

**Checklist for Applications for Veterinary Clinical Trials to the Danish Medicines Agency**

Documents in the application must be compiled into a single PDF file.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Not relevant** |
| 1. Cover letter   * any special conditions that the DMA should be aware of |  |  |  |
| 2. Notification form including billing information and sponsor's or applicant’s signature |  |  |  |
| 3. Co-notification from other participating centres if there is more than one trial site in the trial (section 3.2 of the guidelines) |  |  |  |
| 4. Trial protocol (see section 5 of the guidelines) |  |  |  |
| 5. Product summary if the product is marketed. This document is used as a reference document to assess whether an adverse event is unexpected (see section 12 of the guideline). |  |  |  |
| 6. If possible Investigator's Brochure (IB) if the product is not marketed. This document is used as a reference document to assess whether an adverse event is unexpected (see section 12 of the guideline). |  |  |  |
| 7. Quality documentation for the investigational product and any placebo (IMPD) if the product is not marketed. See section 7 of the guidelines. |  |  |  |
| 8. Example of labels |  |  |  |
| 9. Documentation (e.g., sent emails) that the manufacturer has been informed about the trial (section 3.1 of the guidelines) |  |  |  |
| 10. Any appendices |  |  |  |
|  |  |  |  |