European Medicines Agency
Veterinary Medicines and Inspections

EMEA/CVMP/195792/2009

OPINION OF THE COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE ON THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

PROCEDURE No EU/09/165/NOV

Name of the substance: Valnemulin (INN)

Basis for the opinion

Pursuant to Article 6 of Council Regulation (EEC) No 2377/90 of 26 June 1990, as amended, Novartis Animal Health Inc submitted to the EMEA on 6 January 2009 an application for the establishment of maximum residue limits for valnemulin in rabbits.

Opinion

The Committee, having considered the application as set out in the appended European Public MRL Assessment Report, recommends the establishment of maximum residue limits for the above mentioned substance in accordance with the following table:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
Valnemulin	Valnemulin	Rabbit	50 µg/kg 500 µg/kg 100 µg/kg	Muscle Liver Kidney	

The Icelandic and Norwegian CVMP members agree with the above-mentioned recommendation of the Committee.

The analytical method is presented in annex to the appended European Public MRL Assessment report.

The present Opinion is forwarded to the European Commission and to the applicant together with its appendices.

London, 16 April 2009

Signature on file

Dr. G. Moulin
Chairman, on behalf of the CVMP

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ANNEX I

European Public MRL Assessment Report
(EPMAR)