



FOR OFFICIAL USE ONLY

Ref: M-7817

13 January 2016

Dr Lyndsay Lawrence
AgriHealth NZ Ltd
Level 1, 89 Grafton Road
Grafton, Auckland 1010
New Zealand

Dear Dr Lawrence,

CONFIRMATION: OVERSEAS SITE GMP COMPLIANCE

The APVMA has now completed its review of the facility listed below, and is satisfied that this manufacturer meets the requirements for the manufacture of the products nominated in the Pre-Audit Notification form (FM_MQL45) dated 4 November 2015.

The following site was last inspected for GMP compliance by an APVMA-authorized auditor on **24-26 November 2015**. Provided no further contrary evidence is received, the APVMA will recognise the GMP compliance of this site, for the steps and/or products specified, for a period of 30 months from the date of the last inspection.

Therefore, provided no further contrary evidence is received, the following site will be recognised until **26 May 2018** for the following steps and product types:

Manufacturing site name:

Alke Saglik Urunleri A.S.

Manufacturing site address:

Merkez Organize Sanayi Bolg,
2. Kisim 10.Cd No: 7,
Tokat Turkey

Steps of Manufacture:

Quality assurance (QA) of raw materials, formulation including blending, wet milling, filling, aseptic filling, packaging, labelling, sterilisation (heat and filtration), microbiological reduction treatment (heat and chemical), analysis and testing (physical, chemical, endotoxin testing, antibiotic assay, microbiological and sterility test), storage and release for supply

Products/ types:

Category 1 — sterile injectable products

Cloxacillin dry cow intramammary syringes

Amoxicillin and clavalonic acid lactating cow intramammary syringes

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