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Locke Lord QuickStudy: FDA Announcement on User Fees for the Over-the-Counter (OTC) Drug Program for FY 2021?

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On March 26, 2021, the FDA announced it will collect OTC user fees for Fiscal Year 2021 from owners of OTC Monograph Facilities that were in operation for the period from January 2020 through December 2020. As we previously reported here and here, and confirmed in today's notice, facilities that responded to the COVID-19 Public Health Emergency by producing hand sanitizers under the Emergency Use Authorizations (EUA) will be exempt from paying User fees. Manufacturers of active drug ingredients are also exempt from paying user fees.

User Fees are Due Monday, May 10, 2021[1]

The Federal Register notice announcing collection of the FY OTC User fees highlighted the sections of the OTC Reform bill that define Monograph Facilities that are required to pay user fees:

- An OTC monograph drug facility (MDF) 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 (see section 744L(10) of the FD&C Act);
- A contract manufacturing organization (CMO) facility is an OTC monograph drug facility where neither the owner nor any 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 (see section 744L(2) of the FD&C Act); and
- Fees due from MDF's are $20,322 for FY 2021
- Fees due from CMO's are $13,548 for FY 2021

The FDA's User Fee announcement can be found here. Note there is no reduction for small businesses. Users will be identified based upon FDA's OTC registration and listing data basis.

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1 FDA's Notice states that the facility fees will be due 45 days after the date of publication of this notice.

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