|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | | **ADVANCE NOTIFICATION** 1 (4)  **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 | | | |

Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency

P.O.Box 55, FI-00034 FIMEA, FINLAND | Tel. +358 29 522 3341 | registry@fimea.fi | www.fimea.fi | Business ID: 0921536-6

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | 2 (4) | | |
| **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 | | | Control group | |
| Number of animals by gender | | | 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). | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | 3 (4) | |
| **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: | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **APPENDIX 1** 4 (4) | |
| **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 | | |
| 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 | | |
| 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 | | |
| Phone | E-mail | |