

Industry Notification: Furlough

Oct. 1, 2013

In the absence of either an FY 2014 appropriation or a Continuing Resolution for FDA, beginning on October 1 and continuing until the date of enactment of an FY 2014 appropriation or Continuing Resolution ("lapse period"), agency operations will be limited to the following:

- Emergency work involving the safety of human life or the protection of property;
- Criminal law enforcement work; and
- Activities funded by carryover user fee balances, including user fee balances under the Prescription Drug User Fee Act (PDUFA), Generic Drug User Fee Amendments (GDUFA), Medical Device User Fee Amendments (MDUFA), Animal Drug User Fee Act (ADUFA), Animal Generic Drug User Fee Act (AGDUFA), and Family Smoking Prevention and Tobacco Control Act. Carryover user fee balances will only be spent on activities for which the fees are authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

With respect to medical product user fees, during the lapse period, FDA will not have legal authority to accept user fees assessed for FY 2014 until an FY 2014 appropriation for FDA is enacted. This will mean that FDA will not be able to accept any regulatory submissions for FY 2014 that require a fee payment and that are submitted during the lapse period.