

Coronavirus Disease 2019 (COVID-19) FDA Guidance Regarding Manufacture of Hand Sanitizers March 2020

Purpose of Document

The Food and Drug Administration (FDA) has received questions concerning compounding of alcohol-based hand sanitizers due to the COVID-19 pandemic. The FDA has issued 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/or 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.

OVERVIEW OF FDA GUIDANCE

- On March 20, 2020, the FDA issued guidance for the manufacture of hand sanitizers by businesses not currently regulated by the FDA and for Pharmaceutical Compounders.
- The FDA's guidance documents apply only to handrub products prepared using the United States Pharmacopoeia or Food Chemical Codex grade ingredients specifically described in the guidance and consistent with World Health Organization recommendations.
- The guidance documents discuss product labeling and certain manufacturing methods and reporting requirements, such as that manufacturers must have a way to accept and submit adverse event reports to the FDA for any products they manufacture.*
- Many jurisdictions have distilleries that switched production to hand sanitizer. Please share the information provided here with any distilleries considering this switch.
- There is no guidance currently relating to homemade hand sanitizer products.

FDA GUIDANCE DOCUMENTS AND ANNOUNCEMENTS

- Guidance Document for Producing Product: <https://www.fda.gov/media/136289/download>
- Guidance Document for Compounding Product: <https://www.fda.gov/media/136118/download>
- *Press Announcement: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-guidance-production-alcohol-based-hand-sanitizer-help-boost>

FDA EMAIL ADDRESSES

- compounding@fda.hhs.gov
- CDERCompliance@fda.hhs.gov