BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Aussie's IDT to manufacture 23 generic drug

April 14, 2015 | News | By BioSpectrum Bureau

Aussie's IDT to manufacture 23 generic drug



Singapore: US FDA has accepted the transfer of ownership of 23 generic drug products to Australia based IDT. Formalising change of ownership is a process whereby the vendor and the purchaser both submit correspondence informing the FDA that the transfer of a drug registration has occurred.

IDT will now move on to the manufacture of exhibit batches of drug product that will be placed on stability studies. The data from the exhibit batch manufacture and stability work form the basis of a submission to the FDA to re-activate the marketing approval of the products.

Dr Paul MacLeman, managing director and CEO, IDT Australia, said, "I am pleased to say that IDT is now the registered owner of these US generic drug products."

"The successful manufacture of Doxazosin in IDT's Boronia solid oral dosage form facility is a turning point for the Company in that we have now shown that IDT has the personnel, equipment and resources required to manufacture these newly acquired products in-house."