12 April 2024

FDA Audit Results

ANO confirms that the FDA have published a warning letter today regarding our OOS (Out of Specification) procedures with respect to testing in our laboratory. The manufacturing facility, Quality Management System, and customer complaint processes received NIL observations or issues.

The OOS Procedures relate to 67 bags out of 3500 bags manufactured and tested over the last 4 ½ years. The TGA identified issues with our OOS process in early 2023 and the majority of these 67 OOS processes were prior to 2023.

ANO confirms that no batches were ever released to customers without fully passed test results.

We will be sending the FDA and the TGA our final risk assessment reports on Monday 15 April and the Board has formed a belief at this stage that this nonconformity could not have had any impact on the efficacy or safety on any of our customers' products and an external report from an independent consultant confirming verbal advice to this effect is forthcoming.

Authorized by:

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Managing Director

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