# Drug Submission Application Form for: Human, Veterinary or Disinfectant Drugs and Clinical Trial Application/Attestation[[1]](#footnote-1)

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| **Part 1 - Manufacturer/Sponsor and Drug Product Information** |
| **Health Canada Use Only[[2]](#footnote-2):**  | 1. Submission No.  | 2. Responsible Area | 3. File No. | 4. Date of Receipt |
| YYYY | MM | DD |
|  |  |  |  |  |  |  |  |
| 5. Type of Submission | 6. Number of Volumes / Compact Discs | 7. Schedule and/or Prescription Status |
| 8. Brand or Proprietary or Product Name (should be the same as the brand name on the product label):  |
| 9. Proper, Common or Non-Proprietary Name: |
| **A) Manufacturer/Sponsor (In cases where a DIN/Notice of Compliance (NOC) is issued, this will be the DIN/NOC Owner)** **(For CTA, CTA-A, VIND and VIND-AM, refer to attached Guidance)** |
| 10. Company Code | 11. Manufacturer/Sponsor Name (Full Legal Name - No Abbreviations):  |
| 12. Street/Suite | 13. City/Town | 14. Prov./State | 15. Country | 16. Postal/ZIP Code |
| **Contact Person for Manufacturer/Sponsor (In cases where a DIN/NOC is issued, this is the DIN/NOC Owner contact)** |
| 17. Name | 18. Telephone No. | 19. Fax No. | 20. Language Preferred  English  French |
| 21. Title  | 22. E-mail |
| **B) Contact for THIS Drug Submission** |
| 23. Company Name (Full Name - No Abbreviations) |
| 24. Street/Suite/Post Office Box | 25. City/Town | 26. Prov./State | 27. Country | 28. Postal/ZIP Code |
| 29. Name | 30. Telephone No. | 31. Fax No. | 32. Language Preferred  English  French |
| 33. Title  | 34. E-mail |
| **C) Regulatory Mailing Address (Complete where a DIN is to be issued, refer attached Guidance)** | **Same as A Above ****N/A (Not Applicable): ** |
| 35. Company Name (Full Name - No Abbreviations) |
| 36. Street/Suite/Post Office Box | 37. City/Town | 38. Prov./State | 39. Country | 40. Postal/ZIP Code |
|  **Regulatory Mailing Contact** | **Same as A Above ** |
| 41. Name | 42. Telephone No. | 43. Fax No. | 44. Language Preferred  English  French |
| 45. Title  | 46. E-mail |
| **D) Canadian Importer (Complete ONLY where Address in A is not in Canada. EXCEPTION for CTAs, see footnote)[[3]](#footnote-3)** | **Same as C Above ** |
| 47. Name of Importer (Full Name - No Abbreviations) |
| 48. Street/Suite/Post Office Box | 49. City/Town | 50. Province | 51. CountryCANADA | 52. Postal Code |
| **E) Address to which the Drug Notification Form (DNF)/NOC are to be sent:** | **As Above: A:  B:  C:  D: ****N/A: ** |
| **53. Related Submissions (referred to in this submission):** |
| **A)** Type | Control No. | Brand Name | Manufacturer/Sponsor Name | File No. | Date Cleared |
| Associated DIN(s) :Reason for Submission: |
| Attach separate sheets (same format) if necessary. Number of pages attached: \_\_\_\_\_\_\_\_ |
| **Part 2 - Drug Product Formulation Information** |
| 54. Proposed Shelf Life years months at o C. |
| 55.Country(ies) of Manufacture |
| 56. Medicinal (Active) Ingredient(s) **-** If the ingredient was sourced from Animal/Human, complete and submit Appendix 4.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **CAS No. (if applicable)** | **Ingredient Name** | **Standard** | **Strength** | Units | **Per** | **Calculated as Base?** | **Animal/ Human Source** |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** | ⁭ **Yes** | ⁭ **No** |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** | ⁭ **Yes** | ⁭ **No** |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** | ⁭ **Yes** | ⁭ **No** |

 |
| 57. Non-medicinal Ingredient(s) -If the ingredient was sourced from Animal/Human, complete and submit Appendix 4.For formulation variations pertaining to the same DIN (for example [e.g.] multiple flavourings, colours, fragrances), fill out the variant name and list all the non-medicinal ingredients for each variant type.Variant Type [if applicable]: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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| --- | --- | --- | --- | --- | --- | --- |
| **CAS No. (if applicable)** | **Ingredient Name** | **Standard** | **Strength** | Units | **Per** | **Animal/ Human Source** |
|  | **A) Preservatives** |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** |
|  | **B) Colouring Agents** |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** |
|  | **C) Other[[4]](#footnote-4)** |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** |
|  | **D) Capsule Shell Ingredients (if applicable)**  |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** |
|  |  |  |  |  |  | ⁭ **Yes** | ⁭ **No** |

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| 58. Animal and/or Human Sourced Material(s) Used at Any Stage in the Manufacture of the Drug - If the material was sourced from Animal/Human, complete and submit Appendix 4.

|  |  |  |  |
| --- | --- | --- | --- |
| **CAS No. (if applicable)** | **Material Name** | **Standard** | **Present in Final Container** |
|  |  |  | ⁭ **Yes** | ⁭ **No** |
|  |  |  | ⁭ **Yes** | ⁭ **No** |

 |
| 59. Is any ingredient listed under Section 56 or 57 a Nanomaterial?  Yes  NoIf Yes, provide the name of the ingredient: |
| 60. Dosage Form |
| 61. Container Type Package Size |
| 62. Therapeutic/Pharmacological Classification  |
| 63. Route(s) of Administration |
| 64. Drug Product  Biologic /  Radiopharmaceutical  Pharmaceutical  Disinfectant  Drug and Medical Device |
| 65. Drug Use  Human [  Paediatric (0-18 years of age)  Adult ]  Radiopharmaceutical  Veterinary   Disinfectant [  Hospital  Food Processing  Domestic  Barn  Institutional/Industrial  |
| 66. Is this a Non-prescription drug to which one or more Schedule A claims apply?  Yes  NoIf Yes, complete and attach the Schedule A Form (Appendix 5). |
| 67. Proposed Indication/Use |
| 68. Proposed Dosage (by age / species - include maximum daily dose) |
| 69. Draft of Proposed Canadian Labels (inner and outer) enclosed?  Yes  No Package Insert enclosed?  Yes  NoFor CTAs, CTA-As, VINDs and VIND-AMs labels should not be submitted unless requested by the appropriate Directorate. |
| 70. Rationale for all SNDS, SANDS,EU SNDS, EU SANDS (all human drug types); (VSNDS), (VSANDS) (all veterinary drug types); or for biological drug DIN submissions  |
| ☐ New route of administration, dosage form and/or strength☐ New claims/use, indications, recommended administration or dosage regime☐ Change in formulation or method of manufacturing with clinical/bio data☐ Change in drug substance/product (site, method, equipment, process control) | ☐ Replace sterility test with process parametric release ☐ Confirmatory studies☐ Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 71. Type of Notifiable Change (NC) (for Biologic or Radiopharmaceutical drug quality changes) (if applicable)  |
| ☐ Change in specifications (medicinal or non-medicinal ingredient,pharmaceutical form, analytical method)☐ Change in expiry period/storage conditions☐ Change in manufacturing method☐ Change in manufacturing site | ☐ Change in container size for parenteral drug☐ Change in packaging specifications for parenteral/inhalation drug☐ Change in packaging material composition☐ Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Complete Sections 72 - 74 for Veterinary Products only** |
| 72. Species and Subtypes Recommended for use | 73. Used for treatment of food-producing animals?  Yes  No |
|  \_ \_ \_ | 74. Withdrawal TimeSpecies \_ \_ \_ | Days \_ \_ \_ | Hours \_ \_ \_ |

**I, the undersigned, certify that the information and material included in this drug submission application is accurate and complete[[5]](#footnote-5).**

|  |  |  |
| --- | --- | --- |
| 75. Name of Authorized Signing Official | 76. Signature | 77. Date |
|  |  | YYYY | MM | DD |
|  |  |  |  |  |  |  |  |
| 78. Title | 79. Telephone No. | 80. Fax No. |
| 81. Name of Company to which the Authorized Signing Official Belongs |

**Appendix 1 - for Clinical Trial Applications and Amendments only**

**Template Authorisation for a Third Party to Import the**

**New Drug Described in this Clinical Trial Application or Amendment[[6]](#footnote-6)**

I, authorize .

 (list each applicable importer [name and address],

 .

 add more space as necessary or attach a list of importers)

 attached list of importers □ Yes □ No

to import the new drug for the purposes of the clinical trial described within this application.

 **Signed:** .

 **Print name:** .

 **Title:** .

 **Clinical Trial Sponsor:** .

 **Date:** .

**Appendix 2 - For All Applications**

**Template Authorisation for a Third Party To Sign/File a Drug Submission**

 **Application on Behalf of the Manufacturer/Sponsor[[7]](#footnote-7)**

I, authorize .

 (third party person)

of to file a drug submission

 (third party company name)

application for on behalf of

 (name of product)

 .

 (Manufacturer / Sponsor Name- Section 11 on application)

 **Signed:**  .

 **Print name:**  .

 **Title:**  .

 **Manufacturer/ Sponsor:** .

 **Date:** .

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| **Appendix 3 - Clinical Trial Application Information****(for Clinical Trial Applications for human drugs only)** |
| 82. Clinical Trial Protocol Number (must be assigned) | 83. Clinical Trial Protocol Title |
| 84. Is the investigational product obtained from the Canadian market?   Yes DIN(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No Country(ies) obtained:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 85. Anticipated Clinical Trial Composition (check all that apply): Paediatric population (0-18 years of age)  Females  Males Adult population   Females  Males | 86. Phase of Clinical Trial (check appropriate box): Phase I - bioequivalence study (7-day administrative target) Phase I - study in healthy humans (30-day default) Phase I - other (30-day default) Phase II (30-day default) Phase III (30-day default) Other (please specify): \_ |
| 87. Information regarding Research Ethics Board that has refused to approve the protocol and/or informed consent form enclosed?  Yes  No  N/A  Not known at this time |
| 88. Clinical Trial Site Information Form enclosed for all sites known at time of application?  Yes  No  No sites are known at this time |

In respect of the clinical trial identified in Appendix 3 of this Drug Submission Application form we certify that:

1. The information and material contained in, or referenced by, this application are complete and accurate and are not false or misleading.
2. If requested by Health Canada, additional information or samples required to assess this application will be provided within two calendar days following receipt of the request from Health Canada.
3. The clinical trial will be conducted and the drug used in accordance with the protocol and the requirements set out in Division 5 of the *Food and Drug Regulations* or the *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19*, for the period of 1 year from the coming into force date*.* The clinical trial will be conducted in accordance with good clinical practices.
4. For applications filed under Division 5 of the *Food and Drug Regulations*, the trial or amendment will not commence at any site until receipt of a No Objection Letter from the Therapeutic Products Directorate or the Biologic and Radiopharmaceutical Drugs Directorate of Health Canada, or the elapse of 30 calendar days following receipt of the complete application by Health Canada, whichever comes first, and the receipt of the Research Ethics Board Approval.

The *Order Respecting Certain Time Limits under the Food and Drugs Act (COVID-19)* extends the default period for review of applications and amendments made under Division 5 of the *Food and Drug Regulations* (FDR) from 30 days to 45 days. It will be in place for all complete applications received by Health Canada on or prior to November 16, 2020.

For applications submitted under the *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19*, the trial or amendment will not commence at any site until receipt of a Notice of Authorization from the Therapeutic Products Directorate or the Biologic and Radiopharmaceutical Drugs Directorate of Health Canada, and the receipt of Research Ethics Board Approval.

1. Records will be maintained for a period of 25 years and will be accessible for on-site inspection by Health Canada Inspectors.

|  |  |  |  |
| --- | --- | --- | --- |
| 89. Senior Medical Officer or Scientific Officer in Canada | 90. Tel. No. and Address | 91. Signature | 92. Date |
| YYYY | MM | DD |
|  |  |  |  |  |  |  |  |
| 93. Senior Executive Officer | 94. Tel. No. | 95. Signature | 96. Date |
| YYYY | MM | DD |
|  |  |  |  |  |  |  |  |

**Appendix 4 - Drug Product Formulation Information –**

**Animal and/or Human-Sourced Ingredients / Materials**

**If you have checked “No” for *all* the questions listed in section 56, 57, and 58, thereby indicating that there are *no* animal and/or human-sourced ingredients, then do not complete this appendix.**

Please complete a separate Appendix 4 for ***each*** individual ingredient and/or material used at any stage in the manufacture of the drug product that was identified as animal and/or human-sourced in ‘Part 2 - Drug Product Formulation Information’ of the Drug Submission Application form.

Attach separate sheets (same format) if necessary. Number of pages attached: **\_\_\_**

|  |  |
| --- | --- |
| 97. Ingredient/Material Name: | 98. Used As: Medicinal (Active) Ingredient Non-Medicinal Ingredient Material used at any stage in the Manufacture of the drug |
| 99. Sourced from:  Human  Animal Animal Species (please specify) |
|  Non-human primates \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Aquatic species such as fish, molluscs and crustaceans \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Avian such as chicken, turkey and duck \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Bovine such as cattle, bison \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Canine \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Caprine such as goat \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Cervidae such as deer, elk (wapiti) and moose \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Equine such as horse \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Feline such as cat \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Ovine \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Porcine such as pig \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Rodents such as mouse, hamster, rat and rabbit \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Controlled population Yes No | Biotechnology-Derived Animal Yes No  | Cell Line Yes No |

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| 100. Tissues or Fluids of Origin: |
| **Nervous system** brain  brain stem cerebellum cerebrospinal fluid dorsal root ganglia dura mater hypothalamus retina/optic nerve spinal cord trigeminal ganglia other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Digestive system** appendix bile distal ileum large intestine saliva/salivary gland small intestine other than distal ileum stomach other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Reproductive and urinary systems** colostrum kidney mammary glands milk/milk products ovaries  placenta placental fluid semen testes urine other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Cardio-respiratory system** heart/pericardium lung nasal fluid tracheaother (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Immune system** lymph nodes spleen thymus tonsils other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Skin and glandular system**adrenal gland or tissue hair, feathers, hooves liver pancreas pituitary gland skin/hides thyroid/parathyroid other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Musculo-skeletal system**  abdomen bones (other than vertebral column and skull) collagen muscle (please specify) ­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ skull tendons/ligaments vertebral column other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Other tissues or Fluids of origin**: adipose tissue/omentum (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ascites antler velvet serum whole blood  plasma embryonic tissue fetal tissue bone marrow eyes/cornea  gall bladder other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

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| 101. Age of animals (in months):  |
| 102. Country/Countries of origin of animal(s): |

**Appendix 5 - Schedule A Form for Nonprescription Products**

**(excluding Natural Health Products)**

Please note that this form is only to be completed for nonprescription products that have associated Schedule A claims.

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| **Part A - Drug Product Identification** |
| 103. Manufacturer/Sponsor: | 104. Product Name: | 105. Drug Identification Number (DIN), if issued: |

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| **Part B – Schedule A Information** |
| 106. Please check the disease(s)/disorder(s) that apply to the claims made. |
|  Acute alcoholism Acute infectious respiratory syndromes Acute psychotic conditions Appendicitis Asthma Congestive heart failure Dementia Diabetes Glaucoma Hepatitis Nausea and vomiting of pregnancy Rheumatic fever Sexually transmitted diseases Thrombotic and Embolic disorders Ulcer of the gastro-intestinal tract |  Acute anxiety state Acute inflammatory and debilitating arthritis Addiction (except nicotine addiction) Arteriosclerosis Cancer Convulsions Depression Gangrene Haematologic bleeding disorders Hypertension Obesity Septicemia Strangulated hernia Thyroid disease |

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| **Part C - Schedule A Claims/Indications** |
| 107. Please list the Schedule A Claims/Indications associated with this product: |

1. The Guidance Document: Health Canada 3011: Drug Submission Application Form for: Human, Veterinary or Disinfectant Drugs and Clinical Trial Application/Attestation provides instructions on each field of the form. Please read it in its entirety prior to completing the form. [↑](#footnote-ref-1)
2. Shaded areas are for Health Canada use only. [↑](#footnote-ref-2)
3. For clinical trial applications (human drugs), if clinical trial drugs are to be imported into Canada, importers should be authorized by the sponsor, **regardless of the sponsor's location**. Appendix 1 should be completed and submitted for each importer in Canada. Canadian importer(s) must be located within Canada. Refer to the attached guidance and the “Guidance for Clinical Trial Sponsors” for roles and responsibilities. [↑](#footnote-ref-3)
4. For products regulated solely by Division 1: state the purpose of any non-medicinal ingredient(s) included under “Other” on a separate attached sheet. [↑](#footnote-ref-4)
5. If the signing official is a third party acting on behalf of the manufacturer/sponsor identified in section 11, a letter of authorization, signed by the manufacturer/sponsor (section 11), must be filed with the completed submission application form (see Appendix 2). [↑](#footnote-ref-5)
6. Submit with application if the clinical trial sponsor is authorizing one or more third parties to import the new drug for the purposes of the clinical trial described within this application. An authorisation is required for each clinical trial application. As additional importers are identified, additional copies of Appendix 1 should be provided to Health Canada. If the importer has not changed when a clinical trial application amendment is filed, Appendix1 does not need to be re-submitted. [↑](#footnote-ref-6)
7. Submit with application only if party signing the application is a third party acting on behalf of the Manufacturer/Sponsor identified in section 11. A separate authorisation is required for each application. [↑](#footnote-ref-7)