|  |  |  |  |
| --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | |  |  | **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 THE REGISTRATION OF A NEW**  **VETERINARY HOMEOPATHIC REMEDY**  **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. 7 entitled ‘Guidance on the Homeopathic Registration Scheme’.**  **SECTION 1 – ADMINISTRATIVE DETAILS** |

**1. Proposed Product Name:**

**2. Registered Company Number:**

**3.** **Name and Address of Proposed Registration Holder:**

Company Name:

Address:

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

Name:

Email Address:

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

Email Address:

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

Email Address:

**SECTION 2 – PRODUCT DETAILS**

7. Pharmaceutical Form:

8. Homeopathic Stock(s):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Stock Name** | **Specification** | **Dilution** | **Scale** | **Relevant Registration** | **Applications**  **Other** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

9. Other Constituents:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Name/Specification** | **Modifier** | **Quantity / Dose Unit of % Quantity** | **Unit** |
| Diluent |  |  |  |  |
| Pharmaceutical Base Ingredient |  |  |  |  |

10. Nature of Container and Closure:

|  |  |
| --- | --- |
| Nature of Container |  |
| Nature of Closure |  |
| Pack Size |  |
| Unit |  |
| Shelf-Life A |  |
| Shelf-Life B |  |

11. Route of Administration:

12. Intended Target Species:

13. Proposed Legal Status:

14. Proposed withdrawal period(s):

**SECTION 3 – APPLICATION STATUS**

15. If this remedy has been registered for human use under the MHRA’s scheme, please provide the following details; the name by which the remedy is known under the scheme, the registration number, and the date of registration.

|  |  |  |
| --- | --- | --- |
| **Name of Remedy** | **Registration Number** | **Date of Registration** |
|  |  |  |

16. If this remedy has been registered for veterinary use in any other Member State(s) please provide the following details; the name of the Member State(s), the registration number(s), and the date(s) of registration.

|  |  |  |
| --- | --- | --- |
| **Member State** | **Registration Number** | **Date of Registration** |
|  |  |  |

**SECTION 4 – MANUFCATURING DETAILS**

17. Name, Address and Manufacturer’s Authorisation number for all the proposed sites for manufacture of the homeopathic stocks.

|  |
| --- |
|  |

18. Name, Address and Manufacturer’s Authorisation number for all the proposed sites for manufacture of the pharmaceutical base.

|  |
| --- |
|  |

19. Name, Address and Manufacturer’s Authorisation number for all the proposed sites for manufacture of the finished remedy.

|  |
| --- |
|  |

**SECTION 5 – ADDITIONAL INFORMATION**

20. Please complete the following to indicate where the necessary additional information for your remedy may be found.

|  |  |  |
| --- | --- | --- |
| (a) | A brief description of the method of manufacture:  Please indicate the page number at which it may be found. |  |
|  |  |  |
| (b) | A specimen, or mock-up, of the proposed packaging. Labels and package leaflet (where applicable):  Please indicate the page number at which it may be found. |  |
|  |  |  |
| (c) | Have you provided an index to your dossier?  If yes, please indicate the page number at which it can be found. |  |
|  |  |  |
| (d) | Have you provided details of the finished product specification?  If yes, please indicate the page and paragraph number at which it can be found. |  |
|  |  |  |
| (e) | Are there any special warnings necessary for your remedy?  If yes, please indicate the page and paragraph number at which it can be found. |  |
|  |  |  |
| (f) | Are there any special storage requirements for your remedy?  If yes, please indicate the page and paragraph number at which it can be found. |  |
|  |  |  |
| (g) | Is a withdrawal period necessary for your remedy (i.e. is it intended for food-producing species)?  If yes, please indicate the page and paragraph number at which  it, and the supporting data, can be found. |  |
|  |

21. Please provide the following addresses, where applicable:

i). The Storage Premises.

|  |
| --- |
|  |

ii). The Assembler.

|  |
| --- |
|  |

iii). The Importer.

|  |
| --- |
|  |

iv). The Distributor.

|  |
| --- |
|  |

v). The site at which quality control will be carried out.

|  |
| --- |
|  |

**SECTION 6 – 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.** | | | | |