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SPECIAL

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NOTICE

EIMERIA SPECIES

[in the product: PARACOX-8 ANTICOCCIDIAL VACCINE FOR CHICKENS]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Schering-Plough Pty Ltd, for the approval of three new active constituents/live attenuated oocysts of Eimeria species namely, *Eimeria brunetti HP*, *Eimeria mitis HP and Eimeria Praecox HP*.

The APVMA also has before it an application from the same applicant, for the registration of a new product, PARACOX-8 ANTICOCCIDIAL VACCINE FOR CHICKENS ('the product'). The product contains oocysts of seven Eimeria species: the three new species under consideration and four species the APVMA has previously approved as active constituents, namely *Eimeria acervulina* HP, *Eimeria maxima* CP and MFP, *Eimeria necatrix* HP and *Eimeria tenella*. The product is to be used as an aid in the control of coccidiosis in chickens caused by the above-mentioned *Eimeria* species.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the applications for approval of the three new active constituents and the application for the registration of the product should be granted.

Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the approval and registration. Comments must be received by the APVMA within 28 days of the date of this Gazette.

Particulars of the new active constituents

1. Oocysts of *Eimeria mitis*
   Common name: *Eimeria mitis* – precocious/attenuated
   Species: *Eimeria mitis* HP

2. Oocysts of *Eimeria Praecox*
   Common name: *Eimeria praecox* – precocious/attenuated
   Species: *Eimeria praecox* HP

3. Oocysts of *Eimeria brunetti*
   Common name: *Eimeria brunetti*– precocious/attenuated
   Species: *Eimeria brunetti* HP

Identity and purity:	Identity by oocyst dimensions and biological differences (i.e. prepatent time, output per standard inoculum dose).
Purity:	By single oocyst passages
Sterility:	As per British Pharmacopoeia (Vet)

Cat. No. S4508
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Extraneous agents:	As per European Pharmacopoeia (Vet)
Mycoplasma:	As per British Pharmacopoeia (Vet)
Mode of action:	Stimulate active immunity in the gastrointestinal tract of chickens
Gene technology:	Not applicable

Summary of Use: As an aid in the control of coccidiosis in chickens caused by the following seven Eimeria species: *Eimeria mitis* HP, *Eimeria Praecox* HP, *Eimeria brunetti* HP, *Eimeria acervulina* HP, *Eimeria necatrix* HP, *Eimeria tenella, Eimeria maxima* MFP, *Eimeria maxima* CP,

Particulars of the Product

Product name
PARACOX-8 ANTICOCCIDIAL VACCINE FOR CHICKENS

Name of Applicant
Schering-Plough Animal Health
Level 4, 66 Waterloo Road
North Ryde NSW 2113

Active constituents
Eimeria mitis HP, *Eimeria praecox* HP, *Eimeria brunetti* HP, *Eimeria acervulina* HP, *Eimeria necatrix* HP, *Eimeria tenella, Eimeria maxima* MFP, *Eimeria maxima* CP

Adjuvant
NA

Pharmaceutical form
Sterile bulk oocyst suspensions in Phosphate Buffer Solution.

Target species
Chickens

Indications for use
As an aid in the control of coccidiosis caused by the following seven *Eimeria* species in chickens: *Eimeria mitis* HP, *Eimeria praecox* HP, *Eimeria brunetti* HP, *Eimeria acervulina* HP, *Eimeria necatrix* HP, *Eimeria tenella, Eimeria maxima* MFP, *Eimeria maxima* CP.

Directions for use
Contraindications:
DO NOT administer in conjunction with other anticoccidial agents. Food and water provided at any stage before or after vaccination must be free from anticoccidial agents including sulphonamides and antibacterial agents having anticoccidial activity. Only healthy birds are to be vaccinated.

Dosage and administration:
0.1mL of the product per bird, administered in the drinking water to chickens between the ages of 5 and 9 days inclusive.

Withholding period:
Nil

Summary of the APVMA's Evaluation of the Active Constituent and the Product

The APVMA has evaluated the chemistry and manufacturing aspects of the active constituents and the product, including starting materials, master seed organism (source, isolation, identification, testing), culture medium, vaccine production, storage, quality control and batch release analysis and found then to be acceptable.

The APVMA is satisfied that the proposed use of the product for oral administration to chickens in the drinking water as an aid in the control of coccidiosis caused by any of the seven Eimeria species, would not be likely to have an effect that is harmful to human beings, the environment or trade.

The APVMA is satisfied that the data addressing the efficacy and safety of the product demonstrate that this product is likely to be safe and effective under Australian conditions when used as directed according to the label instructions.

Written submissions on the APVMA's proposal to grant the application for approval of the active constituents, *Eimeria mitis* HP, *Eimeria praecox* HP, *Eimeria brunetti* HP, and registration of the product should be addressed in writing to:

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