# ASX Announcement

**8 June 2018**

# UPDATE ON RESPONSE TO FDA WARNING LETTER

IDT Australia Limited (IDT) provides the following market update regarding the Company's activities in response to the Warning Letter received from the U.S. Food and Drug Administration (FDA):

IDT's remediation activities commenced immediately following the FDA audit and are now well underway. These activities have included changes to IDT's quality and operational personnel as well as changes to IDT's processes and systems.

From a business operations standpoint, the FDA warning letter does not contain any enforcement conditions limiting or preventing the importation or sale of IDT's products in the U.S. IDT's order book through to the end of the 2018 financial year is strong and the Company's highest priorities right now are fully addressing the FDA's concerns and meeting our obligations to customers.

IDT has assembled an internal team comprised of personnel from Quality, Operations and Microbiology; along with several Technical Specialists to compile the response, drive remediation activities and effect improvements to the ongoing quality and operational systems at IDT. The Company has also engaged industry specialist external consultants including Mr Andrew Giles from SeerPharma to assist with the remediation program. These individuals have deep experience in dealing with the requirements of regulatory agencies including the FDA, and management of the associated remediation activities. A short biography for Mr. Giles provided in the Appendix below.

IDT's response to the FDA is due within fifteen working days' of receipt of the warning letter. The Company has put in place an action plan to address all of the FDA's concerns and will formally respond to the warning letter within the stated timeframe.

ENDS

For further information please contact:
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**APPENDIX**

**Andrew Giles**: **Senior GMP Consultant SeerPharma**
(B.App.Sc. Chemistry/Microbiology; GradDip. Computing)

Mr Andrew Giles has over 30 years of experience in the pharmaceutical industry. This includes 11+ years of experience as a GMP inspector for the Therapeutic Goods Administration, 14+ years of experience in a sterile parenteral products manufacturing company, DBL/F.H. Faulding/Mayne, 3 years of experience with a complementary medicine/veterinary product manufacturer, Enzacor and 3 years of experience in sustained release oral dosage forms manufacturer, F.H. Faulding (SA). While in the industry, Andrew held roles as a Senior GMP Inspector, IT Compliance Manager QA, Research and Development Project Services Manager, Production Manager, Products Chemist and Pellet Technologist.