Drug firms face ANDA blues

The delay in approval of generic drug applications, which has been slowly declining annually, witnessed its lowest run rate in the first half of fiscal 2015 (which is defined by the US Food and Drug Administration as year ending October 30). Data collated by JPMorgan analysts shows that average approvals based on cumulative applications has dropped from 51% in fiscal 2013 to 47% in fiscal 2014 and is now hovering at 23%, reports Pallavi Ahir in Mumbai. The regulator had introduced the GIDERA programme in 2012, specifically to accelerate the number of pending drug approvals and is hoped to achieve this by increasing number of drug reviewers and imposing a user fee on the applicants.

Continued on Page 2