



9<sup>th</sup> January 2026

## FDA Update

ANO has been notified of an Import Alert in the USA. We are aware that 7 other manufacturers across Australia in the past 18 months that have been issued with Import Alerts including the manufacturer of the company that was part of the television report in early December 2025. The board believes the alerts are based on broader issues around tariffs.

The company has engaged US-based regulatory consultants, including former FDA officials, who will be on-site in Brisbane next week to conduct a comprehensive review of our Good Manufacturing Practice (GMP) systems and ensure that we are 100% compliant with the FDA and address any outstanding regulatory requirements.

While the specific details of the FDA's concerns are being clarified, we are proactively preparing a corrective action plan. ANO intends to submit a formal petition to the FDA to request the lifting of this alert within the next 4 to 8 weeks. At this point, we do not anticipate significant financial impact unless the alert is not lifted before the financial year ended 2026.

The recent television report in early December 2025 may have contributed to this FDA decision, and we will continue to update the market as the board considers its legal options.

**Authorised by:**

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