HOW DOES THE LATEST HHS DECISION ON FDA FACILITY FEES DECISION AFFECT MY BUSINESS?

The answer to this question lies in any one of three cases. Find your situation, and we will give you our current best understanding of the HHS ruling submitted to the Federal Register on Jan. 5th, 2021. Then check the end of the document for timely reminders from TTB and DOT!

CASE #1: "Our company has made and packaged all the sanitizer that our community needed. We are not interested in making more, but we have some amount left to sell or donate."

In this case, ACSA would recommend that you either deregister your company (or stay de-registered if you have already done so), and delist your product and deactivate your labeler code. The latest instructions from the FDA are as follows (in order):

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 Reporting"
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 (or a date that you anticipate clearing out remaining stock)

8. Click on “Save Product”
    - 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”

CASE #2: “Our company would like to continue making sanitizer for our community for sale or donation throughout the pandemic, **or** we still have

sanitizer to be bottled, and raw ingredients and packaging to use up making sanitizer before we can deregister our company."

In this case, ACSA would recommend that your company either remain registered - doing nothing or re-register if you have already deregistered (also relist your product and reactivate your labeler code, if you have done either of these steps).

The HHS ruling means that you are free to continue making sanitizer throughout the course of the pandemic and you will NOT be subject to the OTC Monograph facility fees. Once the Public Health Emergency has been discontinued, you will have *at least* 12 months (*December 31st of the following year*) to transition away from the business and deregister before fees will be assessed.

CASE #3: "Our company has made substantial investment into the sanitizer operation and long-term supply contracts. Moving away from production would inflict long-term financial harm on us. That being said, a $14,000 fee is prohibitive and disproportionate to our size."

During the course of the Public Health Emergency, your company can continue just as you have been without incurring any fee. ACSA will continue to engage with HHS and FDA officials in the incoming administration to advocate for reasonable FDA fees after the US government declares the public health crisis terminated. We will continue to advocate for fairness and predictability for our small businesses. We recognize that this country needs domestic production of sanitizer and it should support domestic small businesses who can accommodate that need.

TTB: TTB has **extended its authorizations** allowing the production of hand sanitizer under a nonindustrial permit and without formula approval through June 30, 2021. This applies only to DSPs producing sanitizer strictly in accordance with the FDA temporary guidance.

DOT: The special rules for shipping of hand sanitizer expired on 10/31/20, and distilleries are now required to have employees fully trained in all applicable **transportation HAZMAT regulations** regarding the shipping of hand sanitizer. Hand sanitizer manufactured and packaged prior to that date may still be shipped to end users under the former guidance until March 31, 2021.