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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 VARIATION TO AN EQUINE STEM CELL CENTRE AUTHORISATION (ESCCA)**  *This form should be used by applicants who wish to vary an equine stem cell centre authorisation. A separate application should be made for each proposed change.*  **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 Authorisation Holder:**

Company Name:

Address:

**2. Authorisation No.**

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

Name:

Email Address:

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

Email Address:

**5.** **e-Issuing Details:** Email address of where the authorisation documentation should be sent to (if different from 3 above).

Email Address:

6. Type of variation required. ***Please tick one box only***

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| --- | --- | --- | --- |
| 1 | Name and/or address of the authorisation holder |  |  |
| 2 | Change in the species |  |  |
| 3 | Change in the collection process |  |  |
| 4 | Addition of blood consitituents |  |  |
| 5 | Change in the production process |  |  |
| 6 | Other, please state reason: |  |  |

**SECTION 2 - BACKGROUND FOR CHANGE**

(*Please give brief background explanation for the proposed change to your authorisation.*

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| **Present** | **Proposed** |

* Specify the precise present and proposed wording or specification.
* For labelling changes - underline or highlight the changed words presented in the table above, or provide as a separate Annex.

7. Amended text proposals for labels are included:  Yes  Not Applicable

**SECTION 3 - OTHER APPLICATION(S)**

*(Please provide brief information on any on-going variation(s), or other variation(s) submitted in parallel, if applicable.*

Not Applicable

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8. 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.** | | | | |