ADVANCE NOTIFICATION
Veterinary clinical trial

FOR OFFICIAL USE

Application number	
Date received	Date processing began
Handler	

TITLE OF THE TRIAL

PRINCIPAL INVESTIGATOR (List other investigators participating in the trial in Appendix 1)

Name of principal investigator	
Address	
Phone number	E-mail
If the principal investigator is not a veterinarian, give the name of the principal veterinarian here	
Address	
Phone number	E-mail

MANUFACTURER AND IMPORTER OF THE MEDICINE

Manufacturer	
Manufacturer's contact person	
Address	
Phone number	E-mail
Importer	
Address	
Phone number	E-mail

SPONSOR

Sponsor	
Address	
Phone number	E-mail
Sponsor's contact person	
Address	
Phone number	E-mail

INVESTIGATIONAL VETERINARY PRODUCT	**CONTROL PRODUCT**
Name of the product, pharmaceutical form and ATC code	Name of the product, pharmaceutical form and ATC code
Qualitative and quantitative composition	Qualitative and quantitative composition
Method of administration, dosage and duration of medication	Method of administration, dosage and duration of medication
Withdrawal periods proposed for food-producing species and justification	Withdrawal periods proposed for food-producing species and justification
Supplier of the medicine for the trial (factory, wholesaler or pharmacy)	Supplier of the medicine for the trial (factory, wholesaler or pharmacy)
Trial phase ☐ preclinical ☐ clinical	
If the product already has a marketing authorisation elsewhere, please indicate the country or countries	

CLINICAL TRIAL

Proposed duration of trial (start and end dates) -				
Purpose of the trial and brief summary of the research plan				
Type of trial (controlled or uncontrolled, randomised, blind)				
Animal species	Study group Number of animals by gender ♀	♂	Control group Number of animals by gender ♀	♂
If clinical veterinary trials with the investigational veterinary product have been conducted in Finland earlier, give the title(s) of the trial(s).				

MULTICENTRE TRIAL

Number of clinics participating in the trial	Total number of study animals
Research centres in Finland, their principal investigators and number of study animals. Also give information on the dosage if it differs between centres.	

SIGNATURES

I have read the reports issued by the sponsor on the medicine. I will keep a research diary during the veterinary clinical trial and notify the Finnish Medicines Agency Fimea or the sponsor of any serious adverse events observed in the course of the trial and any substantial changes to be made to the research plan. I have read the Fimea directive on veterinary clinical trials and the relevant European Union guidelines.

Place and date	Principal investigator's signature and name in block letters

I hereby affirm that the information given above on the medicine is correct. The sponsor will submit to Fimea a report on the findings of the veterinary clinical trial and will immediately inform Fimea if the trial is discontinued or never begun, and why.

Place and date	Sponsor's signature and name in block letters

APPENDICES TO THE ADVANCE NOTIFICATION

- ☐ Research plan
- ☐ Consent of the owner or holder of the trial animals
- ☐ Investigator's info package
- ☐ Info letter for the owner
- ☐ Receipt for payment of the advance notification processing fee
- ☐ Recruitment advertisement
- ☐ Ethics committee statement
- ☐ Copy of the animal testing permit
- ☐ Other investigators in the project (see Appendix 1)
- ☐ Other, please specify:

DETAILS ON OTHER INVESTIGATORS

Name of investigator	Degree or qualification
Address	
Phone	E-mail
Name of investigator	Degree or qualification
Address	
Phone	E-mail
Name of investigator	Degree or qualification
Address	
Phone	E-mail
Name of investigator	Degree or qualification
Address	
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Phone	E-mail
Name of investigator	Degree or qualification
Address	
Phone	E-mail