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**NOTICE OF TERMINATION OF THE TEMPORARY  
REGISTRATION FOR THE MANUFACTURING OF ALCOHOL BASED HAND  
SANITIZER**

**TO: Entities that applied for temporary registration**  
**SUBJECT: Termination of temporary registration**

The California Department of Public Health (Department) will officially terminate the temporary registration for the manufacturing of alcohol based hand sanitizers, **effective December 31, 2021**. If you possess a temporary registration, this means you may no longer manufacture alcohol based hand sanitizers after December 31, 2021, and you may no longer sell or distribute it after March 31, 2022. If you wish to continue to manufacture alcohol based hand sanitizers after December 31, 2021, you must apply for and obtain the Department's [Drug Manufacturing License](#) and also [register with the U.S. Food and Drug Administration \(FDA\)](#).

You are being contacted because you have been issued the Department's temporary registration for manufacturing alcohol based hand sanitizers, an over-the-counter (OTC) drug, in response to the COVID-19 pandemic.

**Ending temporary registration**

The [Governor's Executive Order N-68-20](#), signed on June 5, 2020, states a temporary registration allows an entity to manufacture an over-the-counter drug until the earliest of three things occurs, one of which is when the FDA withdraws its applicable federal guidance: "An entity that receives a temporary registration may manufacture over-the-counter drugs or medical devices under that temporary registration until the earliest of the following occurs: (i) The expiration of a six-month registration period, after which that entity may apply for a further temporary registration; (ii) The Department of Public Health suspends or rescinds any applicable temporary registration; or (iii) The FDA withdraws or otherwise terminates any applicable federal guidance (including, but not limited to, previously issued guidance for firms that lack federal registration)."

On October 12, 2021, the FDA announced it intends to withdraw, effective December 31, 2021, its guidances regarding temporary policies for manufacturers that were not drug manufacturers at the time to produce certain alcohol based hand sanitizers during the public health emergency:

- "Effective Dec. 31, 2021, companies manufacturing alcohol-based hand sanitizers under the temporary policies must cease production of these products.



After that date, manufacturers wishing to continue producing hand sanitizers can do so provided they comply with the tentative final monograph for over-the-counter topical antiseptics and other applicable requirements, including the FDA's Current Good Manufacturing Practice requirements."

- "Hand sanitizers manufactured before or on December 31, 2021, and produced under the temporary guidances can no longer be sold or distributed by manufacturers after March 31, 2022."

In line with the FDA ending the temporary guidances for manufacturing alcohol based hand sanitizers, the California Department of Public Health will officially terminate the state's temporary registration of alcohol based hand sanitizers effective December 31, 2021.

### **What you should do now**

Under your temporary registration, you may continue to manufacture alcohol based hand sanitizers through December 31, 2021, and you may sell or distribute remaining hand sanitizers through March 31, 2022. You do not need to contact the Department.

If you wish to continue to manufacture alcohol based hand sanitizers after December 31, 2021, you must apply for and obtain the Department's [Drug Manufacturing License](#) and also [register with the FDA](#). You should start this process as soon as possible to allow for review and processing time. Per California Health and Safety Code (HSC) Section 111615: "No person shall manufacture any drug or device in this state unless he or she has a valid license from the department."

If you have any questions regarding this information or the application process, you may contact the Drug & Medical Device Licensing Desk at [FDBMedDevice@cdph.ca.gov](mailto:FDBMedDevice@cdph.ca.gov), or (916) 650-6500.