Timeline for Implementation of OTC Monograph Reform Fees

Assumptions:

1. If S. 2740 as passed by the Senate on December 10, 2019, passes the House of Representatives without further changes, the law is effective on enactment, i.e., during FY2020, which started October 1, 2019. User fees would be collected in FY2020 to cover FY2021 activities.
2. Note if the House were to pass the bill after March 9, 2020, amendments to adjust user fee dates will be needed in the bill.
3. Fiscal years covered by the bill as passed by the Senate are 2021-25.
4. Effective date is the date the bill is signed into law by the President.
5. No other regulations needed for implementation.
6. No statutory changes to S. 2740. If there are changes, the Senate would have to concur.

Timeline:

Dec 31, 2019  Retroactive date for facilities subject to monograph drug facility fee requirement. In future years, facility fees will be assessed on monograph facilities with activities as of December 31 or at any time in the preceding year unless the facility has ceased all monograph activities and updated its facility registration before December 30. In future years, FDA anticipates publishing a notice for firms to audit/amend facility registrations ahead of the deadline date.

Mar 9, 2020  FDA to publish facility fee amount. For future years, FDA will set and publish the facility fee for that fiscal year by the second Monday in March. (See second assumption above.)

June 1, 2020  Facility fees are due the later of June 1, 2020, or 45 days after FDA publishes a notice on the fee amount (or, in years after FY2021, the first business day after enactment of appropriations authority). Fees are due ahead of the upcoming fiscal year.

June 21, 2020 at earliest  20 calendar days after 2020 due date, FDA posts a public arrears list for facilities failing to pay. Same in future years. OTC monograph drugs manufactured in such facility will be deemed misbranded. OTC monograph drug order requests submitted by a sponsor or requestor not paying fees will be considered incomplete, and ineligible for closed meetings.
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Feb 1, 2022  FDA publishes first report to Congress on implementation of their fee authority, fee uses and collections