

Temporary Alcohol-Based Hand Sanitizer Manufacturer Registration Process

If you wish to manufacture alcohol-based hand sanitizer in the state of California and are not currently licensed with the department as an over-the-counter (OTC) drug manufacturer, you can now apply for a temporary OTC drug manufacturer registration, based on the [Governor's Executive Order N-68-20](#).

You must submit an application for a temporary registration to the Department of Public Health. The application must include a self-certification of compliance with the current or most up-to-date [temporary FDA guidance](#) for the preparation of alcohol-based hand sanitizer. The firm must not be currently registered with the FDA as an OTC drug manufacturer.

Once you have received the temporary registration notification, you may manufacture OTC alcohol-based hand sanitizer until the earliest of the following occurs: (1) the expiration of a six-month registration period, after which that entity may request to extend the registration period for another six months, (2) the Department suspends or rescinds any applicable temporary registration, or (3) the FDA withdraws or otherwise terminates any applicable federal guidance.

Once you have completed the temporary registration application and self-certification you can email the documents to FDBMedDevice@cdph.ca.gov or mail them to the department at the address listed on the application. The department will not issue a certificate for this temporary registration. Once the application and self-certification have been reviewed to meet the minimum requirements, the department will issue you an email in response to your application and self-certification submission with the expiration date of the temporary registration.