APPLICATION FORM

APPLICATION FOR THE ESTABLISHMENT OF MRL(s) FOR A PHARMACOLOGICALLY ACTIVE SUBSTANCE TO BE USED IN VETERINARY MEDICINAL PRODUCTS IN ACCORDANCE WITH REGULATION (EC) No. 470/2009

PART I: Administrative Data

Name of substance for review, using INN (where attributed):						
Name and address of applicant:						
Name, address, telephone number and fax number of company contact point for all correspondence arising in connection with the application:						
Type of application (please tick):	Full	☐	Extension	☐	Modification	☐
Legal basis (please tick):	Article 3	☐	Article 15	☐	Article 9a[1]	☐
	Article 9b	☐	Article 11	☐	Article 27[2]	☐
Marketing authorisation of veterinary medicinal products in the EU (please tick):	Does the applicant hold a marketing authorisation in the EU for a veterinary medicinal product containing the substance? Yes ☐ No ☐, or Has the applicant submitted a marketing authorisation application in the EU for a veterinary medicinal product containing the substance? Yes ☐ No ☐ If the response to both questions above is “No”: Has the applicant the intention to submit an application for a marketing authorisation containing the substance and concerned species in the EU Yes ☐ No ☐					
Rapporteur:						
Co-rapporteur:						

1 Requests from the European Commission or Member States only.
2 Requests from the European Commission or Member States only.

PART II: SUMMARY OF THE EVALUATION PROPOSED BY THE APPLICANT

Name of Substance for review, using INN (where attributed):				
Is the substance used in veterinary medicinal products as (please tick):	Active ingredient?	☐	Excipient, preservative, etc?	☐

Please summarise the anticipated pattern of veterinary use:		
Target Species	Major indications	Dose regimen

Overall NOEL used for the determination of ADI (mg/kg bw/day):	
Reference to relevant study (including location in the dossier):	

Uncertainty factor proposed:				
ADI proposed (µg/kg bw):				
ADI proposed (µg/60 kg person):				
MRL required? (Please tick)	Yes	☐	No	☐
If yes, what is the marker residue proposed:				

Food commodity	**Proposed MRLs (µg/kg)**	
Muscle		
Fat/Skin+Fat		
Liver		
Kidney		
Milk		
Eggs		
Honey		

Description of the proposed analytical method:	
Limit of quantification (LOQ)	
Reference (including location in the dossier):	
Evaluations performed by other EU or international bodies:	Has the substance been evaluated by other EU or international bodies? Yes ☐ No ☐ If the response to the above question is “yes”, please indicate the name of the EU body(ies), the date(s) of evaluation(s) and the outcome(s)

I hereby certify that all information relating to the establishment of MRLs for the above-mentioned substance, whether favourable or unfavourable, has been submitted with this application.

Date:		Signature:	