-0139. The collection of information for "Postmarketing Adverse Drug Experience Reporting" has been approved under OMB control number 0910-0230. The collection of information for "MedWatch: Adverse Event and Product Experience Reporting System (Paper-Based)" has been approved under OMB control number 0910-0291. The collection of information for "Format and Content Requirements for Over-the-Counter Drug Product Labeling" has been approved under OMB control number 0910-0340. The collection of information for "FDA Adverse Event and Products Experience Reports; Electronic Submissions" has been approved under OMB control number 0910-0645. The collection of information for "Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act" has been approved under OMB control number 0910-0800.

### IV. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: March 17, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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