Request for Classification of a Borderline Product for Animal Use

Refer to the HPRA ‘[Guide to the Definition of a Veterinary Medicinal Product and the Classification Process](http://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/adv-g0002-guide-to-definition-of-a-veterinary-medicinal-product-and-the-classification-process-v9.pdf?sfvrsn=33)’ (available on the HPRA website) when completing this form. Specific documents detailed below and the appropriate fee must accompany this form.

If there is insufficient space in the boxes provided, please attach any additional pages as necessary. Enter ‘N/A’ if sections are not applicable to your classification request.

1. ADMINISTRATIVE INFORMATION

|  |  |
| --- | --- |
| Date of submission of this application |  |
| Has this product previously been submitted for a classification decision? (If so, please provide the date of the original submission and the previous case number.) |  |
| Name and address of the organisation making this application | Name:  Address: |
| Applicant’s contact details | Contact person:  Phone/Fax:  Email: |

1. PRODUCT INFORMATION

|  |  |  |
| --- | --- | --- |
| Name of product | |  |
| Description of product type and route of administration (e.g. tablet, liquid for oral administration, cream for application to skin) | |  |
| Composition of product (including concentrations and excipients if possible) | |  |
| Intended use of product (target animal species, purpose) | |  |
| Is the product intended as a feed intended for a particular nutritional purpose as listed in Commission Regulation (EU) 2020/354 establishing a list of intended uses of animal feed intended for particular nutritional purposes, as amended? | |  |
| Is the product intended as a biocide as described in the Biocidal Products Regulation (Regulation (EU) No 528/2012)? |  | |
| Is the product considered as out of scope of the veterinary medicines legislation and, if appropriate, has evidence been provided to suitably demonstrate the absence of a pharmacological and/or toxicological effect on physiological function at the dosage used? |  | |
| Has the product already been approved as out of scope of the veterinary medicines legislation by another regulatory agency in the EU (if so, please specify)? |  | |
| Product label, including package leaflet and carton if relevant. Please attach. |  | |

1. fees and signature of applicant

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| --- | --- |
| Complete the Veterinary Medicines Fee Application Form available on the [Veterinary Medicines Fees](http://www.hpra.ie/homepage/veterinary/regulatory-information/veterinary-medicines-fees) section of the HPRA website and submit the fee form and proof of payment with this application. (Fee code no. 582)  Enter fee submitted (€): | |
| Signature of applicant:  I certify that the information and documentation submitted with this application is correct in detail and all the information requested has been supplied. | |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print/type name: | Status (job title):  Date: |

Forward the completed classification request form, with attachments, fee form and proof of payment to Receipts and Validation at [submissions@hpra.ie](mailto:submissions@hpra.ie).