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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. FDA–2020–N–2246

Notice that Persons that Entered the Over-the-Counter Drug Market to Supply Hand Sanitizer During the COVID-19 Public Health Emergency are not Subject to the Over-the-Counter Drug Monograph Facility Fee

AGENCY: Department of Health and Human Services (HHS), Food and Drug Administration (FDA).

ACTION: Notice

SUMMARY: The Department of Health and Human Services is issuing this Notice to clarify that persons that entered into the over-the-counter drug industry for the first time in order to supply hand sanitizers during the COVID-19 Public Health Emergency are not persons subject to the facility fee the Secretary is authorized to collect under section 744M of the Food, Drug, and Cosmetic Act.

DATES: This Notice is effective (INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER).

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402 4585.

SUPPLEMENTARY INFORMATION:

On December 29, 2020, FDA published a Notice in the **Federal Register** entitled *Fee Rates Under the Over-the-Counter Monograph User Fee Program for Fiscal Year 2021*. 85 FR 85646. The Department since withdrew that Notice because it was not approved by the Secretary. For the reasons provided below, the Department is clarifying 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).

In March 2020, FDA issued a temporary policy to enable increased production of alcohol-based hand sanitizers.[1] The agency acknowledged "that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers," and that some were relying on home-made hand sanitizers as a result.[2] FDA issued the guidance in response to requests from "certain entities that are not currently regulated by FDA as drug manufacturers" that nevertheless rose up to meet this public health need.[3] FDA stated it "does not intend to take action against firms that" produce hand sanitizer products during the COVID-19 Public Health Emergency, provided the firm's activities are consistent with the guidance.[4]

The guidance, which FDA amended after the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), Pub. L. No. 116-136, 134 Stat. 281 (March 27, 2020) became law, contains no mention of user or facility fees. FDA's website on Hand Sanitizers and COVID-19, contains a sub-bullet under the link to the guidance announcing that "the facility fee applies to all

[1] FDA, Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry (Mar. 2020; updated Aug. 7, 2020).
[2] *Id.* at 3.
[3] *Id.*
[4] *Id.*

OTC hand sanitizer manufacturers registered with FDA, including facilities that manufacture or process hand sanitizer products under this temporary policy," but that language was added about the same time as the aforementioned withdrawn Notice was published in the **Federal Register**.[5] Entities that began producing hand sanitizers in reliance on the guidance were understandably surprised when FDA contacted them to collect an establishment fee in excess of $14,000.[6]

FDA's purported authority for these facility fees comes from the CARES Act. In section 3862 of the CARES Act, Congress provided the Secretary with the authority to assess user and facility fees from "each person that owns a facility identified as an OTC drug monograph facility on December 31 of the fiscal year or at any time during the preceding 12-month period." FD&C Act 744M(a)(1)(A), 21 U.S.C. 379j-72(a)(1)(A). An "OTC drug monograph facility" is defined, in relevant part, as "a foreign or domestic business or other entity that is under one management, either direct or indirect; and at one geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug." FD&C Act 744L(10)(A)(i)(I)-(II), 21 U.S.C. 379j-71(10)(A)(i)(I)-(II).

The Department has concluded that persons that entered the over-the-counter drug market in order to produce hand sanitizers in reliance on the guidance cited above are not "identified as . . . OTC drug monograph facilit[ies]" and are thus not subject to the facility fees authorized under section 744M of the FD&CT Act, 21 U.S.C. 379j-72. The Department reached this conclusion for two reasons. First, as the guidance itself acknowledges, the parties at issue are not in the drug manufacturing business. Many of them produce alcoholic beverages. These

[5] An archived version of the website shows the language at issue was not on the website as late as December 29, 2020. See: https://web.archive.org/web/20201229105739/https://www.fda.gov/drugs/coronavirus-covid-19-drugs/hand-sanitizers-covid-19.

[6] This surprise, coupled with the guidance's silence on facility fees, raises reliance interests concerns under the Supreme Court's decision in *Department of Homeland Security v. Regents of the University of California*, 140 S. Ct. 1891 (2020)

entities do not hold themselves out to the public as drug makers nor does the public generally encounter them as such. Under the extraordinary circumstances presented by the COVID-19 pandemic, the Department declines to identify these entities as OTC drug manufacturing facilities.

Second, imposing facility fees on these entities is inconsistent with Congress' stated intent elsewhere in the CARES Act. Section 2308 of the Act provides a temporary exemption from excise taxes for distilled spirits "use[d] in or contained in hand sanitizer produced and distributed in a manner consistent with any guidance issued by the Food and Drug Administration that is related to the outbreak of virus SARS–CoV–2 or coronavirus disease 2019 (COVID–19)." It is unlikely Congress intended to save these entities from excise taxes only to impose tens of thousands of dollars in facility fees from an unfamiliar regulator. The Department declines to discern such a design under these circumstances.

In conclusion, the Department clarifies that persons that were not registered with FDA as drug manufacturers prior to the COVID-19 Public Health Emergency, which then later registered with FDA for the purpose of producing hand sanitizers, are not "identified" as "OTC drug manufacturing facilit[ies]" under section 744M of the FD&C Act, 21 U.S.C. 379j-72, and are thus not subject to the facility fee contained therein. The Department's conclusion does not apply to such persons 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. In those cases, the Department may identify such persons as OTC drug manufacturing facilities.

Dated: January 05, 2021.

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.