



ASX Announcement

28 August 2019

FDA REVISES IDT's FACILITY INSPECTION CLASSIFICATION

IDT Australia Limited (IDT) provides the following market update regarding the Warning Letter received from the U.S. Food and Drug Administration (FDA) in May 2018: IDT has received formal correspondence from the Director of the FDA's Division of Drug Quality Office of Manufacturing Quality Office of Compliance closing-out the FDA's inspection of IDT Australia Limited's facility which occurred during the period 20-31 May 2019. The FDA has concluded that this inspection is now closed and have determined that the inspection classification of IDT's facility be restored from Official Action Indicated ("OAI") back to Voluntary Action Indicated ("VAI").

Prior to receiving the FDA Warning Letter in May 2018 IDT maintained a VAI facility inspection classification. An inspection classification of VAI for Good Manufacturing Practice compliance means that the FDA's assessment of any pending marketing applications referencing IDT's facility will no longer be directly impacted.

The FDA have confirmed that further correspondence, including details of the closeout for Warning Letter 320-18-55, dated May 23, 2018, will be forthcoming.

"The FDA's reclassification of IDT's facility inspection status from OAI to VAI is a very pleasing development for IDT." said IDT Australia Limited's Chief Executive Officer Dr David Sparling. "IDT will continue working hard to meet the commitments we have made to the FDA and we will stand-by for what we hope to be a positive outcome on the status of the Warning Letter."

IDT will update the market when more information comes to hand.

ENDS

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About IDT

IDT (ASX:IDT) is a public Australian pharmaceutical manufacturing company based in Boronia, Victoria, Australia. It has extensive experience in the development and production of high potency and high containment pharmaceutical products for local and international clients. IDT's facilities are cGMP compliant and are regularly audited by the US FDA and Australian TGA. With an experienced team of specialists within world-class facilities, IDT provides a full-scale service for new drug development and scale-up, commercial active drug manufacture as well as a variety of finished drug dose forms.