ADVICE SUMMARY

PRODUCT APPLICATION

Product name: FLUKAZOLE C PLUS SELENIUM COMBINATION FLUKE AND ROUNDWORM DRENCH FOR CATTLE
Applicant: VIRBAC (AUSTRALIA) PTY LTD
Product number: 56706
Application number: 36654

Purpose of Application and Description of Use: Variation of label approval to extend the use to include claims for control of 2 week old fluke and inhibited Ostertagi.

Active Constituent(s): OXFENDAZOLE
SODIUM SELENATE
TRICLABENDAZOLE

Regulatory Decision:
To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval
1. Label must contain an Expiry Date and Batch Number (Vet only)

Non-Standard Conditions of Registration/Approval
Nil
ADVICE

State/External Efficacy Reviewer

To support the application data from two trials were provided in conjunction with some published supporting information. The trial designs were suitable for establishing the efficacy of the product formulation against early immature (2 week old) fluke and for determining the bioequivalence of the oxfendazole component of the formulation with registered products containing oxfendazole.

The liver fluke efficacy trial showed that the product when applied in accordance with the label directions was 100% effective against early immature liver fluke (2 week old).

The bioequivalence trial demonstrated that the pharmacokinetics of oxfendazole in the combination formulation of the proposed product was similar to that of oxfendazole when given alone as with Virbac Oxfen LV Anthelmintic For Sheep Cattle And Goats (40267). The demonstration of oxfendazole bioequivalence in the trial, abstracts of scientific papers and copies of labels of registered oxfendazole products which deliver the same dose rate (4.5mg/kg) all supported the claim for activity of the product against inhibited larvae of *Ostertagia ostertagi*. Referenced product labels included Virbac Oxfen C Anthelmintic for Cattle (39816), Coopers Systamex Concentrated Drench for Beef And Dairy Cattle and Horses (36099), Coopers Systamex Anthelmintic Drench for Cattle Oral (48226) and Farnam Worma Drench Broad Spectrum Oral Anthelmintic for Horses and Cattle (46725).

The data provided justify the proposed changes to label claims to include efficacy against early immature (including 2-week old) *Fasciola hepatica* and against inhibited (hypobiotic) larvae of *Ostertagia ostertagi* in cattle. Directions for use and other label instructions relevant to product efficacy are justified by the data provided.

Data relied on to provide the advice

<table>
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<tr>
<th>Data No</th>
<th>Data Source*</th>
<th>Author(s)</th>
<th>Title</th>
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<td>S</td>
<td>Boray JC</td>
<td>Efficacy of triclabenazole and its combination with oxfendazole against early immature and adult Fasciola hepatics in cattle</td>
<td>1998</td>
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<td>Boray JC</td>
<td>Bioequivalence of a combination of triclabendazole and oxfendazole, triclabendazole alone and oxfendazole alone in cattle</td>
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<td>Yazwinski TA <em>et al</em></td>
<td>Efficacy of oxfendazole as administered by intraruminal injection to naturally infected calves</td>
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<td>Berger J &amp; Tema BO</td>
<td>Oxfendazole: anthelmintic activity in calves artificially infected with six species of nematodes and in calves naturally infected with tapeworms.</td>
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<td>Kirstner TP <em>et al</em></td>
<td>Efficacy of oxfendazole against inhibited <em>Ostertagia ostertagi</em> in naturally infected cattle</td>
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<td>Efficacy and Safety</td>
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<td>Borgsteede FH</td>
<td>A field trial with a new anthelmintic oxfendazole in naturally infected calves.</td>
<td>1977</td>
<td>Efficacy and Safety</td>
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*S = Data submitted with the application
*I = Data inherited (that is, referenced) from another application*