Today, FDA has taken additional action to help ensure widespread access to alcohol-based hand sanitizers that are free of contamination. The agency issued updated guidances to provide additional clarification on testing of alcohol used in hand sanitizers manufactured under FDA's temporary policies to help ensure that harmful levels of methanol are not present in these products.
We have updated our guidances to provide clarification that companies test each lot of the active ingredient (ethanol or isopropyl alcohol (IPA)) for methanol if the ethanol or IPA is obtained from another source. FDA recommends using the test methods described in the USP monograph for alcohol (ethanol) and conducting the testing in a laboratory that has been previously inspected by FDA and is compliant with current good manufacturing practice (CGMP).

Any alcohol (ethanol) or IPA found to contain more than 630 ppm methanol does not fall within the policies described in the temporary guidances and may be considered evidence of substitution and/or contamination. Alcohol-based hand sanitizers that are contaminated with methanol are subject to adulteration charges under the FD&C Act. The alcohol (ethanol) or IPA should be destroyed following guidelines for hazardous waste and the manufacturer or compounder should contact FDA regarding the test results and the alcohol's source.

The temporary guidances have also been updated to provide adverse event reporting guidelines for state-licensed pharmacies and outsourcing facilities.

The updated guidances also include an additional denaturant formula. Denaturing alcohol in hand sanitizers is critical to deter children from unintentional ingestion. Consumer and health care personnel safety is a top priority for FDA, and an important part of FDA's mission is to protect the public from harm, especially as we seek to facilitate an increase in the supply of hand sanitizer.
Additionally, with a recommendation from the agency, the United States Pharmacopeia (USP) issued a notice of intent to revise alcohol monographs to include a *Limit of Methanol* test in the identification (ID) section.

For questions, contact FDA at COVID-19-Hand-Sanitizers@fda.hhs.gov.

Thank you,

Sadhna Khatri, Pharm.D., MPH, MS, MEd
CDR, U.S. Public Health Service
Professional Affairs and Stakeholder Engagement | Office of Center Director
Center for Drug Evaluation and Research |Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993