17 November 2025

FDA Inspection Update

The Board advises that the Company has received correspondence from the U.S. Food and Drug Administration (FDA) following its routine inspection conducted in July 2025. The FDA has identified several Good Manufacturing Practice (GMP) compliance issues requiring remediation. There is currently no impact on supply to our U.S. customers and no concerns were raised regarding the quality or testing of our products.

The FDA observations relate primarily to supplier qualification and precursor handling processes, the GMP Agreement, digital record-keeping systems, and the timing of the 2024 Product Quality Review (PQR), which was completed in June rather than March and three observations regarding sunscreen manufacture of 3,500 tubes, which Antaria ceased manufacturing in March 2023. The FDA also confirmed that matters raised in its April 2024 letter have been satisfactorily closed.

To ensure full alignment with FDA requirements—which differ substantially from those of the Therapeutic Goods Administration (TGA)—the Company will engage specialised U.S. regulatory consultants to conduct a comprehensive review of all FDA-related GMP compliance activities.

Antaria has committed to the following actions:

- Engaging U.S. regulatory consultants to manage all FDA-related matters, with an on-site review of our facility scheduled for early January 2026.
- Providing additional GMP training for Directors and selected staff over the next three months.
- Increasing investment and resourcing to support ongoing FDA GMP compliance.
- Supplying the FDA with a detailed update in early December 2025.
- Providing the FDA with a quarterly progress report, including confirmation (following the consultants' January visit) that the identified GMP issues have been addressed at the end of February 2026.

At this point the Board formed a view that all outstanding observations have been or are being resolved with further information to be supplied to the FDA shortly.

The Company will continue to keep the market informed of any material developments.

Authorised by:
Geoff Acton (B.Com CA)
Managing Director