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Client Alert

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FDA Establishes – And HHS Immediately Withdraws – New OTC Drug User Fee Rates

UPDATE: On January 12, 2021, the Department of Health and Human Services ("HHS") published notice that persons who entered the over-the-counter ("OTC") drug market to produce hand sanitizers in reliance on the Food and Drug Administration's Temporary Guidance during the COVID-19 Public Health Emergency are not subject to the OTC drug monograph facility fees. However, OTC fees may apply if a person (1) manufactures, distributes, and sells OTC drugs in addition to hand sanitizer or (2) continues 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. *See* 86 Fed. Reg. 2420 (Jan. 12, 2021).

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Important Questions Remain about Scope and Status

Last week, on December 29, 2020, the Food and Drug Administration ("FDA") published a notice setting the amount of new annual facility fees for both for over-the-counter ("OTC") monograph drug product manufacturers and for OTC monograph drug product contract manufacturing organizations ("CMOs"). The annual facility fee for OTC monograph drug manufacturers – the so-called Monograph Drug Facility ("MDF") fee – was set at $14,060,[1] and the annual facility fee for CMOs was set at $9,373.[2] According to the notice, for FY 2021, facility fees would have come due February 12, 2021.[3]

However, just two days later, on December 31, 2020, the Department of Health and Human Services ("HHS") withdrew the FDA notice and directed FDA to cease enforcement of the OTC user fees[4] -- at least for the time being. HHS' action responded to criticism that fees would apply to OTC hand sanitizer manufacturers operating under FDA's "Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)" (the "Temporary

Policy").[5,6] Many of those manufacturers are "small businesses who stepped up to fight COVID," and HHS specifically acknowledged the distilleries.[7] Coupling HHS' withdrawal notice and the recently-added statutory requirement for OTC monograph user fees, the status and scope of the MDF and CMO fees is presently unclear. There may be near-term opportunity for input.

I. OVERVIEW OF THE OTC MONOGRAPH DRUG USER FEE PROGRAM ("OMUFA")

Congress established new user fees to fund FDA activities related to the OTC monograph drug review, as part of the "Coronavirus Aid, Relief, and Economic Security Act" ("CARES Act").[8] As we discussed in a client alert last spring, in addition to establishing OTC user fees, the CARES Act significantly reformed FDA's OTC drug review process.[9] The new user fees consist of (1) an annual facility fee for both finished drug manufacturers and CMOs, and (2) OTC monograph order request fees.[10] FDA refers to the OTC Monograph Drug user fee program as "OMUFA."[11]

A. Annual Facility Fees

Under the legislation, Congress authorized FDA to set an annual facility fee beginning with FY 2021.[12] As noted, FDA set the MDF fee at $14,060. Congress prescribed that the "amount of the fee for a contract manufacturing organization facility shall be equal to two-thirds of the amount of the fee for an OTC monograph drug facility." Accordingly, under the statute, the annual fee for CMOs was set at $9,373.[13]

An "OTC monograph drug facility" is a foreign or domestic business that is "engaged in manufacturing or processing the finished dosage form of an OTC monograph drug" at one geographic location and under one management.[14] Separate buildings may be considered a single OTC monograph drug facility if, among other things, the buildings are "under a single FDA establishment identifier and capable of being inspected by the Food and Drug Administration during a single inspection."[15] Under the statute, a CMO is "an OTC monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States."[16]

For FY 2021, facility fees were set to be due 45 days after publication of the notice, which (based on the December 29, 2020 publication date) would have been February 12, 2021.[17] Going forward, annual facility fees will be due on the first business day of June.[18] Failure to pay the facility fee within 20 days after the due date causes all the drugs manufactured by the facility to be deemed misbranded.[19]

B. OTC Monograph Order Request Fees

An OTC monograph order request ("OMOR") is an industry-initiated request submitted to FDA for an administrative order (1) stating that a drug or therapeutic class of drugs (e.g., antacids, antiperspirants, cough-cold remedies) is generally recognized as safe ("GRASE"), is not required to have an approved new drug application ("NDA") or abbreviated new drug application ("ANDA"), and may be sold OTC, and (2) providing the requirements for the manufacturing and marketing of the drug or class of drugs.[20] Fee amounts for industry-initiated OMORs were not affected by the December 29, 2020 Federal Register notice that established the OMUFA annual facility fees. Rather, the fees for industry-initiated OMORs were established by Congress in March 2020 when the CARES Act was enacted as follows:

- $500,000 for Tier 1 OMORs.
- $100,000 for Tier 2 OMORs.[21] Going forward, these amounts will be adjusted for inflation.[22]

By contrast, user fees for NDAs currently range from $1,437,921 to $2,875,842 (depending on whether clinical data is contained in the application),[23] and the user fee for an ANDA is $196,868.[24]

A Tier 2 OMOR is a request for a minor change to an OTC monograph. Tier 2 OMORs include requests:

- to reorder existing information in the Drug Facts label;
- to add information to the "Other information" section of the Drug Facts label;
- to modify the "Directions for use" section of the Drug Facts label to conform to a minor change to the drug formulation permitted under FD&C Act § 505G(c);
- to standardize the concentration or dose of a specific finalized ingredient within a particular monograph;
- to change ingredient nomenclature to align with nomenclature of a standards-setting organization; or
- to add an interchangeable term for the label.[25]

A Tier 1 OMOR is any request that is not a Tier 2 request.[26]

OMOR fees are due at the time the OMOR is submitted.[27] If, however, the request is submitted for the purpose of adding or strengthening safety labeling—i.e., a contraindication, warning, or precaution; a statement about risk associated with misuse or abuse; or an instruction about dosage and administration that is intended to increase the safe use of the OTC drug—then no fee is required.[28]

II. STATUS OF THE USER FEE NOTICE AND IMPLICATIONS

Immediately after FDA announced the FY 2021 MDF and CMO facility fees, alcohol distillers that have been manufacturing OTC hand sanitizer under FDA's Temporary Policy objected that the fees were both unexpected and unfair, considering the public health emergency underlying their manufacture of hand sanitizers. A statement released by the Distilled Spirits Council quoted the HHS Chief of Staff as responding:

- "In the [Temporary Policy], the 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. Importantly, the guidance contains no discussion regarding user fees or any indication such fees would be due by these entities, many of which would be entering the drug manufacturing business for the first time."
- "This action was not cleared by HHS leadership, who only learned of it through media reports late yesterday. HHS leadership convened an emergency meeting late last night to discuss the matter and requested an immediate legal review. The HHS Office of the General Counsel (OGC) has reviewed the matter and determined that the manner in which the fees were announced and issued has the force and effect of a legislative rule. Only the HHS Secretary has the authority to issue legislative rules, and he would never have authorized such an action during a time in which the Department is maximizing its regulatory flexibility to empower Americans to confront and defeat COVID-19. Because HHS OGC has determined the notice is really a legislative rule and that no one at FDA has been delegated authority to issue such a rule, the notice is void. HHS leadership, based on this legal opinion, has ordered the Federal Register Notice to be withdrawn from the Federal Register, meaning these surprise user fees will not need to be paid."
- "Small businesses who stepped up to fight COVID-19 should be applauded by their government, not taxed for doing so. I'm pleased to announce we have directed FDA to cease enforcement of these arbitrary, surprise user fees. Happy New Year, distilleries, and cheers to you for helping keep us safe!"[29]

This afternoon, on January 4, 2021, HHS posted a Federal Register notice withdrawing FDA's December 29, 2020 statement of facility fees under the OMUFA program for FY 2021. HHS stated:

> FDA lacked the delegated authority to issue the Notice. … The Department is further informing the public that FDA has been ordered to cease further collection efforts related to the Over-the-Counter Drug Monograph User Fee Program until further action is announced in the Federal Register. … FDA has also been ordered to cease collections activities related to the Over-the-Counter Monograph User Fee Program ("OMUFA") until, with the approval of the Secretary, the Department issues further direction concerning FDA's administration of OMUFA which provides the public with notice and opportunity for comment.[30]

Given both the HHS notice and the anticipated January 2021 change of Presidential administration, the future of OMUFA is uncertain. King & Spalding will, however, continue to follow the issues and the implications for various types of drug manufacturers or sponsors. For example, although HHS focused on distillers who have manufactured hand sanitizer, additional types of companies also entered the hand sanitizer market under FDA's Temporary Policy.

Furthermore, today's notice of user fee withdrawal impacts all categories of OTC monograph drugs, not only hand sanitizers. If attempts are made to carve out products manufactured under the Temporary Policy, then other producers of OTC drug products could raise questions about any inconsistent application of the law that is not aligned with the statute. At a minimum, FDA may need to clarify its position about the legal authority under which specific OTC hand sanitizer products are marketed (e.g., OTC monograph vs. individualized finding of safety and effectiveness of the formulation at issue).[31]

Please let us know if you have questions concerning the OMUFA user fees, OTC monographs, or other matters impacted by FDA's new framework for regulating OTC drug products. We are well-positioned to advocate on these complex issues involving approval, manufacturing, and distribution requirements and policy.

[1] *See* FDA, Notice, *Fee Rates Under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021*, 85 Fed. Reg. 85,646 (Dec. 29, 2020) [hereinafter "*OTC User Fees Notice*"].

[2] *See id.*; *see also* Federal Food, Drug, and Cosmetic Act ("FD&C Act") § 744M(a)(1)-(2).
[3] *See OTC User Fees Notice*, 85 Fed. Reg. at 85,646.
[4] *See* Document Number 2021-00030 (filed Jan. 4, 2021; to be published in Federal Register dated Jan. 6, 2021), *available at* https://www.federalregister.gov/public-inspection/2021-00030/fee-rates-under-the-over-the-counter-monograph-drug-user-fee-program-for-fiscal-year-2021-withdrawal.
[5] *See* FDA, Guidance for Industry, *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)* (updated Aug. 7, 2020).
[6] *See* Distilled Spirits Council, *Struggling Distillers Hit With Surprise $14,000 FDA Fee For Producing Hand Sanitizer During Pandemic* (Dec. 31, 2020).
[7] *See* https://twitter.com/SpoxHHS/status/1344782160084037639.
[8] *See* CARES Act, Pub. L. 116-136, § 3862 (enacted Mar. 27, 2020).
[9] *See* K. Sampson, C. Markus & L. Dwyer, Client Alert, *Congress Enacts OTC Monograph Reform* (Apr. 30, 2020).
[10] *See* FD&C Act § 744M(a)(1)-(2).
[11] *See OTC User Fees Notice*, 85 Fed. Reg. at 85,646.
[12] *See* FD&C Act § 744M(c)(4)(A).
[13] *See id.* § 744M(a)(1)(B)(ii).
[14] *Id.* § 744L(10)(A).
[15] *Id.* § 744L(10)(B)(iii).
[16] *Id.* § 744L(2).
[17] *See OTC User Fees Notice*, 85 Fed. Reg. at 85,646.
[18] *See* FD&C Act § 744M(a)(1)(D).
[19] *See id.* § 744M(e).
[20] *See id.* § 505G(b)(5).
[21] *See id.* § 744M(a)(2)(A)(i)-(ii).
[22] *See id.*
[23] *See* FDA, *Prescription Drug User Fee Amendments* (updated Sep. 14, 2020).
[24] *See* FDA, *Generic Drug User Fee Amendments* (updated Dec. 7, 2020).
[25] *See* FD&C Act § 744L(9).
[26] *See id.* § 744L(8).
[27] *See id.* § 744M(a)(2)(B).
[28] *See id.* § 744M(a)(2)(C).
[29] *See* Distilled Spirits Council, *Distilled Spirits Council President Chris Swonger Statement Regarding HHS' Swift Action to Halt FDA Fees for Distillers Producing Hand Sanitizer During the Pandemic* (Jan. 1, 2021).
[30] *See* n.4, *supra*.
[31] In "standardized hand sanitizer listing templates" published during 2020, FDA advised companies to select the marketing category "OTC monograph not final."