|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|

|  |  |  |
| --- | --- | --- |
|  |  | **Veterinary Medicines Directorate**Woodham Lane, New HawAddlestone, SurreyKT15 3LSUnited KingdomTel: +44 (0)1932 336911Fax: +44 (0)1932 336618Search for VMD on GOV.UK |

**APPLICATION FOR A NEW AUTOGENOUS VACCINE AUTHORISATION (AVA)***This form should be used by applicants who wish to place on the market an autogenous vaccine manufactured from pathogens or antigens obtained from an animal and used for the treatment of that animal and/or animals on the same site, or in the same breeding/rearing supply chain.***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’.**Each new application should be accompanied by a supporting veterinary surgeon justification (Annex 1), which is available on the VMD website**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:

**5.** Type of authorisation required. ***Please tick one box only***

|  |  |  |  |
| --- | --- | --- | --- |
| (i) | Autogenous Vaccine Authorisation – Standard (AVA-S): |  |  |
|  | An AVA-S covers the on-going production of the products specified in the authorisation.  |  | [ ]  |
|  |  |  |  |
| (ii) | Autogenous Vaccine Authorisation – Individual (AVA-I): |  |  |
|  | An AVA-I covers the production of a single batch of product  |  | [ ]  |

**SECTION 2 – PROPOSED AUTHORISATION DETAILS**

6a. The name of the supervising veterinary surgeon(s)

AND/OR

6b. The name of the person with sufficient qualifications and experience to manufacture the product safely

7. The address of the premises where the autogenous vaccine(s) is to be manufactured (if different to 1 above)

**SECTION 3 – PRODUCT DETAILS**

8. Name of product(s) and/or target organism(s)

9. Species to be vaccinated

10. Disease(s) to be treated

11. Pharmaceutical form(s)

12. Please confirm that the TSE declaration and format table have been supplied with the application

 Yes [ ]  No [ ]

13. Proposed shelf-life of the product, if applicable

14. Dosage(s) for each target species

15. Route of administration and amounts to be administered to complete vaccination schedule

**SECTION 4 – MANUFACTURING DETAILS**

16. Method(s) of Manufacture

 Summary of each standard production method, outlining key steps, e.g. collection and transport of infected material, antigen isolation and purification, antigen production process (including media types), inactivation, blending (including ingredients) and filling. Maximum antigen batch and blend volumes should be specified.

17. Method(s) of Sterility Testing

18. Other Quality Control test(s)

19. Details of the Quality Assurance/Quality Control Scheme

20. Method(s) of batch Safety Testing for each target species:

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

 Yes [ ]  No [ ]

22. 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 [ ]

|  |
| --- |
| **SECTION 5 – 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 inBLOCK 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.** |