A close-up of a logo

Description automatically generated **INFORMATION FOR APPLICANTS**

1. The application form must be duly completed **in all respects.**
2. Handwritten applications will not be accepted.
3. Each page must be initialled.
4. The application must be submitted to the **Registrar: Act 36 of 1947.**
5. All applications must be accompanied by the prescribed registration fee.
6. Please refer to “Submission Document Requirements” for a full explanation of the application process.
7. For further information visit our website at <https://www.dalrrd.gov.za/index.php/core-business/agricultural-production/inspection-services/agriculture-inputs-control>

**FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947**

**(Act 36 of 1947), as amended.**

**APPLICATION FOR: AMENDMENT OF THE REGISTRATION OF A STOCK REMEDY (SRA03)**

**Use of this form: This form (SRA03) is for amendments only, and is intended as an interim measure, which will allow amendments to be evaluated faster, as unnecessary information is not included. For amendment applications that have been submitted prior to the introduction of this form, completion of an SRA03 will be requested on a case-by-case basis (where unnecessary information has been included). For amendment applications submitted after the introduction of this form, please complete, and submit with this form.**

|  |  |
| --- | --- |
| **TRADE NAME OF PRODUCT:** |  |
| **G/REG NUMBER:** |  |

**IMPORTANT: Complete only sections 1, 2, 3, and 13, and those relevant to the amendment applied for. Cross out and initial all other sections.**

**If this is an addition, then do not include existing information, only include that which is being added.**

|  |  |
| --- | --- |
| **1. TYPE OF AMENDMENT** | **Indicate by X** |
| Change of shelf life of final product/Storage conditions/Additional stability data in support of a (previously submitted or approved) shelf life |  |
| Change of/Additional packaging material or pack size of the final product |  |
| Change in specifications of raw material or final product |  |
| Change of label, for ease of use/better understanding by users/Change of safety instructions |  |
| Change of formulation/composition |  |
| Change of/Additional source of Active Pharmaceutical Ingredient |  |
| Change of Manufacturing Process (including Quality Assurance & Control) |  |
| Change of/Additional Manufacturing Site |  |
| Change of/Additional Manufacturer |  |
| Change of Withdrawal Period |  |
| Change of/Additional Target Species (with their additional therapeutic claims and withdrawal periods) in Food-Producing Animals (FPAs) |  |
| Change of/Additional Target Species (with their additional therapeutic claims) in non FPAs |  |
| Change of/Additional Therapeutic Claim and/or dosage for FPAs, with no change in withdrawal period |  |
| Change of/Additional Therapeutic Claim and/or dosage for FPAs, with a change of withdrawal period |  |
| Change of/Additional Therapeutic Claim and/or dosage for non-FPAs |  |
| **Other amendment (not listed)** |  |
|  |  |
|  |  |
|  |  |
|  |  |
| **2. SUMMARY OF AMENDMENTS REQUESTED** | |
| **List each amendment requested (number them sequentially), with the following details under each listed amendment:**   * Describe and summarise the amendment(s) * Relevant, valid motivation for the amendment(s) * List the documentation submitted in support of the amendment(s) | |
|  | |
|  | |
|  | |
|  | |
|  | |
|  | |
|  | |
|  | |
|  | |
|  | |
|  | |
|  | |
|  | |
|  | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **3. APPLICANT DETAILS** | | | | | | |
| Corporate name of company or applicant |  | | | | | |
| Company registration number |  | | | | | |
| Name of designated contact person |  | | | | | |
| Applicant is: | Importer |  | Manufacturer |  | Other  (specify) |  |
| Applicant Physical Address |  | | | | | |
| Applicant Postal Address |  | | | | | |
| Applicant Fax no. |  | | | | | |
| Contact Person Tel no. (and area code) |  | | | | | |
| Contact Person Email Address |  | | | | | |
| Regulatory Affairs Manager Tel no (if diff from Contact Person) |  | | | | | |
| Regulatory Affairs Manager Email (if diff from Contact Person) |  | | | | | |

|  |  |  |
| --- | --- | --- |
| **4. PRODUCT DETAILS** | | |
| Designation | Trade Name: |  |
| Trade Mark: |  |
| **Description of product** | | |
| Type of formulation (e.g. injectable solution, suspension, powder, ointment, etc.) |  | |
| Route of administration (e.g. injectable, oral, spray, intramammary, etc.) |  | |
| Function of product (e.g. vaccine, anthelmintic, etc.) |  | |
| If anthelmintic, indicate coding |  |
| Target species (e.g. cattle, pigs, horses, dogs, etc.) List individually, separated by commas |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| **5. ACTIVE INGREDIENT(S) DETAILS** | | | |
| Please note: Recent proof of GMP compliancy of the manufacturer(s) must be submitted as part of the dossier | | | |
| Active Ingredient(s): (Common names) | Manufacturer:  (Name and address) | Active ingredient minimum percentage purity OR minimum titre per dose | Page Ref: |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **6. MANUFACTURER DETAILS** | | | | | | | |
| Please note: Recent proof of GMP compliancy and/or quality assurance certification of the manufacturer(s) must be submitted as part of the dossier | | | | | | | |
| Manufacturer of final product (Name): | Address: | | | | | | Page Ref: |
|  |  | | | | | |  |
|  |  | | | | | |  |
|  |  | | | | | |  |
| **Analytical Laboratory** (Indicate by X) | In-house |  | | Contract |  | | |
| Please note: Recent Proof of GLP and/or accreditation with a recognised authority must be attached and submitted as part of the dossier | | | | | | | |
|  |  | | | | | |  |
| **Packer/s** (Indicate by X) | In-house |  | Contract | | |  | |
|  |  | | | | | |  |
|  |  | | | | | |  |
| **Final Product Release Control (FPRC)** | | | | | | | |
|  |  | | | | | |  |
|  |  | | | | | |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **7. COMPOSITION** | | | | |
| Ingredients of final product   * Common name (not trade name) * For biologicals, the pathogen nomenclature + strain/type | Function (e.g. active, solvent, emulsifier, etc.) | Unit formula concentration (e.g. /dose, /ml, /tablet etc. as in dossier under Formulation) | Specifications or titre requirements (must coincide with final product release specifications as in dossier) | Page Ref |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **Veterinary vaccines with a diluent**  Full particulars of the diluent must be given in the separate table below (if applicable) | | | | |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **Other processes**  Processes (e.g. coating of tablets) etc. can be included below (if applicable) | | | | |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **8. TOXICOLOGY (Rodent)** | | | | |
| **Active ingredient(s)** | Acute Oral  (LD50 mg/kg) | Dossier Page Ref | Acute Dermal  (LD50 mg/kg) | Page Ref |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **Formulated Product (if applicable)** | Acute Oral  (LD50 mg/kg) | Dossier Page Ref | Acute Dermal  (LD50 mg/kg) | Page Ref |
| Experimental (liquids)  Calculated (powders and solids) |  |  |  |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **9. WITHDRAWAL PERIOD** | | | | | | |
| Species | | Food (e.g. meat, milk, eggs, edible tissues, etc.) | | Proposed Withdrawal Period | | Page Ref |
|  | |  | |  | |  |
|  | |  | |  | |  |
|  | |  | |  | |  |
|  | |  | |  | |  |
|  | |  | |  | |  |
| **Residue Studies** (Formulation as applied for) | | | | | | |
| Active ingredient: | Species (used in residue depletion studies) | | Target tissue (e.g. meat, milk, fat, liver, kidneys, eggs, etc.) | | Lowest MRL used for calculating Withdrawal Period | Page Ref |
|  |  | |  | |  |  |
|  |  | |  | |  |  |
|  |  | |  | |  |  |

|  |  |  |
| --- | --- | --- |
| **10. PACKAGING DETAILS** | | |
| **Immediate containers** | | |
| Volume/quantity per pack | Packaging material/container (e.g. glass/HDPE vial, bottle, blister pack, etc.) | Page Ref |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| Method of closure of immediate containers |  | |
| **Secondary containers** | | |
| Pack size(s)/Number of units in each | Packaging material/container (e.g. box, etc.) | Page Ref |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| **Description of how the package insert is presented** |  | |

|  |  |  |
| --- | --- | --- |
| **11. SHELF LIFE** | | |
| Indicate Conditions (e.g. Temp/Humidity) |  | |
| Pack size(s) | Stability of product (years/months) | Page Ref |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **IMPORTANT: Please complete the section below accurately and completely, as it impacts on other legislation within DALRRD** | | | | |
| **12. CONTROLLED DISEASES** | | | | |
| Are claims of treatment or prevention of a controlled or notifiable disease  (Act 35 of 1984) being made: | Yes |  | No |  |
| If yes, list the controlled or notifiable diseases: | | | | |
|  | | | | |
|  | | | | |

|  |  |  |
| --- | --- | --- |
| **13. DECLARATION BY APPLICANT OR THE DULY APPOINTED REPRESENTATIVE** | | |
| Trade Name of Product: |  | |
| For and on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (company name in South Africa), I hereby certify that the above mentioned information and the data provided in support of this application are to the best of my knowledge true, correct and complete. | | |
| Name in full (printed) | | Signature |
| Date: | | Official title: |
| Official Stamp of Applicant/Company: | |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FOR OFFICIAL USE ONLY** | | | | |
| **Registration is:** | Recommended |  | Not Recommended |  |
| Technical Adviser: |  | | | |
| Date: |  | | | |