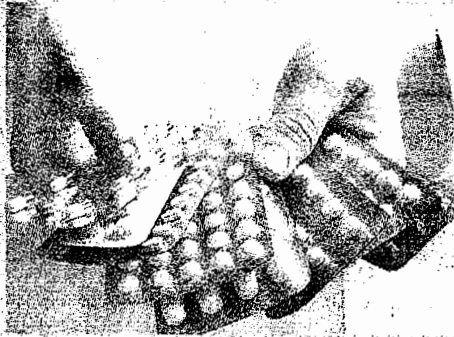


Drug firms face ANDA blues



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 61% in fiscal 2005 to 47% in fiscal 2012 and is now hovering at 28%, reports Pallavi Ail in Mumbai.

The regulator had introduced the GDUFA programme in 2012, specifically to accelerate the number of pending drug approvals and it hoped to achieve this by increasing number of drug reviewers and imposing a user fee on the applicants.

■ **Continued on Page 2**

Global generic drug applications & approvals

| | FY01 | FY05 | FY10 | FY11 | FY12 | FY13 | FY14 |
|------------------------------------|------|------|------|------|------|------|-------|
| ANDAs submitted | 307 | 766 | 813 | 893 | 1103 | 968 | 1,473 |
| Approvals (incl. tentative) | 310 | 467 | 426 | 458 | 517 | 440 | 406 |
| % approvals | 101% | 61% | 52% | 51% | 47% | 45% | 28% |

*FY means year ending October 30

Source: JPMorgan

ANDA filing run-rate has picked up over the last two years, but approvals remain tepid

| | FY10 | FY11 | FY12 | FY13 | FY14 | H1 FY15 |
|-------------------|------|------|------|------|------|---------|
| Dr Reddy's | 14 | 7 | 17 | 19 | 13 | 11 |
| Sun Pharma | 30 | 28 | 22 | 13 | 29 | 15 |
| Lupin | 37 | 21 | 25 | 21 | 20 | 8 |
| Glenmark | 13 | 13 | 12 | 18 | 20 | 11 |
| Cadila | 14 | 24 | 21 | 25 | 50 | 23 |
| Aurobindo | 13 | 24 | 30 | 34 | 78 | 42 |

Source: Company reports

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