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Locke Lord QuickStudy: Case Closed: Facilities That Manufactured Hand Sanitizers During the Pandemic Will Not Be Charged User Fees

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On January 12, 2021, the Department of Health and Human Services issued yet another Federal Register notice announcing that Persons that Entered the Over the Counter drug market to supply hand sanitizers during the COVID-19 Public Health Emergency will not be subject to the over the counter Monograph Drug Facility fees. However, as noted in HHS's notice, this exception does not apply to such entities which (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.

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