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07 Mar 2016 | **Analysis**

User Fee Goal Dates

by

Estimated FDA review deadlines for pending applications. Updated weekly.

Under PDUFA V, FDA is expected to act on applications for novel agents – new molecular and biologic entities – within 12 months of receipt under standard review and eight months under priority review, thanks to a two-month filing period added to the review goals for NMEs and NBEs. The review timeline remains 10 months for standard and six months for priority review for earlier applications and for non-novel submissions, like new formulations and delivery methods or new indications. Resubmissions with significant new data or analyses have a six-month goal. FDA may extend review timelines by three months for major amendments.

Click on column headers to sort the data by parameters like sponsor or therapeutic category. To see new submissions, sort by Date Received. To see upcoming goals for FDA action, sort by Goal Date.

The search box can be used to filter results. To see only products that aren't yet approved, enter *pending* in in the search box. Products with an asterisk (*) are new molecular or biological entities; to restrict the results to NMEs and novel biologics enter an * in the search box.

The chart lists applications with user fee goals in the future and tracks recent FDA actions. To preserve the forward-looking focus of the User Fee Goals chart, a new chart has been added at the bottom for User Fee Goals In 2015 And Earlier. This chart retains all the information that was gathered by the FDA Performance Tracker on approved products as well as ones with missed goal dates; applications that are understood still to be under active review will continue to be tracked on the main User Fee Goals chart.

Click here to see full-screen version of the User Fee Goal Dates chart

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Click here for full-screen view of the User Fee Goals In 2015 And Earlier Missed Goals chart

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Keep up with chart updates or search anytime at our *FDA Performance Tracker homepage*.