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Locke Lord QuickStudy: HHS Withdraws FDA's "Arbitrary, Surprise" OTC User Fee and ?Proposals for FY 2021?

Locke Lord LLP

WRITTEN BY

Sharon A. Blinkoff | Wasim K. Bleibel

As is typical with the FDA, the Agency chose the end of the year to publish the fees it intended to ?collect from over-the-counter (OTC) monograph drug manufacturers under the OTC Monograph User ?Fee Act (OMUFA). In its notice, FDA would assess annual Facility Fees for two types of OTC drug ?manufacturers: 1) Monograph Drug Facility (MDF)? [1]? and 2) Contract Manufacturing Organization ??(CMO)[2]??. ?

The MDF Facility Fee was set at $14,060 and the Facility Fee for CMOs was set at $9,373. In addition to the Facility Fees, the notice covered the OTC monograph order request fees for Monograph modifications of $100,000 for a tier 1 application and $500,000 for a tier II application. FDA also announced that it would commence levying the Fees 45 days from the issuance of the December 29 Federal Register notice, and these Fees would apply to any company that were listed in the FDA's OTC database after December 31, 2019.

After OMUFA was established, certain companies understood that fees were on the horizon, however, other companies did not. In particular, distilleries and other companies that stepped up during the early stages of the pandemic and went from producing distilled spirits to producing much-needed hand sanitizer, a monograph product, would now be subject to the payment of these newly-established Facility Fees. FDA's move went viral and within just two days, Brian Harrison, HHS Chief of Staff, tweeted that, "Small businesses who stepped up to fight COVID-19 should be applauded by their government, not taxed for doing so" and that HHS had "directed FDA to cease enforcement of these arbitrary, surprise user fees." Then again, on January 5, 2021, Brian Harrison issued another statement through Twitter stating that "HHS remains firmly committed to protecting small businesses who joined the fight against COVID-19, and tonight we are issuing a notice to further protect distilleries from unfair regulation and fees for as long as we are in this emergency."

On January 6, 2021, HHS, published a notice withdrawing the December 29 FDA OTC User Fee, ordering the FDA to "cease further collection efforts related to the [OTC] Monograph User Fee program until further action is announced in the Federal Register." The Secretary announced this action on the basis that the FDA's action was not authorized by the Secretary and directed that no further action be taken until, with the approval of the Secretary, the Department issues further direction concerning FDA's administration of the OMUFA fee proposal which provides the public with notice and an opportunity for comment.

The question of how quickly the New Secretary of HHS will act on this once the new Administration is in place remains to be seen. Hopefully those companies that stepped up and who joined the fight against COVID-19 will

have sufficient time to withdraw their registrations so they are not taxed retroactively with the User Fees. As these fees are an essential part of the newly reformed program, it is only a matter of time for a new notice to be issued. However, as required by Secretary Azar, interested parties will have an opportunity to comment on FDA's new proposal.

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1. MDF facility is an OTC monograph drug facility is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug.
2. CMO facility is an OTC MDF where neither the owner or affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

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