

NOTICE

Reconsideration of Approvals and Registrations Related to Dimetridazole

In accordance with Part 2 Division 4 of the Agvet Codes, the APVMA has reconsidered registrations of all products containing dimetridazole and the approvals of all associated product labels. The affected products are listed in Table 1.

Table 1: Registered products containing dimetridazole

Product number	Product name	Registrant	Approval number
35556	Dimetridazole FG	Agribusiness Products Pty Ltd	35556/01
38037	Emtryl Premix for Feed Medication	BEC Feed Solutions	38037/0900
38038	Emtryl Soluble Dimetridazole Soluble Powder 400g/kg	BEC Feed Solutions	38038/0900
50141	Bronson and Jacobs Dimetridazole (D.M.Z.) Oral	Bronson and Jacobs Pty Ltd	50141/0798
50743	CCD Dimetridazole (Water Soluble Powder)	Ridley Agriproducts Pty Ltd	50743/1200 50743/0201
52812	CCD DMZ 225 Premix (Dimetridazole)	Ridley Agriproducts Pty Ltd	52812/0600 52812/0801

Dimetridazole is a member of the 5-nitroimidazole class of antiprotozoals. It is currently approved for the treatment and prevention of histomoniasis (blackhead) in poultry, particularly turkeys, and trichomoniasis (canker) in pigeons and caged birds. Blackhead is caused by a protozoan species, *Histomonas meleagridis*. Canker is caused by another protozoan, *Trichomonas gallinae*. Dimetridazole is also approved for the prevention of swine dysentery in pigs caused by the bacterium *Brachyspira hyodysenteriae*.

Cancellation of registrations and label approvals

Following the finalisation of its reconsideration, the APVMA is no longer satisfied that dimetridazole, when used in accordance with the existing approved instructions for use:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
- would not be likely to have an effect that is harmful to human beings.

As an outcome of the review, the APVMA has cancelled the registrations of four products containing dimetridazole and their associated label approvals because the conditions of registration and label approval of these products cannot be varied in a way such that the requirements for continued registration and label approval could be met. The four products are listed in Table 2.

Table 2: Cancelled dimetridazole product registrations and label approvals

Product number	Product name	Registrant	Approval number
35556	Dimetridazole FG	Agribusiness Products Pty Ltd	35556/01
38037	Emtryl Premix for Feed Medication	BEC Feed Solutions	38037/0900
50141	Bronson and Jacobs Dimetridazole (D.M.Z.) Oral	Bronson and Jacobs Pty Ltd	50141/0798
52812	CCD DMZ 225 Premix (Dimetridazole)	Ridley Agriproducts Pty Ltd	52812/0600 52812/0801

The APVMA has also cancelled label approval 50743/1200, which is the non-current label approval of product number 50743 – CCD Dimetridazole (Water Soluble Powder), because the label does not contain adequate instructions.

Variation of label approvals and affirmation of registrations

The APVMA is satisfied that the conditions to which two label approvals are currently subject can be varied in a way to ensure that the requirements for continued label approval will be complied with. Therefore the APVMA has varied the conditions of label approval for the labels of the two products listed in Table 3 and the APVMA is satisfied that the labels of these products now meet the prescribed requirements for continued registration.

The APVMA is satisfied that the continued registration of the products listed in Table 3, in accordance with their instructions for use:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
- would not be likely to have an effect that is harmful to human beings

–and therefore has affirmed these product registrations.

Table 3: Products registrations that have been affirmed and label approval numbers varied as an outcome of the review

Product number	Product name	Registrant	Label approval number to be varied
38038	Emtryl Soluble Dimetridazole Soluble Powder 400g/kg	BEC Feed Solutions	38038/0900
50743	CCD Dimetridazole (Water Soluble Powder)	Ridley Agriproducts Pty Ltd	50743/0201

The detailed reasons for these decisions can be found in the APVMA Final Review Report and Regulatory Decision document which can be obtained from the APVMA website (www.apvma.gov.au) or by request to:

The Veterinary Medicines Review Contact Officer
Australian Pesticides and Veterinary Medicines Authority
PO Box E240
KINGSTON ACT 2604

Phone: (02) 6210 4749
Email: chemrev@apvma.gov.au.