

Indian firms get FDA approval for 110 generic drugs

16 September 2013 | News | By BioSpectrum Bureau



Singapore: India pharmaceutical companies have yet again emerged as the biggest overseas sources of medicines sold in the US, according to data from the US Food and Drug Administration (FDA).

Out of the 290 original Abbreviated New Drug Application (ANDA) approvals issued by the US FDA in 2013, at least 110 are from Indian companies or entities owned or controlled by an Indian firm. This has taken India's share in the original ANDA approvals to nearly 40 percent in the US market this year.

Amongst the big companies that have received generic drug approvals from the American regulator are entities belonging to Sun Pharma, Lupin, Aurobindo Pharma, Zydus, Glenmark, Dr. Reddy's, Emcure, Wockhardt, Torrent, Claris, Alkem, Ipca, Cipla, Famy Care, Natco, Hetero and Alembic.

While India produces nearly 40 percent of generic and over-the-counter products, its share in the finished dosage medicine segment is about 10 percent. FDA data shows that India shipped pharmaceutical products worth over \$4 billion to the United States in 2012, with a growth of around 30 percent from the previous year.

As per data compiled by IMS Health, Lupin, followed by Dr Reddy's, Cadila Healthcare and Aurobindo Pharma were the top Indian drug seller in the American market last year by prescriptions.