DISTILLED SPIRITS COUNCIL
OF THE UNITED STATES

FDA Sanitizer Over-The-Counter Monograph User Fee Program FAQs

I'm a distiller who temporarily produced hand sanitizer in 2020 in response to the pandemic, does the OTC Monograph User Program facility fee apply to me?

- No, the Department of Health and Human Services (HHS) has clarified "that persons that entered the over-the-counter drug market to supply hand sanitizer products in response to the COVID-19 Public Health Emergency are not subject to the facility fee the Secretary is authorized to collect under section 744M of the Food, Drug, and Cosmetic Act (FD&C Act)."

- The FDA Over-The-Counter Monograph User Fee Program facility fees ("OTC fee") were originally set to apply to distilleries that manufactured or processed hand sanitizer products under the FDA temporary policies during the COVID-19 pandemic. However, due to the advocacy efforts of DISCUS and others in the industry, HHS has since determined that persons who entered the over-the-counter drug market to supply hand sanitizer products in response to the COVID-19 public health emergency are **not subject to the facility fees** the Secretary is authorized to collect under section 744M of the Food, Drug, and Cosmetic Act (FD&C Act). As explained further in this pre-publication Federal Register notice, HHS is declining to identify these entities as OTC drug manufacturing facilities since "distilleries are not primarily in the drug manufacturing business" and "imposing facility fees on these entities is inconsistent with Congress' stated intent elsewhere in the CARES Act."

Is there an expiration date or any other limitations to the HHS exception to the OTC fee?

- This exception from the OTC fees does not apply to those "that (1) manufacture, distribute, and sell over-the-counter drugs in addition to hand sanitizer or (2) continue to manufacture (as opposed to hold, distribute, or sell existing inventories) hand sanitizer products as of December 31 of the year immediately following the year during which the COVID-19 Public Health Emergency is terminated. In those cases, the Department may identify such persons as OTC drug manufacturing facilities." Thus, if the public health emergency is declared to be over at some point in 2021, distilleries would be exempted from paying these facility fees through December 31, 2022.

Can I still continue to make and sell hand sanitizer in 2021?

- Yes, distilleries are still allowed to produce hand sanitizer for the duration of the public health emergency per FDA's temporary policies (*Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency*

** Disclaimer: Nothing in this document constitutes legal advice. We recommend that you consult with your attorney and the FDA directly with any questions about your specific business considerations.*

(COVID-19) Guidance for Industry and *Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry*). Your facility must be registered with FDA, as outlined in those policies, to continue producing hand sanitizer to assist with the COVID-19 pandemic.

I de-registered my facility to avoid incurring the 2022 OTC facility fee, do I need to re-register?

- If you de-registered your facility to avoid the fee prior to the exemption and wish to continue producing hand sanitizer according to the temporary policies, you should re-register before you restart any production activities. FDA should not require the OTC drug facility fee per the HHS Notice outlined above.

I produced hand sanitizer in 2020 but do not expect to continue production into 2021. I currently have some sanitizer stock remaining that I would like to deplete either through donation or sale. Do I need to renew our registration to deplete this stock or should I de-register the facility?

- If you are no longer manufacturing hand sanitizer and do not expect to continue production, you should deregister your establishment and can continue to distribute the product previously produced. FDA eDRLS Staff has provided the following instructions in that regard:

> If you are no longer manufacturing the hand sanitizer, you should deregister the establishment. You can include a future end marketing date (date you expect the inventory to finish) for the products you are still distributing to properly delist to those products.
>
> Please see the following link to our webpage with instructions on the registration and listing process, which includes information on deregistration.
>
> https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-drug-registration-and-listing-instruction
>
> In order to properly delist the products you are still marketing, you can follow the section on "Updates to listing" and include future end marketing dates in the listing SPLs (at the step where you need to modify the listing data elements).
>
> Please refer to 21 CFR 207 for the requirements regarding reviewing, updating and the deadlines for registration and listing information.

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Who should I contact with specific questions about my registration or practices?

- If you have further questions about your specific registration or practices, please reach out to edrls@fda.hhs.gov, CDERCollections@fda.hhs.gov or call 301-796-7900.

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