



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: MOBILITY MLD 26 LARGER DOGS
Applicant: ROYAL CANIN AUSTRALIA PTY LTD
Product number: 62915
Application number: 44288

Purpose of Application and Description of Use: Registration of a therapeutic pet diet for the maintenance of joint health and mobility in dogs.

Active Constituent(s):

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval

1. Containers must meet AgVet Code Regulation 18
2. Product must not be supplied without meeting GMP Requirements
3. Label must contain an Expiry Date and Batch Number

For full conditions, refer to http://www.apvma.gov.au/advice_summaries/adv_summaries.shtml

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External Efficacy Reviewer

Data and/or justification was provided in support of the application to register a therapeutic pet diet intended to assist in the maintenance of joint function and aid in the prevention of osteoarthritis in dogs. Two published papers were provided which validated the effectiveness and safety of this diet. The application was assessed by an external reviewer who determined that the product would not be likely to have an unintended effect that is harmful to the target animals and would be effective in promoting joint health in adult and geriatric dogs. Joint disorders, in particular osteoarthritis, are common in older dogs especially those breeds with inherited defects. The claim is made that this product is a complete and balanced food which can be fed for long periods and contains green-lipped muscle (GLM) extracts, hydrolysed derivatives of glucosamine and chondroitin and omega-3 fatty acids all which are claimed to have a role in the maintenance of joint health. The diet contains rice which is a highly digestible source of carbohydrate. The reviewer was satisfied that the product would be effective as claimed on the label (ie. should assist in the treatment and management of canine osteoarthritis when monitored by a veterinarian) and would not be likely to have an unintended effect that is harmful to the target animals. The product is intended to be provided by veterinarians and used under veterinary supervision. The diet is formulated to meet the nutritional profiles established by the Association of American Feed Control Officials - 2005 (AAFCO).

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
27302	S	Servet E, Biourge V, Marniquet P	Dietary Intervention can Improve Clinical Signs in Osteoarthritic Dogs	2006	Efficacy and Safety	Efficacy	Public	
27304	S	Bierer TL, Bui LM	Improvement of Arthritic Signs in Dogs fed Green-Lipped Mussel (<i>Perna canaliculus</i>).	2002	Efficacy and Safety	Efficacy	Public	

* S = Data submitted with the application

I = Data inherited (that is, referenced) from another application