**Drug Submission Application Form for:**
**Human, Veterinary or Disinfectant Drugs and**
**Clinical Trial Application/Attestation**

The attached Drug Submission Application form is designed to assist manufacturers and sponsors in submitting information required to initiate the evaluation of any one of the following types of submissions:

- Clinical Trial Application (CTA) (human drugs)
- Clinical Trial Application Amendment (CTA-A) (human drugs)
- Veterinary Investigational New Drug (VIND) (veterinary drugs)
- Veterinary Investigational New Drug Amendment (VIND-AM)(veterinary drugs)
- New Drug Submission (NDS)
- Supplement to a New Drug Submission (SNDS)
- Abbreviated New Drug Submission (ANDS)
- Supplement to an Abbreviated New Drug Submission (SANDS)
- Notifiable Change (NC)
- Drug Identification Number (DIN) Application (Division 1)
- Post-Authorization Division 1 Change
- Administrative Change (only applies to manufacturer/sponsor and/or product name change and licensing agreements).

**The attached Guidance Document provides instructions on each field of the form. Please read it in its entirety prior to completing the form.**

**For Drug Identification Number applications, a separate completed HC/SC 3011 must be provided for each formulation, strength and dosage form. For all other submission types, only a separate completed Part 2 must be provided for each formulation, strength and dosage form.**

**Note:** Additional or supplementary information for a submission already filed need only be accompanied by a copy of the letter from Health Canada requesting additional information.

**This page does not form part of the application**

## Guidance for Completing the Drug Submission Application Form

| Section # | GUIDANCE | SUNNYBROOK SPECIFIC GUIDANCE |
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| Cover page | Clinical Trial Applications and Amendments for human drugs should be sent **directly to the applicable Directorate** as follows:<br><br>**Pharmaceutical Drugs**<br>Office of Clinical Trials<br>Therapeutic Products Directorate<br>Health Canada<br>5th Floor, Holland Cross, Tower B<br>Address Locator: 3105A<br>1600 Scott Street<br>Ottawa, Ontario, Canada K1A 0K9<br><br>**Biological/Radiopharmaceutical Drugs**<br>Biologics and Genetic Therapies Directorate<br>Regulatory Affairs Division<br>Health Canada<br>Address Locator: 0701A<br>200 Tunney's Pasture Driveway<br>Ottawa, Ontario, Canada K1A 0K9<br><br>Investigational New Drug Submissions and amendments and all other submissions for **Veterinary Drugs** should be sent directly to the Veterinary Drugs Directorate as indicated on the cover page. | TPD for Schedule F (prescription drugs) and Schedule Ethical (non-prescription drugs).<br><br>BGTD for Schedule C (radiopharmaceuticlas) and Schedule D (biologicals) |
| | **PART 1 - Manufacturer/Sponsor and Drug Product Information** | |
| 1-4 | Health Canada Use Only | |

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| 5 | The type of submission being presented to Health Canada. Allowable entries are:<br>1. CTA (Clinical Trial Application)<br>2. CTA-A (Clinical Trial Application Amendment)<br>3. NDS (New Drug Submission)<br>4. SNDS (Supplemental New Drug Submission)<br>5. ANDS (Abbreviated New Drug Submission)<br>6. SANDS (Supplemental Abbreviated New Drug Submission)<br>7. NC (Notifiable Change)<br>8. DIN (Drug Identification Number submission - all types[1])<br>9. PDC (Post-Authorization Division 1 Change[2])<br>10. ADMIN (Administrative manufacturer name/product name change/licensing agreements)<br>11. VIND (Veterinary Investigational New Drug)<br>12. VIND-AM (Veterinary Investigational New Drug Amendment)<br>13. VNDS (Veterinary New Drug Submission)<br>14. VSNDS (Veterinary Supplemental New Drug Submission)<br>15. VANDS (Veterinary Abbreviated New Drug Submission)<br>16. VSANDS (Veterinary Supplemental Abbreviated New Drug Submission)<br>17. VNC (Veterinary Notifiable Change)<br>18. VDIN (Veterinary Drug Identification Number submission - all types[3])<br>19. VPDC (Veterinary Post-Authorization Division 1 Change[7])<br>VADMIN (Veterinary Administrative manufacturer name/product name change/licensing agreements) | CTA (Clinical Trial Application)<br><br>OR<br><br>CTA-A (Clinical Trial Application Amendment) |
| 6 | Where applicable, state the number of volumes contained in the drug submission. Indicate the number of original volumes, followed by the number of duplicate copies. | 1/1 |
| 7 | **Schedule:** Complete only if the drug is included in **Schedule C** (radiopharmaceuticals) and/or **Schedule D** (biologicals) to the *Food and Drugs Act*, **Schedule F** (prescription drugs) to the *Food and Drug Regulations* and please identify if the product falls under the *Controlled Drugs and Substances Act* (CDSA). | |

1 Drug Identification Number (DIN) submissions for pharmaceutical, biological and disinfectant drugs that are not subject to Division 8, Part C of the *Food and Drug Regulations* (that is, that are not considered to be new drugs).

2 Post-Authorization Division 1 Change / Veterinary Post-Authorization Division 1 Change (PDC/VPDC) is a notification process for changes to previously authorized Division 1 drugs (other than those requiring an amended Drug Identification Number/Veterinary Drug Identification Number (DIN/VDIN) application)

3 Veterinary Drug Identification Number (DIN) submissions for pharmaceutical and disinfectant drugs that are not subject to Division 8, Part C of the *Food and Drug Regulations* (that is, that are not considered to be new drugs)

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| 8 | The **brand** or proprietary or product name is the name assigned by the manufacturer/sponsor to distinguish the drug (product) and under which the drug is to be sold/advertised. The brand name is also the name used to identify the product in all correspondence related to the submission and on the product label(s) and Product Monograph/Package Insert if applicable. If the brand name has not yet been determined, e.g. CTA, VIND, or NDS submissions, the proper or common name of the drug or the research code may be used.<br><br>**For CTAs, CTA-As, VINDs and VIND-AMs,** please enter the name of the investigational product. Where more than one investigational product manufactured by the sponsor is used in the clinical trial, all of them should be captured and a separate Part 2 should be completed for each one of them. If the manufacturer of the investigational product is not the sponsor of the trial, at least Section 56 must be completed. (Note: an investigational product corresponds to a product involved in the conduct of a clinical trial. It could be a product not available in Canada, a product in development or a product already approved in Canada but used outside the approved indication.)<br><br>**If *after* filing a NDS, ANDS, DIN, VNDS, VANDS or VDIN submission, but *prior to* completion of submission review, you wish to change the brand name identified in the filed application form, submit written notice of the proposed change to the same address to which the original application was sent (see cover page), with a note of the submission number and original product name.** If you wish to change the product name after the submission has been cleared, refer to the Health Canada policy "Changes in Manufacturer's Name and/or Product Name". | |
| 9 | The **proper name** for a product is the name assigned to the drug in Section C.01.002 of the *Food and Drug Regulations*, or in boldface type in other Sections of the *Regulations*, or the name of the drug in its finished form identified in the title of a monograph, or in any of the official publications listed in Schedule B to the *Food and Drugs Act*.<br>Example: Acetaminophen<br>Ferrous Sulphate Tablets<br><br>The **common name** is the name by which a single ingredient drug is commonly known/designated in scientific or technical journals **other than** the publications referred to in Schedule B to the *Food and Drugs Act*. The common name includes the pharmaceutical form when used in relation to the finished drug product.<br><br>If there is no proper name and the drug is comprised of a single medicinal ingredient, enter the common name. If there is no proper name and the drug is comprised of more than one medicinal ingredient, all common names should be captured. For a clinical trial application, **all** the active substances which are investigational should be listed and separated by slashes (/). | |

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| **Block A** | **Manufacturer/Sponsor Information:** The information to be provided in Block A (10-22) pertains to the manufacturer/sponsor in whose name the drug submission is filed and, where a Drug Identification Number (DIN)/Notice of Compliance (NOC) is to be issued, **the company in whose name the DIN/NOC will be registered, (that is [i.e.], the DIN/NOC owner) and whose name must be included on the product label and Product Monograph/Package Insert.**<br><br>**For CTAs and CTA-As**, sponsor is defined by Division 5, Part C of the *Food and Drug Regulations* as the individual, corporate body, institution or organization that conducts a clinical trial. Indicate the full name of the sponsor in whose name the subject CTA or CTA-A is being filed. Do not abbreviate the sponsor's name. Note that the sponsor is not necessarily the company that fabricates the drug product. For Investigator-initiated CTAs and CTA-As: if the sponsor is defined as an individual, please also indicate the name of the affiliated institution/organization<br>**For VINDs and VIND-AMs**, the same definition of sponsor applies. | |
| 10 | **Company code:** Where known, enter the 4- or 5- digit company code assigned by Health Canada, to the manufacturer/sponsor company e.g. 4567. **If unknown, please leave this section empty**. | |

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| 11 | Indicate the **full legal** name of the manufacturer/sponsor in whose name the subject drug submission is being filed and, where applicable, **in whose name the DIN/NOC is to be registered**. Do not abbreviate the company name. Note that the manufacturer/sponsor is not necessarily the company that fabricates the drug product. Please be advised not to use the wording or abbreviation " dba - doing business as" in the Manufacturer/sponsor name e.g. Hamilton Brothers dba Hamilton Family. Companies can either enter Hamilton Brothers or Hamilton Family or they can enter Hamilton Brothers a division of Hamilton Family.<br><br>**If *after* filing a NDS, ANDS, DIN, VNDS, VANDS or VDIN submission and *prior to* completion of submission review, you wish to change the manufacturer/sponsor name, submit written notice of the change to the same address to which the original application was sent (see cover page), with a note of the submission number and original manufacturer/sponsor name.** If you wish to change the manufacturer/sponsor name after the submission has been cleared, refer to the Health Canada policy "Changes in Manufacturer's Name and/or Product Name". Note also that such an Administrative Change submission that cross-references the original NDS, ANDS, VNDS or VANDS must be submitted and cleared before changing the manufacturer/sponsor name for an already filed SNDS, SANDS, NC, VSNDS , VSANDS, or VNC submission<br><br>**For CTAs and CTA-As**, sponsor is defined by Division 5, Part C of the *Food and Drug Regulations* as the individual, corporate body, institution or organization that conducts a clinical trial. Indicate the full legal name of the sponsor in whose name the subject CTA or CTA-A is being filed. Do not abbreviate the sponsor's name. Note that the sponsor is not necessarily the company that fabricates the drug product. For Investigator-initiated CTAs and CTA-As: if the sponsor is defined as an individual, please also indicate the name of the affiliated institution/organization.<br><br>**For VINDs and VIND-AMs**, the same definition of sponsor applies. | **For CTA's:**<br>'Sunnybrook Research Institute'<br><br>**For CTA-A's:**<br>Same as original CTA. Refer to the original CTA for your clinical trial. |
| 12-16 | Provide the **full** mailing address of the manufacturer/sponsor identified in Section 11. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (12), the city/town (13), the province/state (14), the country (15) and the postal or zip code (16). It is not allowed to use a Post Office (PO) Box instead of street/suite to describe the manufacturer's/sponsor's address. | Address of the Qualified Investigator (or Scientific Officer/Investigator) at Sunnybrook Research Institute. |

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| 17-22 | Provide the name of the principal contact (17) located at the address (12-16) of the manufacturer/sponsor company identified in Section 11 and the information needed to contact that individual, i.e., telephone and fax numbers (18-19), position/title (21), e-mail address (22), and if applicable, language preference (20).<br><br>Operational and system requirements dictate that this name must be the same for all DINs registered to the manufacturer/sponsor identified in Section 11 where more than one DIN is held by that company. **Note that this is NOT necessarily the contact for the subject drug submission but the *principal* contact for the given manufacturer/sponsor at the address given**.<br><br>**Due to short performance target associated with clinical trials in Canada, this section provides another contact person in case the contact listed in Block B cannot be reached.** | Name of Qualified Investigator (or Scientific Officer/Investigator) and their Sunnybrook contact information. |
| **Block B** | **Contact for the subject drug submission:** Information provided in Block B (23-34) pertains to **the contact specific to the subject drug submission**, i.e., the person/company to whom Health Canada should direct correspondence about the subject submission. To avoid confusion, **Block B *must* be completed even if the submission contact is identified under another role.** | Contact for this drug submission may be an individual at Sunnybrook (name and contact information) such as the research coordinator or nurse.<br><br>OR<br><br>The name and contact information associated with a contracted Clinical Research Organization, if applicable.<br><br>****NOTE:** If there are any questions related to the submission, this is the person that will be contacted by Health Canada and therefore should be an individual that is accessible. |
| 23 | Enter the name of the company to which the drug submission contact belongs (i.e., is a staff member). Do not abbreviate the company name. If the contact does not belong to a company, enter the name of the contact. | |
| 24-28 | Enter the address of the company identified in Section 23. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (24), the city/town (25), the province/state (26), the country (27) and the postal or zip code (28). Include the PO Box number (24) if a post office box is used. | |
| 29-34 | Provide the name of the contact for the subject drug submission (29), i.e., the name of the individual to whom Health Canada should direct correspondence about the subject drug submission. Provide the information needed to contact that individual, i.e., telephone and fax numbers (30-31), position/title (33), e-mail address (34), and if applicable, language preference (32). Please note that it is the discretion of Health Canada to decide the method of correspondence. | |

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| **Block C** | **Regulatory Mailing Address:** The information to provide in Block C (35-46) pertains to where and to whom Health Canada should direct regulatory mail **other than correspondence specific to the subject drug submission (Block B)**, e.g. annual notification, regulatory/policy amendment notices as they apply to DINs registered to the manufacturer/sponsor identified in Section 11. Check "Same as A above" or, if different, complete Sections 35-46. Operational and system requirements dictate that the regulatory mailing name/address must be the same for all DINs registered to the manufacturer/sponsor identified in Section 11 where more than one DIN is held by that company.<br><br>**For CTAs, CTA-As, VINDs and VIND-AMs, check N/A if Block C is not applicable. If N/A has been checked, the remaining fields should be empty.** | Indicate N/A (Not Applicable) |
| 35 | Enter the **full** name of the company who will act on behalf of the manufacturer/sponsor identified in Section 11 with respect to processing of regulatory mail issued by Health Canada e.g. annual notification, regulatory/policy amendment notices as they apply to DINs registered to the manufacturer/sponsor identified in Section 11. | |
| 36-40 | Enter the address of the company identified in Section 36. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (36), the city/town (37), the province/state (38), the country (39) and the postal or zip code (40). Include the PO Box number (36) if a post office box is used. | |
| 41-46 | Provide the name of the principal contact located at the address identified in Sections 36-40 and the information needed to contact that individual, i.e., telephone and fax numbers (42-43), position/title (45), e-mail address (46), and if applicable, language preference (44). Please note that it is the discretion of Health Canada to decide the method of correspondence. | |
| **Block D** | **Canadian Importer:** is responsible for the sale of this product in Canada. Complete Block D (47-52) only if the address of the manufacturer/sponsor identified in Sections 11-16 is NOT located in Canada. If the company is the same as that identified in Section 35, check "Same as C above", or, if different, complete each part of Block D.<br><br>**Exception for CTAs and CTA-As**, 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. List each applicable importer authorized to import the new drug for the purposes of the trial outlined in the application. Canadian importer(s) must be located within Canada. Refer to the "Guidance for Clinical Trial Sponsors" for further details. 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 (CTA-A) is filed, Appendix 1 does not need to be re-submitted. | Leave all fields blank if the clinical trial drug(s) will not be imported. |

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| 47 | Enter the full name of the Canadian Importer. Canadian importer(s) must be located within Canada. | |
| 48-52 | Enter the address of the company identified in Section 47. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (48), the city/town (49), the province (50), and the postal code (52). Do not edit/change the country name "Canada" in section 51. | |
| **Block E** | If a DIN or NOC is to be issued, indicate to which one of the above addresses the Drug Notification Form (DIN) or NOC should be sent, i.e., the address in Block A, B, C or D. Check all applicable options. | Indicate N/A (Not Applicable) |
| 53 | Where **related drug submissions** (e.g. a CTA preceding a CTA-A, a CTA preceding a NDS, an NDS relevant to a CTA, the parent NDS for a SNDS or a DIN preceding a PDC) are referenced in the subject drug submission, provide the submission type (see section 5 above), the control number (submission number), the brand name of the drug, the manufacturer/sponsor of the related submission, the file number for the related submission, the date cleared, associated DINs (if any) and the reason for the related submission (e.g. brief protocol description of a CTA, reason for supplement, etc.).<br><br>The proper, common or non-proprietary name should be entered if the Brand Name was unknown at the time of the application. Only applications referenced in the subject drug submission should be listed under this section. Duplicate and complete section 53 in its entirety as necessary.<br><br>Associated DIN(s): Enter the DINs of the products (if any) that are directly affected by the current submission. This will help locate the product to update any changes, e.g., updating the Product Monograph or other information in Drug Product Database (DPD). If there is no DIN issued for the product, please enter N/A for not applicable. | Include previous submissions (CTA/CTA-A) for the same study and their corresponding information as indicated in the table.<br><br>OR<br><br>Any related submissions for a different study that should be referenced (phase I/phase II).<br><br>****NOTE:** Ensure this information is referenced in Section 1.7.4 "Information on Prior-related Applications" CTA/CTA-A package and Table of Contents. Recommend including at a minimum the NOL for previous submissions for the same study.<br><br>In the case of related submissions for a different study, recommend providing a 1-page summary of the relationship between the 2 studies and the NOL if available. |
| | **PART 2 - Drug Product Formulation Information** | |
| 54 | The proposed expiry/shelf life is the length of time in years and months up to which the drug product maintains its labelled potency, purity and physical characteristics.<br><br>**For CTAs, CTA-As, VINDs and VIND-AMs**, it is not necessary to fill in this section if the drug product to be used in the clinical trial is marketed in Canada or if the investigational product used is for a Bioequivalence/Bioavailability study. | Leave Blank |

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<td>55</td>
<td>Provide the name of the country(ies) where the final dosage form of the drug product is manufactured/fabricated, e.g., if the drug product is in the dosage form of a tablet or solution, enter the country(ies) where the tablet or solution was fabricated. This may not necessarily be the country(ies) where the product is packaged/labeled.<br><br>For CTAs, CTA-As, VINDs and VIND-AMs, please indicate N/A if the manufacturer of the investigational product is not the sponsor of the trial.</td>
<td>Indicate N/A (Not Applicable) for pharmaceuticals and biologics that are marketed or approved in Canada.</td>
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<td>56</td>
<td>List the medicinal (active) ingredient(s) that contribute to the proposed use of the product, by its/their proper or common name(s). Where the standard of manufacture of an ingredient complies with a Schedule B compendial standard, use the applicable abbreviation for that compendium, e.g. United States Pharmacopeia (USP), British Pharmacopoeia (BP). Where the specifications for ingredient manufacture deviate from and exceed or are equivalent to the compendial standard, manufacturer’s standard (Mfr Std) may be indicated. Please enter N/A if no compendial standard exists for the active ingredient.<br><br>The strength of the medicinal (active) ingredient(s) should be expressed as follows:<br><br>Discrete pharmaceutical forms (e.g. tablet) - g or mg / pharmaceutical form<br>Powder for oral use - g or mg/mL, g or mg / dosage unit (e.g. /5mL)<br>Liquid for parenteral use - mg/mL or %<br>Liquid for oral use - g or mg/mL, g or mg / dosage unit (e.g. /5mL)<br>Cream, ointment, lotion, etc. - mg or mL/g, g or mg/mL or %<br>Powder for solution, etc. - units/dosage unit (e.g. /20 mL vial)<br><br>Examples: (If the ingredient was sourced from Animal/Human, please complete and submit Appendix 4.)
<table>
<tr><th>CAS No. (if applicable)</th><th>Ingredient Name</th><th>Standard</th><th>Strength</th><th>Units</th><th>Per</th><th colspan="2">Calculated as Base?</th><th colspan="2">Animal/ Human Source</th></tr>
<tr><td>564-25-0</td><td>Doxycycline (as doxycycline hyclate)</td><td>USP</td><td>100</td><td>mg</td><td>tablet</td><td>☑ Yes</td><td>☐ No</td><td>☐ Yes</td><td>☑ No</td></tr>
<tr><td>86541-74-4</td><td>Benazepril Hydrochloride</td><td>USP</td><td>5</td><td>mg</td><td>tablet</td><td>☐ Yes</td><td>☑ No</td><td>☐ Yes</td><td>☑ No</td></tr>
<tr><td>n/a</td><td>Antithrombin III (Human)</td><td>n/a</td><td>1350 - 1650</td><td>IU</td><td>vial</td><td>☐ Yes</td><td>☑ No</td><td>☑ Yes</td><td>☐ No</td></tr>
</table>
</td>
<td>Include as much information that is publicly available on the label or in the product monograph for pharmaceuticals and biologics that are marketed or approved in Canada.<br><br>For all other drug products, contact the Manufacturer for complete information.</td>
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| | In the above examples, the strength of the active moiety doxycycline (supplied as doxycycline hyclate) is declared and is therefore calculated as the base. In the case of benazepril hydrochloride, it is the strength of the salt that is declared and therefore the strength is not calculated as the base.<br><br>**Identify whether the ingredient was sourced from animal/human. If the ingredient was sourced from Animal/Human, please complete and submit Appendix 4.**<br><br>**For Drug Identification Number applications, a separate HC/SC 3011 must be completed and provided for each formulation and strength. For all other submission types, only a separate Part 2 must be duplicated, completed, and provided for each formulation and strength. If all the information is the same for the remaining sections then there is no need to repeat these sections for each strength/dosage form.**<br><br>**For example, if the application is for a Division 8 (new drug) with two strengths (i.e.: 5mg and 10mg) and the strength is the only difference affecting Part 2 then only section 56 and 57 should be duplicated.** | |
| 57 | List the non-medicinal ingredient(s) in a similar manner to the medicinal (active) ingredients in section 56 above, except that there is no requirement to indicate whether the ingredient is calculated as the base or salt. **List the preservative(s) first followed by the colouring agent(s). The remaining non-medicinal ingredient(s) should go under in Section C - Other, and if applicable, list the ingredients used in capsule shell in Section D. For products regulated solely under Division 1, state the purpose of any non-medicinal ingredients included under Section C - Other on a separate sheet.**<br><br>For formulation variations pertaining to the same DIN (e.g. multiple flavourings, colours, fragrances), please fill out the variant name and list all the non-medicinal ingredients for each variant type.<br><br>**Identify whether the ingredient was sourced from animal/human. If the ingredient was sourced from Animal/Human, please complete and submit Appendix 4.**<br><br>**For CTAs, CTA-As, VINDs and VIND-AMs**, it is not necessary to fill in this section if the drug product to be used in the clinical trial is marketed in Canada or if the investigational product is meant for any Bioequivalence/Bioavailability studies. | Leave blank for pharmaceuticals and biologics that are marketed or approved in Canada.<br><br>For all other drug products, contact the Manufacturer for complete information. |

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| 58 | List the Animal/Human-sourced material(s) for each individual drug product ingredient and/or material used at any stage in the manufacture of the drug product including excipient or processing aid source from human and/or animal tissue.<br><br>Enter CAS # (if applicable), Material Name and Standard for the Human/Animal sourced material used in the manufacturing of the product. Select the option Yes for the column "Present in Final Container" if the ingredient is present in the final container (based on the quality standard applicable for the product).<br><br>For clinical trial applications **for pharmaceutical products**, Appendix 4 should not be submitted, provided that the required information or attestations are included in the application. | Leave blank for pharmaceuticals and biologics that are marketed or approved in Canada.<br><br>For all other drug products, contact the Manufacturer for complete information. |
| 59 | Select the appropriate option based on Health Canada's working definition of Nanomaterials:<br><br>Health Canada considers any manufactured substance or product and any component material, ingredient, device, or structure to be nanomaterial if:<br>a) It is at or within the nanoscale in at least one external dimension, or has internal or surface structure at the nanoscale, or;<br>b) It is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena.<br><br>For the purposes of this definition:<br>a) The term "nanoscale" means 1 to 100 nanometres, inclusive;<br>b) The term "nanoscale properties/phenomena" means properties which are attributable to size and their effects; these properties are distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material; and,<br>c) The term "manufactured" includes engineering processes and control of matter. | |
| 60 | Identify the proposed dosage form (pharmaceutical form) of the drug product, e.g. tablet, capsule, cream, powder for solution, etc.<br><br>For Drug Identification Number applications, a separate HC/SC 3011 must be completed and provided for each dosage form. For all other submission types, only a separate Part 2 must be duplicated, completed and provided for each dosage form. | |

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| 61 | Identify the type of container(s) to be used and the package size(s) proposed, e.g. bottle, 100 tablets; tube, 50 gm; vial, 5mL.<br><br>**For CTAs, CTA-As, VINDs and VIND-AMs**, please indicate N/A as it is not necessary to fill in this section if the information is unknown at the time of the application. | Indicate N/A (Not Applicable) |
| 62 | Record the appropriate therapeutic and pharmacological classification for the drug, e.g. calcium channel blocker, biological response modifier, histamine $H_2$-receptor antagonist, disinfectant. | Refer to the Product Monograph or the Drug Product Database on Health Canada's website. |
| 63 | Indicate the proposed route(s) of administration, e.g. oral, intravenous, topical, etc. For a disinfectant drug DIN submission, the information collected in this section is its use as mentioned in section 65, so sponsor may enter "Refer section 65" instead of filling out the disinfectant use. | |
| 64 | Indicate whether the drug product is a biologic/radiopharmaceutical, pharmaceutical, disinfectant or a drug and medical device combination. If the product is a drug and medical device combination, also indicate what type of drug it is, e.g. biologic/radiopharmaceutical or pharmaceutical. | |
| 65 | Indicate whether the drug is intended for human (paediatric or adult population – select both if applicable) or veterinary use or as a radiopharmaceutical or as a disinfectant.<br><br>**Paediatric Populations**: is a term defined in the *Food and Drug Regulations* (C.08.004.1) as follows: premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age.<br><br>If the product is a disinfectant, indicate whether it is intended for use on Hospital or Food Processing Surfaces or for disinfection/sterilization of Medical Instruments, or Barn or Domestic or for Institutional/Industrial or Contact Lens | |
| 66 | If this is a nonprescription drug (human and/or veterinary) to which one or more Schedule A Claims applies, please complete and submit Appendix 5. For further guidance and information please consult the '*Draft Guidance Document Schedule A and Section 3 to the Food and Drugs Act*. | Indicate 'No' for pharmaceutical and biologic drug products. |

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| 67 | Indicate the proposed indication/use of the drug, e.g. for use in the treatment of angina and hypertension, to treat the symptoms of hay fever, for the prophylaxis of measles virus infection.<br><br>For a new drug, the proposed indication/use shall be a summary of the indication described in the product monograph. Key scientific terminology should be used for this section.<br><br>For a disinfectant drug, include one of two options: 1) Hard Surface Disinfectant; or 2) Contact Lens Disinfectant. Proposed indications as "disinfectant/sanitizer" or "toilet bowl cleaner" are not permitted. | Provide the proposed indication/use of the drug product as indicated in the clinical trial protocol. Should coincide with that indicated in the PSEAT. |
| 68 | Specify the proposed dosage of the drug product, including the maximum daily dose, e.g. 1 tablet, four times daily. | Provide the proposed dosage of the drug product as indicated in the clinical trial protocol. |
| 69 | Confirm that the draft labels (inner and outer) for use in Canada, including the Package Insert if there is one, are included in the submission. The draft label does not include the Product Monograph.<br>**For CTAs and CTA-As, VINDs and VIND-AMs**, labels should not be submitted unless requested by the appropriate Directorate. | Indicate 'No' in both boxes. |
| 70 | Complete only if the subject drug submission is a SNDS, SANDS (all human drug types), VSNDS, VSANDS (veterinary drugs) or a biological drug DIN submission. Identify the rationale for filing the subject submission, e.g. new route of administration or pharmaceutical form, additional strength. Check all applicable options. | Leave Blank |
| 71 | Complete only if the subject submission is a Notifiable Change to a new (human or veterinary) drug. With reference to the Health Canada "Post-NOC Changes Guidance Document", identify all applicable change(s) to which the subject submission refers. | Leave Blank |
| **72-74** | **Complete Sections 72-74 for veterinary products only** | Leave all fields blank |
| 72 | Specify the species and subtypes for which the drug product is intended, e.g. poultry (species) - laying hens (subtype). | |
| 73 | Indicate whether or not the drug is intended for use in food-producing animals. | |
| 74 | Indicate the proposed withdrawal time for each species identified in Section 72. | |
| 75 | Print the name of the person authorized by the manufacturer/sponsor identified in Section 11 to sign this form, i.e., the person signing the form is certifying that the information provided in the form is consistent with the wishes of the manufacturer/sponsor. | Name of the Qualified Investigator (or Scientific Officer/Investigator) |

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| 76-77 | The signature of the authorized signing official (76) and the date the form is signed (year/month/day) (77). | Signature and date of the Qualified Investigator (or Scientific Officer/Investigator) must be manually and self completed (not electronic). |
| 78-80 | The title of the position held by the authorized signing official (78) and his/her telephone and fax numbers (79-80). | |
| 81 | The name of the company to which the authorized signing official belongs. If the signing official is a third party belonging to a company other than manufacturer/sponsor company identified in Section 11, a letter of authorization signed by the manufacturer/sponsor (section 11) company must be filed with the Drug Submission Application Form (see Appendix 2). | **For CTA's:**<br>This will be listed as Sunnybrook Research Institute (as indicated in section 11) unless the Qualified Investigator (or Scientific Officer/Investigator) is not cross-appointed to SRI (refer to the SRI Grid). If the Qualified Investigator (or Scientific Officer/Investigator) is not cross-appointed, then section 81 will be listed as will be Sunnybrook Health Sciences Centre and Appendix 2 will need to be completed.<br><br>**For CTA-A's:**<br>This must be the same as the original CTA until all research studies are transferred to Sunnybrook Research Institute. |
| **Appendix 1** | Complete **Appendix 1** (or a similar authorization) **for clinical trial applications and amendments only.** The form should be completed and submitted if the clinical trial sponsor is authorizing one or more third parties to import clinical trial drugs into Canada. Each importer authorized to import the new drug into Canada for the purposes of the clinical trial described in this application should be listed. 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, Appendix 1 does not need to be re-submitted.<br><br>A separate HC/SC 3011 and accompanying Appendix 1 should be provided for each protocol. | Leave blank and do not include in the application package. |

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| **Appendix 2** | Complete **Appendix 2** (or a similar authorization) only if the party signing the HC/SC 3011 is a third party acting on behalf of the manufacturer/sponsor company identified in section 11. Note that a separate authorization is required for each application. | Complete only if a 3rd party is signing on behalf of the sponsor.<br>**Please note: This appendix should not be completed even if a CRO is submitting the CTA to Health Canada. Ie. the Investigator and SRI are still signing the 3011, and therefore a third party is not acting on behalf of the sponsor.** |
| **Appendix 3** | Complete **Appendix 3 – Clinical Trial Application Information** for Clinical Trial Application and Clinical Trial Application Amendments only. A signed and dated Appendix 3 is required to be joined to the HC/SC 3011 form when submitting a clinical trial or an amendment (clinical or quality) to a previously approved clinical trial. | Required component of a CTA or CTA-A. |
| 82 | Specify the protocol number of the clinical trial. Note that the protocol number should remain the same for the duration of the trial. It is acceptable to indicate the version or amendment number of the protocol submitted at the time of application; however, the original protocol number must always be indicated. | Health Canada requires this field to be completed. If your protocol is not identified by a number, use the REB Number assigned to the study and provided in the REB provisional/final approval letter. |
| 83 | Specify the clinical trial protocol title. | Full study title as it appears on the protocol and informed consent form. |
| 84 | For an investigational product involved in the clinical trial, indicate whether or not the Canadian marketed product is being used. If the Canadian marketed product is being used, please provide the Drug Identification Number (DIN). If a foreign marketed product is being used, identify the country(ies) from which the product was obtained. If the investigational product is not marketed anywhere, enter N/A. | |

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| 85 | Indicate whether the clinical trial is anticipated to include paediatric population, 0-18 years of age, (females and/or males) and/or adult population (females and/or males).<br><br>**Paediatric Population**: is a term defined in the Food and Drug Regulations (C.08.004.1) as follows: premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age.<br><br>Check all applicable options. | |

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| 86 | Specify what phase of clinical trial is being submitted. For additional information, please consult the Guidance for Clinical Trial Sponsors - Clinical Trial Applications. | **Phase I:** Clinical trials designed to determine the pharmacokinetics/pharmacological actions of the drug and the side effects associated with increasing doses. Drug interaction studies are usually considered as Phase I trials regardless of when they are conducted during drug development. Phase I trials are generally conducted in healthy volunteers, but may be conducted in patients when administration of the drug to healthy volunteers is not ethical.<br><br>**Phase II:** Clinical trials to evaluate the efficacy of the drug in patients with medical conditions to be treated, diagnosed or prevented, and to determine the side effects and risks associated with the drug. If a new indication for a marketed drug is to be investigated, then those clinical trials may generally be considered Phase II trials.<br><br>**Phase III:** Controlled or uncontrolled trials conducted after preliminary evidence suggesting efficacy of the drug has been demonstrated. These are intended to gather the additional information about the clinical efficacy and safety under the proposed conditions of use.<br><br>****NOTE:** Above definitions as references in the Guidance Document For Clinical Trial Sponsors: Clinical Trial Applications 2013-05-29 |
| 87 | If a Research Ethics Board has refused to approve the clinical trial protocol and/or informed consent form, confirm that the information outlined in the "Guidance for Clinical Trial Sponsors" is enclosed in the submission. If no Research Ethics Board has refused to approve the protocol and/or informed consent form, check N/A for not applicable. **If it is not yet known if a Research Ethics Board has refused, check "Not known at this time".** | **Indicate 'Not known at this time'** |

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| 88 | A completed Clinical Trial Site Information Form should be enclosed for each proposed clinical trial site known at the time of the application of a clinical trial or amendment. Please do not provide forms until all fields are completed including section 37 and/or 45 of the Clinical Trial Site Information Form.<br><br>For all clinical trial site information which becomes available after the time of application, a completed Clinical Trial Site Information Form **must** be provided to the appropriate Directorate prior to the commencement of the trial. | Indicate 'No'.<br><br>A completed CTSI can only be submitted after all of the fields are completed. The elements which are unknown at the time the CTA is submitted to Health Canada are the commencement date of the clinical trial in field #35 and the REB approval date in field #47. |
| 89-90 | Print the name of the Senior Medical Officer or Scientific Officer in Canada (89), and his/her telephone number and address (90). This is a scientific or medical officer residing in Canada, representing the sponsor, who is responsible for providing an attestation with respect to the CTA or CTA-A at the time of filing, as outlined in Appendix 3. | Qualified Investigator (or Scientific Officer/Investigator) and their Sunnybrook contact information (address). |
| 91-92 | The signature of the Senior Medical Officer or Scientific Officer in Canada (91), and the date the form is signed (year/month/day) (92). | Signature and date must be manually and self completed (not electronic). |
| 93-94 | Print the name of the sponsor's Senior Executive Officer (93), and his/her telephone number (94).<br><br>**For institutional/ investigator-initiated clinical trials**, the appropriate Department Head may sign in lieu of the Senior Executive Officer. | Michael Julius acts as the Senior Executive Office. No other signatories are authorized.<br><br>416-480-7204 |
| 95-96 | The signature of the sponsor's Senior Executive Officer (95) and the date the form is signed (year/month/day) (96). | Signature and date must be manually and self completed (not electronic). |

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| **Appendix 4** | **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.**<br><br>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.<br><br>For Biologic product, it is allowed to submit human/animal source information for a specific antigen under one branded product as a master then cross reference those in subsequent submissions for different branded products containing the same antigens. In that case the sponsor must indicate cross reference information by stating the brand name, DINs and antigen name on a separate page instead of filling out the human/animal tissue form.<br><br>There is no need to re-submit an Appendix 4 for subsequent submission for the same product if there is no change in medicinal, non-medicinal information and its source.<br><br>The purpose for requesting additional information on animal source ingredients is to collect relevant data on formulation of the drug products and to make use of this information any time during product life-cycle, if required. | |
| 97 | List the animal- and/or human-sourced medicinal and non-medicinal ingredients and materials used at any stage in the manufacture of the drug product by their proper or common name.<br><br>Complete a separate Appendix 4 for each individual drug product ingredient and/or material used at any stage in the manufacture of the drug product that was identified as animal- and/or human-sourced. | |
| 98 | Indicate whether the animal- and/or human-sourced ingredient/material is used as a medicinal (active) ingredient, non-medicinal ingredient, or material used at any stage in the manufacture of the drug product. | |
| 99 | Specify whether the ingredient is sourced from Human and/or Animal(s). For animals, please check the appropriate box and specify the species in the category indicated. For example, if the animal is a cervidae, specify if it is a moose, a deer, an elk, etc.<br><br>**Controlled Population:** Specify whether the ingredient is sourced from an animal(s) belonging to an exclusive population reared specifically with the purpose of controlling disease, or reared specifically for use in the pharmaceutical industry (e.g., relevant certification or standards recognition by national, international or third-party). | |

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| | **Biotechnology-Derived Animal:** Specify whether the ingredient is sourced from a biotechnology-derived animal(s).<br>The *Health of Animals Regulations* under the *Health of Animals Act* defines biotechnology as "The application of science and engineering to the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms". The term "biotechnology-derived animals" is an extension of the definition of biotechnology. It refers to animals which have been generated through biotechnological methods. For more information, please refer to the Canadian Food Inspection Agency's "Animal Health Risk Analysis Framework for Biotechnology-Derived Animals". | |
| 100 | Specify tissues and fluids used to source the ingredients. | |
| 101 | Indicate the age of the animal (in months) at the time the tissue/fluid/macromolecule(s) is sourced. It is acceptable to provide a range of ages (in months). | |
| 102 | Indicate all countries in which the animal was born and resided.<br>The World Organization for Animal Health (OIE) identifies countries according to a BSE Risk Categorization scheme. Drug products containing animal tissue sourced from a "controlled risk" or "undetermined risk" jurisdiction, as defined by the OIE, require a chemistry and manufacturing assessment by Health Canada. Please see the OIE website for more information on BSE risk categorization, available at: www.oie.int | |
| **Appendix 5** | Note that this form is ONLY to be completed for nonprescription products excluding natural health products that have associated Schedule A claims. In other words, if section 66 of the form was checked 'YES', please complete and submit Appendix 5. For further guidance and information regarding Schedule A, please consult the *'Draft Guidance Document Schedule A and Section 3 of the Food and Drugs Act'*. | |
| 103 | Indicate the manufacturer/sponsor as instructed in section 11 above. | |
| 104 | Indicate the product name as instructed in section 8 above. | |
| 105 | Identify the Drug Identification Number (DIN) if it has already been issued. | |
| 106 | Check all the disease(s)/disorder(s) that apply to the claims made. | |
| 107 | List the Schedule A Claims/Indications associated with the product listed in section 104. | |