



FOR OFFICIAL USE ONLY

Ref: 7817

25 March 2015

Dr Lyndsay Lawrence
AgriHealth NZ Ltd
Suite 1.2, 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 28 October 2014.

The following site was last inspected for GMP compliance by an APVMA-authorized auditor on **18, 19 and 20 November 2014**. 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 15 months from the date of the last inspection.

Therefore, provided no further contrary evidence is received, the following site will be recognised until **20 February 2016** 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, secondary packaging, secondary labelling, sterilisation (heat and filtration), microbiological reduction treatment (heat and chemical), analysis and testing (physical, chemical, endotoxin testing, antibiotic assay, microbiological, sterility test), storage and release for supply.

Products/ types:

Category 1 – sterile injectable products

Cloxacillin dry cow intramammary syringes

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