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Dr Reddy's, Zydus, 2 more pharma cos seek more time for their SEZ units

NEW DELHI: Four major pharmaceutical firms including Dr Reddy's Lab, Zydus Technologies and Cadila Healthcare have sought more time to commence production from their SEZ units as they have not been able to obtain the necessary regulatory approvals in time.

The 19-member inter-ministerial Board of Approval, chaired by Commerce Secretary S R Rao, will take decision on all the requests at its meeting on 17 January.

In its request, Dr Reddy's Lab has asked the BoA to extend the validity of its Letter of Permission (LoP) which expired on 12 January (Sunday) . It said the firm has completed all the works relating to the unit (plant & machinery) and at present, trial and validation batches of some products are in progress.

'The unit has invested Rs 122 crore in the project and an amount of Rs 30 crore is likely to be invested on this project towards additional machinery,' the BoA agenda said. Dr



Reddy's Lab Ltd has set up its SEZ unit in Andhra Pradesh. Similarly, Zydus Technologies Ltd has also requested for extension of its LoP beyond 28 June, 2014 as it would take more time to start commercial operations. The agenda said: 'The unit has stated that Transdermal Patches being an extremely complex form of dosage for delivering the medicine to a human body, the regulations are becoming more stringent keeping in view the quality issues in many national and multinational companies.

'On account of the approval pending for the products developed, the units is unable to commence commercial pro-

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duction and it is expected that the same could take 5-7 years from issuance of letter of approval.

Zydus Technologies whas invested Rs 338.90 crore in the project. Ahmedabadbased Cadila Healthcare too, has asked for more time as the validity of its LoP is only till 21st February.

The unit, which will manufacture various pharma products, was set up in Zydus Pharma SEZ in Gujarat.

As per the agenda, "The unit has requested for further extension of the validity of the LoP. It has invested Rs 45.51 crore for construction of factory building and installation of plant and machineries.

'The unit has started trial production of their exhibit batches in their manufacturing premises for study purpose and approval of the respective Pharmaceutical Regulatory Authority of the country for export.'

Amneal Life Sciences has also sought extension for its SEZ unit in Ahmedabad. PII