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| |  |  |  | | --- | --- | --- | |  |  | **Veterinary Medicines Directorate**  Woodham Lane, New Haw  Addlestone, Surrey  KT15 3LS  United Kingdom  Tel: +44 (0)1932 336911  Fax: +44 (0)1932 336618  Search for VMD on GOV.UK |   **APPLICATION FOR A NEW NON-FOOD ANIMAL BLOOD BANK AUTHORISATION (NFABBA)**  This form should be used by applicants who wish to collect and store whole blood and blood products (such as plasma and red blood cells) for use in non-food animals to meet unforeseen or exceptional needs. This authorisation will permit the blood and blood products to be placed on the market without the need for a Marketing Authorisation (MA).  **An incomplete application form may delay the application process.**  **If submitting in hard-copy, please use block capitals.**    **Further guidance about this application type is available in Veterinary Medicines Guidance Note (VMGN) No. 15 entitled ‘Manufacturing Authorisations’.**  **SECTION 1 – ADMINISTRATIVE DETAILS** |  |

**1.** **Name and Address of Proposed Authorisation Holder:**

Company Name:

Address:

**2.** **Contact Details for this Application:**

Name:

Email Address:

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

Email Address:

**4.** **e-Issuing Details:** Email address of where the authorisation documentation should be sent to (if different from 2 above).

Email Address:

**SECTION 2 – PROPOSED AUTHORISATION DETAILS**

3a. The name of the supervising veterinary surgeon(s)

AND/OR

3b. The name of the person who is suitably qualified to operate the blood bank

4. The type of the premises where the blood is to be collected (e.g. Veterinary Practices or Charitable Homing Kennels)

5. The address of the premises where the blood is to be stored (if different to 1 above):

6. The species of animal from which blood is to be collected and stored

**SECTION 3 – MANUFACTURING DETAILS**

7. Describe the method of collection process to ensure consistency of the product

8. Describe the method of collection to ensure the blood is collected in an aseptic manner

9. Describe the method of separation of blood products (if appropriate)

10. Describe the method of storage

11. State the proposed shelf-life of the product

12. Provide details of the facilities, resources and equipment

13. Provide details of the Quality Assurance/Quality Control Scheme:

14. Provide a summary of the action taken to ensure animal welfare

15. Provide a summary of the action taken to ensure the specific disease free status of the donor animal that may be a risk to recipients

16. Please confirm that draft labels have been supplied and are in accordance with the labelling requirements set out in the Regulations.

Yes  No

17. Please confirm if the site holds a valid GMP certificate. If so, please include a copy of the certificate as part of the application package.

Yes  No

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| **SECTION 4 – Declaration**  I apply for the application as described above. I confirm that the information given in support of this application is correct at the time of submission. | | | | |
| 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.** | | | | |