

Deregistering is Not Enough; How to Close the Books on Hand Sanitizer

The U.S. Food and Drug Administration (FDA) is winding down its emergency guidance on hand sanitizer production and recently sent to distillers a notice of intent to inactivate outdated drug listing records. The notice is essentially the FDA telling distillers to clean up their books after the Dec. 31, 2021 deadline to cease production of hand sanitizer and ahead of the March 31, 2022 deadline to cease distribution of hand sanitizer. If you have ceased production and have yet to delist your product, deregister your company and deactivate your labeler code, please follow the instructions below:

The first thing you will want to do is delist the drug product. To do this:

1. Login to your CDER Direct Account
2. Click on "Product Listing and Certification"
3. Click on "Submission Accepted" for the most recently, previously submitted Product Listing
4. Click on "Create New Version" (do not alter any of the information in the Header Details as it is correctly updated for you when you click "Create New Version")
5. Click on the edit tool (pencil/notepad) next to the Product NDC toward the bottom of the page
6. Change the Marketing Status from "ACTIVE" to "COMPLETED"
7. Enter an End Marketing Date that corresponds to the last lot expiration date (we suggest that the end marketing date be on or before 3/31/22, the last date for manufacturers to wholesale sanitizer produced under the emergency guidance)
8. Click on "Save Product"
 - o Repeat steps 5-8 for any additional products in the form
9. Click on "Submit SPL"
10. Wait for the above submission to return as "Submission Accepted"

Then you may De-Register your establishment. To do this:

1. Login to your CDER Direct Account
2. Click on "Establishment Registration"
3. Click on "Submission Accepted" for the most recently submitted Establishment Registration
4. Click on "Create New Version" (do not alter any of the information in the Header Details as it is correctly updated for you when you click "Create New Version")
5. Change the Document Type to "Establishment De-Registration"
6. Click on "Submit SPL" You can repeat the above process for each Establishment Registration containing establishments you want to de-register.

Then you may inactivate the Labeler Code. To do this:

1. Login to your CDER Direct Account
2. Click on "NDC/NHRIC Labeler Code Request"
3. Click on "Submission Accepted" for the most recently, previously submitted Labeler Code Request
4. Click on "Create New Version" (do not alter any of the information in the Header Details as it is correctly updated for you when you click "Create New Version")
5. Change the Document Type to "Labeler Code Inactivation"
6. Click on "Submit SPL"

If you have questions, please send a note to sanitizer@americancraftspirits.org.