

## Application summary

<b>Application number:</b>	ERMA200095, RAC5809
<b>Application type:</b>	Notified, Importation or manufacture for release, Category A
<b>Applicant contact:</b>	Kristen Manson
<b>Applicant:</b>	Regulatory Affairs Consulting Ltd Mt Eden Level 1, 451 Mt Eden Road Auckland 1024 New Zealand
<b>Purpose:</b>	To import or manufacture RAC5809, and import RAC6809 and RAC7809 to be used in the manufacture of RAC5809, for the treatment and prevention of gastric ulcers in horses.
<b>Date formally received:</b>	14 September 2009

### Application summary prepared by Regulatory Affairs Consulting Ltd

This application proposes the NZ manufacture and/or importation of a veterinary medicine (a paste, RAC5809), for the treatment of domestic animals by mouth.

This application also proposes the importation of the active ingredient (pellets) for the manufacture of RAC5809 (RAC6809 and RAC7809).

RAC5809 breaches HSNO thresholds for irritation (6.3B), sensitisation (6.5B), reproductive toxicity (6.8C) and target organ toxicity (6.9B).

The active ingredients (RAC6809 and RAC7809) breach HSNO thresholds for irritation (6.3B, 6.4A), +/- sensitisation (6.5B) and target organ toxicity (6.9B).

Neither RAC5809, nor the active ingredients (RAC6809 and RAC7809), are hazardous to the environment.

Risks to human health are judged insignificant. Human skin or eye contact could possibly occur

(i) Following spillage of the paste or pellets during transport, in storage areas or during use, (ii) During paste manufacture (workers in the manufacturing plant), or (iii) During the paste administration to animals. Repeated ingestion of either the paste or pellet formulations is not at all likely. Implementation of default controls (for labelling, safety data sheets, signage, equipment, packaging, disposal, emergency management) would remove any concerns.

RAC5809 will not pose any additional economic, social or environmental costs. The introduction of this product to the market will increase consumer choice. This increased choice may translate into cheaper prices. RAC5809 is significantly beneficial in terms of animal welfare.