Most Distilleries That Registered to Produce Hand Sanitizer After January 27, 2020 Will Be Exempt from FDA Fees

The US Food and Drug Administration (FDA) published an announcement in the Federal Register on March 26, 2021, that exempts distilleries from an Over-the-Counter Monograph Drug User Fee Assessment (OMUFA) if they registered to produce hand sanitizer after January 27, 2020.

Any spirits producers who registered to make hand sanitizer after that date will not be assessed a fee, provided that those distillers produced sanitizer in accordance with the parameters of the agency's emergency guidance.

On March 27, 2020, new provisions were added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which authorize FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OTC monograph order requests. According to the FDA's published notice:

> *FDA will not assess OMUFA facility fees upon those firms that first registered with FDA on or after the January 27, 2020 declaration of the COVID-19 Public Health Emergency (PHE),[9] solely for purposes of manufacturing hand sanitizer products [10] during the PHE. We note, however, that under the FD&C Act, whether an entity is subject to OMUFA fees has no bearing on whether the entity or the entity's products are subject to other requirements under the FD&C Act. FDA will continue to use its regulatory compliance and enforcement tools to protect consumers, including from potentially dangerous or subpotent hand sanitizers.*
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> *In addition, FDA will not assess a facility fee if the identified OTC monograph drug facility: (1) Has ceased all activities related to OTC monograph drugs prior to December 31 of the year immediately preceding the applicable fiscal year and (2) has updated its eDRLS registration to reflect that change (per section 744M(a)(1)(B)(i) of the FD&C Act). As the applicable fiscal year for fee-setting under this notice is FY 2021, the year immediately preceding the applicable fiscal year is FY 2020. December 31 of FY 2020 is December 31, 2019. Thus, FDA will not assess a FY 2021 facility fee with respect to an*

OTC monograph drug facility that, prior to December 31, 2019, had ceased all activities related to OTC monograph drugs and updated its eDRLS registration to that effect.

Details, and the full text of the FDA's March 26th notice in the Federal Register are accessible online at: https://www.federalregister.gov/documents/2021/03/26/2021-06361/fee-rates-under-the-over-the-counter-monograph-drug-user-fee-program-for-fiscal-year-2021

For more information, contact GrayRobinson's Nationwide Alcohol Industry Team.