In compliance with provisions of the Act No 378/2007 Coll., On p pharmaceuticals, all clinical trials of veterinary medicinal products are subject to the approval of the Institute for State Control of Veterinary Biologicals and Medicaments (ISCVBM). Before the ISCVBM grants the approvalfor the clinicla trials an applicant is required to submit a completed application form and appropriate data and documents (see list below) in two copies.

List of documents and data required for the clinical trials approval:

- completed application form ( see forms )
- proof of payment of administrative fee
- agreement of the Departmental commission for animal protection of the Ministry of agriculture of the Czech Republic
- summary of product characteristics
- pharmaceutical data
- summary of data for examiner
- protocol study

- forms for monitored parameters recording
- information for breeder
- breeder agreement
- agreement of the appropriate regional Veterinary administration
- document on

compliance with good laboratory practice

- document on compliance with good manufacturing practice

- authorisation for person who

# acts on bahalf

# of submitter (if necessary)