FDA Demonstrates Regulatory Flexibility and Relaxes Policies on Hand Sanitizer Amid COVID-19

March 25, 2020 Suzie Trigg, Kayla Cristales

PRACTICES FDA Regulatory and Compliance, Healthcare and Life Sciences, Healthcare Transactions and Regulatory

The rapid spread of Coronavirus Disease 2019 (COVID-19) has sparked public fear and panic-induced stockpiling of alcohol-based sanitizing gels, leaving retailers and consumers without access to hand sanitizer. In response, the FDA has issued two new guidance documents on the preparation of certain alcohol-based hand sanitizer products by compounding pharmacies or by other manufacturing firms that register as over-the-counter (OTC) drug establishments to prepare alcohol-based hand sanitizers. In addition, the Alcohol and Tobacco Tax and Trade Bureau (TTB) has issued guidance that permits distilleries to produce hand sanitizer for the duration of the current emergency. These measures demonstrate the willingness of regulatory agencies to allow for flexible, practical approaches to meeting consumer and Industry needs.

In its recently issued guidance documents, which include the FDA Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (issued March 14, 2020) ("***FDA Compounder Guidance***") and the FDA Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry (issued March 19, 2020) ("***FDA Industry Guidance***"), the FDA has stated that it does not intend to take action against companies that prepare alcohol-based hand sanitizers for consumer use during this public health emergency in accordance with the applicable guidance. To be eligible for enforcement discretion under either FDA guidance *or* the TTB guidance, compounding pharmacies and other manufacturing firms, as well as distilleries, must utilize a specific formulation set forth in World Health Organization (WHO) guidelines, as described more fully in the guidance documents. Notably, FDA has communicated to us (via email on March 20, 2020) its then-current position that, in addition to the TTB guidance, distilleries should *also* follow the FDA Industry Guidance.

To summarize the FDA Industry Guidance, those wishing to produce hand sanitizer in response to the current emergency should adhere to the following requirements:

1. The hand sanitizer should be formulated using only the following United States Pharmacopoeia (USP) grade ingredients (percentage in final product formulation), consistent with WHO recommendations:
    a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (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;
    b. Glycerol (1.45% v/v);
    c. Hydrogen peroxide (0.125% v/v); and
    d. Sterile distilled water or boiled cold water.

    The manufacturer acting solely under the guidance should not add other active or inactive ingredients due to FDA concerns that different or additional ingredients may impact the quality

and potency of the product.
2. The manufacturer should ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used. A simple record should be used to document key steps and controls to assure each batch matches the formula developed for the drug product.
3. The hand sanitizer should be prepared under sanitary conditions and equipment utilized should be well maintained and fit for this purpose.
4. The manufacturer should use the most accurate method of analysis available at the site for verification of alcohol content in samples of the finished drug product before each batch is released for distribution. Methods can include gas chromatography (GC), alcoholmeter, hydrometer, or other chemical analysis of at least equivalent accuracy. The sample tested can be performed on in-process material before filling into the final containers to be distributed.
5. The hand sanitizer should be labeled consistent with the labeling attached to the FDA guidance.
6. New manufacturers that are not currently registered as OTC drug establishments will also have to register with the FDA and will receive automatic confirmation once the registration is complete. However, the registration can be completed contemporaneously and is not a bar to beginning production.

The FDA also advised that companies need to have a way to track adverse events for any products they manufacture and must submit adverse event reports to the FDA in accordance with applicable regulations.