

Mylan holds back \$250 mn in Agila buyout

December 6, 2013 | News | By BioSpectrum Bureau



Singapore: With the US drug regulator, Food and Drug Administration (FDA) issuing a warning letter to one of Agila's Specialties plant, Mylan has said that it is holding back \$250 million of its buyout amount, until the regulatory issues get resolved.

The company has said in a statement that it has regained full commercialization rights for most of Agila's US portfolio, both products already on the market as well as in the pipeline, and is taking back rights to many of its products in Canada, Australia, Brazil, Japan and South Korea.

Mylan CEO Heather Bresch has said that she expected significant expansion from the pair-up as Mylan accelerates the many untapped opportunities.

The company that currently has 1,200 approved injectable products globally and more than 900 pending approvals worldwide, now intends to launch more than 800 injectable products over the next 5 years, 150 of those in the US, Mylan President Rajiv Malik further said.

The FDA had pointed out the quality issues at the Indian plant for using defective gloves in the aseptic processing area in September 2013 and accused the company for not taking the problems seriously enough.