|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | **R:\Logos\VMD Logos\4 Detailed Colour - light green.png** |  | **Veterinary Medicines Directorate**  Woodham Lane, New Haw  Addlestone, Surrey  KT15 3LS  United Kingdom  Tel: +44 (0)1932 336911  Search for VMD on GOV.UK |   **APPLICATION FOR AN ANIMAL TEST CERTIFICATE (TYPE A or B)**  **USING AN IMMUNOLOGICAL / BIOLOGICAL PRODUCT**  **An incomplete application form may delay the application process.**  *Where a section of the application form refers to data supplied within the data package, please clearly indicate the location of this data within the data package, e.g. attachment / PDF name, page number etc.*  **Further guidance about this application type is available on GOV.UK**  **SECTION 1 – ADMINISTRATIVE DETAILS** |

**1.1 Name of Test Product:**

**1.2** **Name and Address of Proposed ATC Holder[[1]](#footnote-1):**

Name:

Company Name:

Address:

Email Address:

Telephone No:

**1.3** **Name and Address of Sponsor[[2]](#footnote-2) (if different to 1.2 above):**

Name:

Address:

Email Address:

Telephone No:

**1.4 Application Type – A or B**

Type:

**1.5** **Contact Details for this Application:**

Name:

Email Address:

Telephone No:

**1.6** **Invoice Details:** Email address of where the invoice should be sent to.

Email Address:

**1.7** **e-Issuing Details:** Email address of where the authorisation documentation should be sent to (if different from 1.4 above).

Email Address:

**1.8 Previous ATC Authorisation No. (if applicable[[3]](#footnote-3)):**

**1.9 Name and address of previous ATC holder (if applicable):**

Name:

Address:

**1.10 If the investigational or control product has a Marketing Authorisation[[4]](#footnote-4) in the UK, another EU or EEA country, or a third country (USA, Canada, Japan, New Zealand and Australia only), please provide the following details:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product name / designation** | **Member State / Country** | **MA no.**  **(Vm no. in UK)** | **Species** | **Dosage / Route** | **Withdrawal Period, if applicable** |
|  |  |  |  |  |  |

If the product is authorised in the EU, EEA, or a third country and does not have a UK marketing authorisation (MA) please attach a copy of the MA and the product SPC (in English translation).

For type A applications only: please highlight the EU or EEA authorised product being used during this study.

**1.11 Please confirm that proposed label(s) and package leaflet(s) have been provided for the test product, and the control or placebo products.**

**Yes:**       **No:**

**\*\*Documents should be compliant with the UK 'Product Literature Standard'**

**1.12 Please confirm that the trial protocol and owner consent form (including safety information to be given to the owner) have been submitted with this application form**

**Yes:**

**SECTION 2 – TRIAL DETAILS**

**2.1** **Nature and purpose of the clinical trial (objectives):**

**2.2** **Target Species (only one per trial):**

**2.3** **Indication(s) or outcomes/endpoints to be investigated:**

**2.4 Test Product:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product name / designation** | **Pharmaceutical form** | **Method of administration** | **Dose rate** | **Treatment schedule** |
|  |  |  |  |  |

**2.5 Control (positive or negative / placebo) product(s):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product name / designation** | **Pharmaceutical form** | **Method of administration** | **Dose rate** | **Treatment schedule** |
|  |  |  |  |  |

**2.6 Maximum no. of animals** (if exact numbers are not known, an estimated maximum number should be provided with confirmation of the exact numbers given in writing before the trial starts, please note if final numbers exceed the estimated maximum a variation must be submitted for consideration before the trial commences):

1. Investigational product (with the test product):
2. Positive controls:
3. Negative controls:
4. Placebo treated controls:

**2.7** **Estimated duration of trial:**

**2.8 Description of eligibility criteria for animals:**

1. Inclusion criteria:
2. Exclusion criteria:

**2.9 Criteria for withdrawal of animals from the trial:**

**2.10 Description of safety monitoring (provision for monitoring, investigating and reporting suspected adverse reactions, details of clinical assessments, blood test, etc):**

**2.11 Name and qualifications (including RCVS registration number, where applicable) of the Investigator(s)[[5]](#footnote-5):**      

**2.12 Details of the test site(s)[[6]](#footnote-6), including the name of the Investigator with responsibility at each individual test site:**

**2.13 Name and qualifications (including RCVS registration number, where applicable) of the overall trial Monitor:**

**2.14 Name and qualifications of the individual with responsibility for pharmacovigilance:**

**2.15 If any trial procedures are authorised and regulated in accordance with the Animals (Scientific Procedures) Act 1986, as amended, these should be identified and the Home Office Project License number should be provided:**

**2.16 Disposal of unused product and empty containers:**

**2.17 Disposal or fate of test food producing animals (not intended to enter the human food chain for food):**

**SECTION 3 – ANALYTICAL INFORMATION**

* **For Type A applications – complete sections 3.1 to 3.5**
* **For Type B applications – completed ALL sections**

**3.1** **Is the product to be trialled already authorised as a veterinary medicine in an EU member state?**

**Yes (go to 3.3):**       **No (go to 3.2):**

**3.2** **Is the product to be trialled already authorised as a human medicine in an EU member state?**

**Yes (go to 3.3):**       **No (go to 3.4):**

**3.3** **Is the authorised veterinary or human product to be administered in accordance with the EU or EEA Marketing Authorisation, i.e. unchanged in the authorised packaging?**

**If yes**, please provide a signed statement to confirm that the dosage form to be trialled will be used in conformance with the EU Marketing Authorisation:      Please also complete sections 3.4 and 3.5. ***If a*** ***placebo product is to be used,*** *please complete section 3.5, 3.7 and 3.8 for the placebo product*.

**If no**, please indicate deviations from MA:      and provide supporting data under relevant headings below. ***If a*** ***placebo product is to be used,*** *please also complete section 3.5, 3.7 and 3.8 for the placebo product*.

**3.4** **Is the active substance from the proposed source already included in products authorised in the EU or EEA for use in animals or humans?**

**Yes (provide details):**

**Animal or Human:**

Go to 3.5

**3.5 Please provide batch release documentation, unless the batch has already been released by the VMD, or other competent authority in another member state:**

Please tick appropriate box:

**Batch release documentation provided:**     , or

**Batch release certificate provided:**      , or

**Batch release certificate to be provided before trial starts:**

**3.6 Please provide justification for any changes in the posology (formulation, manufacture and specification):**

**3.7 If applicable, please provide details for the placebo (formulation, manufacture and specification):**

**3.8 Please confirm that you have provided a table of qualitative and quantitative particulars:**

**3.9 Please provide the following:**

1. Name and address of finished product manufacturer:

1. Name and address of assembler:

1. Name and address of manufacturer of active substance(s):

1. Details of containers and closures

1. Description of stages of manufacture and flow charts

1. Table of blending details

1. Starting materials listed in the Pharmacopoeia

1. Starting materials not listed in the Pharmacopoeia (biological origin, non-biological origin, media)

1. Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies

1. In process control tests

1. Final product specifications, where appropriate

1. Stability data, if appropriate

1. For products containing GMOs (requirements listed in Annex II, Directive 2001/18), please provide evidence that a part B release consent notification has been granted (or applied for) by the UK GM Policy Unit

**SECTION 4 – SAFETY INFORMATION**

This section applies to Type B applications only.

**4.1 Please provide the following:**

1. GLP safety in the target species

1. Study of residues

1. Spread of the vaccine strain (for live vaccines)

1. Dissemination in the vaccinated animal (for live vaccines)

1. Reversion to virulence (for live vaccines)

1. Ecotoxicity

Further data under Part III, Safety, may be required to satisfy the VMD that the proposed use of the product will not adversely affect the safety of the product to the treated or other animals, users and the environment.

**SECTION 5 – EFFICACY INFORMATION**

**5.1** For ALL applications, please provide evidence that supports a reasonable expectation of efficacy (i.e. that the test product will produce the desired effect when used in accordance with the trial protocol). NB. Although detailed efficacy data are not required, brief details of pilot studies etc may be submitted to provide the necessary justification.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SECTION 6 – Declaration by the ATC Holder**  I / We apply for the application as described above. I / we confirm that the information given in support of this application is correct at the time of submission.  I / We apply for an ATC and undertake:   * to abide by the terms and conditions of any ATC issued in response to this application * to ensure that Informed Owner Consent is obtained for animals participating in the trial * to comply with the pharmacovigilance reporting requirements   I / We also undertake to inform the VMD of:   * any matter coming to our attention which might affect the safety in use of the product * the discontinuation of the test with an explanation | | | | |
| Signature |  | Job Title |  |  |
|  |  | |  | |
| Name in BLOCK LETTERS |  | Date |  |  |
| **If any information provided in this application is later found to be false or incorrect, the Secretary of State may suspend or revoke the authorisation.** | | | | |

1. 1 For studies conducted in accordance with GCP‑v the ATC holder is usually the Sponsor, or a person or organisation to whom the Sponsor has legally delegated this responsibility. [↑](#footnote-ref-1)
2. The Sponsor is the individual, company or organisation who takes responsibility for the initiation, management and, usually, the financing of the clinical trial. [↑](#footnote-ref-2)
3. For example, a case where an existing ATC requires a change to its terms that cannot be authorised by way of an ATC variation application and a new ATC application is required. [↑](#footnote-ref-3)
4. If a product has a marketing authorisation (MA) in multiple countries, details of only one MA are required using the following order of preference: UK > EU/EEA > third country. By way of an exception, details of additional MAs must also be provided if they are of particular relevance to this ATC application. [↑](#footnote-ref-4)
5. The Investigator is the individual responsible for all aspects of study conduct at a study site; see VICH Topic GL9 (GCP). If details are not available at the point of application, any additional Investigator details must be submitted for consideration once known by way of an ATC variation application. [↑](#footnote-ref-5)
6. If not available, an estimated maximum number of sites should be provided with confirmation of the exact number plus details given in writing before the trial starts; please note if final numbers exceed the estimated maximum an ATC variation application must be submitted for consideration before the trial commences. [↑](#footnote-ref-6)