Timeline for Implementation of OTC Monograph Reform Fees in S.2740, as introduced October 30, 2019, and favorably reported by Senate HELP Committee, October 31, 2019

Assumptions:

1. If S. 2740 as introduced and favorably reported by the Senate HELP Committee passes the Senate and House without further changes, the law is effective on enactment, i.e., during FY2020, which started October 1, 2019. Any changes in dates would need to pass both houses.
2. Fiscal years covered by the bill 2021-2025
3. Effective date is the date the bill is signed into law by the President
4. No other regulations needed for implementation

FDA fee publication dates are set by statute. FY2021 payment due dates are based on the later of June 1, 2020, as set by statute, or FDA publication.

Timeline:

Dec 31, 2019	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 31. 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, payable in 2020 for fiscal year 2021 (October 1, 2020 – September 30, 2021). For future years, FDA will set and publish the facility fee for the upcoming fiscal year by the second Monday in March.
Later of 45 days or June 1	The later of 45 days after FDA publication or the first business day of June, FY 2021 fees are due. For future years, fees are due the later of June 1 or the first business day after enactment of an appropriations Act providing for collection.
+20 days	20 days after due date, FDA posts a public arrears list for failure to pay. 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 parties are ineligible for closed meetings.
Feb 1	FDA to publish reports to Congress on performance and implementation of their fee authority, fee uses and collections