

Timeline for Implementation of OTC Monograph Reform Fees in H.R. 269, as passed by the House of Representatives, January 8, 2019

Assumptions:

1. If HR 269 as passed by the House on January 8, 2019, passes the Senate without further changes, the law is effective on enactment, i.e., during FY2019, which started October 1, 2018. Any changes in dates by Senate would need to be agreed to by the House.
2. Fiscal years covered by the bill as passed by the House are 2019-2023
3. Effective date is the date the bill is signed into law by the President
4. No other regulations needed for implementation
5. FDA fee publication dates are set by statute. FY2019 payment due dates are based on FDA publication, not a date set by statute

Timeline:

Jan 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 31. In future years, FDA anticipates publishing a notice for firms to audit/amend facility registrations ahead of the deadline date.
Mar 11, 2019	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.
+45 days	45 days after publication, 2019 fees are due. For future years, fees are due on June 1 or the first business day after enactment of an appropriations Act providing for collection.
+20 days	20 days after 2019 due date, FDA posts a public arrears list for failure to pay. Same in future years. OTC monograph drugs manufactured in such facility will be deemed misbranded. Nonprescription monograph drug order requests submitted by a sponsor or requestor not paying fees will be considered incomplete, and ineligible for closed meetings.
Feb 1, 2020	FDA publishes first report to Congress on implementation of their fee authority, fee uses and collections