DRUG SUBMISSION APPLICATION 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 (human drugs)
- Clinical Trial Application Amendment (human drugs)
- Investigational New Drug Submissions (veterinary drugs)
- New Drug Submission
- Supplemental New Drug Submission
- Abbreviated New Drug Submission
- Supplemental Abbreviated New Drug Submission
- Notifiable Change
- Drug Identification Number (DIN) Application
- 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.

Shaded areas are for Health Canada (HC) use only.

Where to send Drug Submission Applications

Human Drugs:

Clinical Trial Applications and Amendments must be sent **directly** to the applicable Directorate (see attached Guidance Document for addresses)

All other drug submission types are to be sent to:

Submission and Information Policy Division
Therapeutic Products Directorate
Finance Building, No. 2
Tunney's Pasture
Address Locator: 0201A1
Ottawa, Ontario K1A 1B9 Fax: (613) 941-0825

Veterinary Drugs:

All veterinary drug submissions (including Investigational New Drug Submissions and amendments) are to be sent to:

Veterinary Drugs Directorate
Holland Cross Tower A
11 Holland Avenue
Address Locator: 3000A
Ottawa, Ontario K1A 0K9 Fax: (613) 946-1125

THIS PAGE DOES NOT FORM PART OF THE APPLICATION

Health Canada / Santé Canada

DRUG SUBMISSION APPLICATION

PART 1 - Manufacturer/Sponsor and Drug Product Information

HC Use Only:	1. Submission No.	2. Responsible Area	3. File No.	4. Date of Receipt MM DD YYYY

5. Type of Submission	6. Number of Volumes	7. Schedule

8. Brand or Proprietary Name

9. Proper, Common or Non-Proprietary Name

A) Manufacturer/Sponsor (In cases where a DIN/NOC is issued, this will be the DIN/NOC OWNER) (For CTA and CTA-A, refer to attached Guidance)

10. Company Code	11. Manufacturer/Sponsor Name (Full Name - No Abbreviations)

12. Street/Suite/PO Box	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/PO 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, see attached Guidance) **Same as A Above ☐**

35. Company Name (Full Name - No Abbreviations)

36. Street/Suite/PO 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/Distributor (ONLY where Address in A is not in Canada)[1] **Same as C Above ☐**

47. Name of Importer (Full Name - No Abbreviations)

48. Street/Suite/PO Box	49. City/Town	50. Prov./State	51. Country	52. Postal/ZIP Code

E) Address to which the Drug Notification Form (DIN)/ Notice of Compliance (NOC) are to be sent: **As Above: A: ☐ B: ☐ C: ☐ D: ☐ Not Applicable: ☐**

[1] **FOR CLINICAL TRIAL APPLICATIONS (HUMAN DRUGS): WHERE THE SPONSOR IS LOCATED OUTSIDE OF CANADA, APPENDIX 1 MUST BE COMPLETED AND SUBMITTED FOR EACH IMPORTER ACTING AS THE SPONSOR'S AGENT IN CANADA. REFER TO THE ATTACHED GUIDANCE AND THE "GUIDANCE FOR CLINICAL TRIAL SPONSORS" FOR ROLES AND RESPONSIBILITIES.**

53. Related Submissions (referred to in this submission):

	Type	Control No.	Brand Name	Manufacturer/Sponsor Name	File No.	Date Cleared
A)						
	Reason for Submission:					
B)						
	Reason for Submission:					
C)						
	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 _____ °C .

55. Medicinal (Active) Ingredient(s)

Ingredient Name	Standard	Strength	Units	Per	Calculated as Base?
					☐ Yes ☐ No
					☐ Yes ☐ No
					☐ Yes ☐ No
					☐ Yes ☐ No
					☐ Yes ☐ No
					☐ Yes ☐ No
					☐ Yes ☐ No

Attach separate sheets (same format) if necessary. Number of pages attached: _____

56. Non-medicinal ingredient(s) (include colouring agents)

	Ingredient Name	Standard	Strength	Units	Per
A) Preservative(s)					
B) Colouring Agents					
C) Other					

Attach separate sheets (same format) if necessary. Number of pages attached: _____

D) For Biological drugs (human) containing non-medicinal ingredients of biological origin, **indicate on a separate sheet** the manufacturer and product name for each non-medicinal ingredient of biological origin.

57. Dosage Form

58. Container Type Package Size

59. Therapeutic/Pharmacological Classification

60. Route(s) of Administration

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61. Drug Product ☐ Biologic/Radiopharmaceutical ☐ Pharmaceutical ☐ Natural Health Product ☐ Drug & Medical Device

62. Drug Use ☐ Human ☐ Veterinary ☐ Disinfectant => ☐ hospital ☐ food processing ☐ instruments ☐ domestic

63. Proposed Indication/Use

64. Proposed Dosage (include maximum daily dose)

65. Draft of Proposed Canadian Labels enclosed? ☐ Yes ☐ No Package Insert enclosed? ☐ Yes ☐ No
Approved foreign labelling enclosed? ☐ Yes ☐ No
*For CTAs and CTA-As labels should not be submitted unless requested by the appropriate Directorate.

66. Rationale for **all** SNDS, SANDS (all human drug types), SABNDS (veterinary drugs), or for biological drug DIN submissions

67. Type of Notifiable Change (NC) submission (if applicable) - human drugs only

- ☐ Change in expiry period/storage conditions
- ☐ Change in formulation
- ☐ Change in manufacturing method
- ☐ Change in manufacturing site
- ☐ Change in text of labelling
- ☐ Change in drug substance (source, synthesis)
- ☐ Change in packaging material composition
- ☐ Change in packaging specifications for parenteral/inhalation drug
- ☐ Change in container size for parenteral drug
- ☐ Change in specifications (medicinal or non-medicinal ingredient, pharmaceutical form, analytical method)
- ☐ Other (specify)

Complete Sections 68 - 70 for Veterinary Products only

68. Species and Subtypes Recommended for use

69. Used for treatment of food-producing animals? ☐ Yes ☐ No

70. Withdrawal Time

Species	Days	Hours

I, the undersigned, certify that the information and material included in this drug submission application is accurate and complete[2].

71. Name of Authorized Signing Official	72. Signature	73. Date YYYY MM DD
74. Title	75. Telephone No.	76. Fax No.
77. Name of Company to which the Authorised Signing Official Belongs		

2 **IF THE SIGNING OFFICIAL IS A THIRD PARTY ACTING ON BEHALF OF THE MANUFACTURER/SPONSOR COMPANY IDENTIFIED IN SECTION 11, A LETTER OF AUTHORIZATION, SIGNED BY THE MANUFACTURER/ SPONSOR COMPANY (SECTION 11), MUST BE FILED WITH THE COMPLETED SUBMISSION APPLICATION FORM, E.G. APPENDIX 2.**

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[3]

I, _____ authorize (list each applicable importer, add more space as necessary) _____

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

Signed: _____

Print name: _____

Title: _____

Clinical Trial Sponsor: _____

Date: _____

[3] **SUBMIT WITH APPLICATION ONLY IF THE CLINICAL TRIAL SPONSOR IS LOCATED OUTSIDE OF CANADA AND IS AUTHORIZING ONE OR MORE THIRD PARTIES TO IMPORT THE NEW DRUG FOR THE PURPOSES OF THE CLINICAL TRIAL DESCRIBED WITHIN THIS APPLICATION. A SEPARATE 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, APPENDIX 1 DOES NOT NEED TO BE RE-SUBMITTED.**

APPENDIX 2 - for all applications

TEMPLATE AUTHORISATION FOR A THIRD PARTY TO SIGN/FILE A DRUG SUBMISSION APPLICATION ON BEHALF OF THE MANUFACTURER/SPONSOR COMPANY[4]

I, _____ authorize _____(third party person)_____

of _____(third party company name)_____ to file a drug submission

application for _____(name of product)_____ on behalf of

_____(manufacturer /sponsor company - Section 11 on application)_____.

Signed: _____

Print name: _____

Title: _____

Manufacturer/Sponsor company: _____

Date: _____

[4] **SUBMIT WITH APPLICATION ONLY IF PARTY SIGNING THE APPLICATION IS A THIRD PARTY ACTING ON BEHALF OF THE MANUFACTURER/SPONSOR COMPANY IDENTIFIED IN SECTION 11. A SEPARATE AUTHORISATION IS REQUIRED FOR EACH APPLICATION.**

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APPENDIX 3 - CLINICAL TRIAL APPLICATION INFORMATION
(for clinical trial applications for human drugs only)

78. Clinical Trial Protocol Number (if assigned)	79. Clinical Trial Protocol Title

80. Anticipated Clinical Trial Composition (check all that apply):	81. Phase of Clinical Trial (check appropriate box):
☐ Pediatric population (0-18 years of age) ☐ Females ☐ Males	☐ Phase I - bioequivalency study (7 day administrative target) ☐ Phase I - study in healthy humans (7 day administrative target) ☐ Phase I - other (30 day default) ☐ Phase II (30 day default) ☐ Phase III (30 day default) ☐ Other - specify: _____

82. Information regarding Research Ethics Board that has refused to approve the protocol and/or informed consent form enclosed?
☐ Yes ☐ No ☐ Not Applicable ☐ Not known at this time

83. Clinical Trial Site Information Form enclosed for all sites known at time of application?
☐ Yes ☐ No ☐ No sites are known at this time

84. Investigator's brochure enclosed?
☐ Yes ☐ No

85. Information regarding human- and/or animal-sourced excipients enclosed?
☐ Yes ☐ No ☐ Not Applicable

86. Quality (chemistry & manufacturing) information enclosed?
☐ Yes ☐ No
☐ Not Applicable - product has received Notice of Compliance and/or Drug Identification Number (DIN)

In respect of the clinical trial identified in Appendix 3 of this 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 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*. The clinical trial will be conducted in accordance with good clinical practices.

4. The trial will not commence at any site until receipt of a No Objection Letter from the Therapeutic Products Directorate or the Biologics and Genetic Therapies Directorate of Health Canada, or 30 calendar days following receipt of the application by Health Canada, whichever comes first.

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

87. Senior Medical Officer or Scientific Officer in Canada	88. Tel. No.	89. Signature	90. Date YYYY MM DD
91. Senior Executive Officer	92. Tel. No.	93. Signature	94. Date YYYY MM DD

Guidance for Completing the Drug Submission Application Form

Section #	GUIDANCE
Cover page	Clinical Trial Applications and Amendments for human drugs should be sent **directly to the applicable Directorate** as follows: **Pharmaceutical Drugs** Therapeutic Products Directorate Clinical Trials & Special Access Programme Finance Building, 2nd Floor Address Locator: 0202C1 Tunney's Pasture Ottawa, Ontario K1A 1B9 **Biological/Radiopharmaceutical Drugs** Biologics and Genetic Therapies Directorate Submission Management Division Health Canada Building #6, 1st Floor Address Locator: 0601E3 Tunney's Pasture Ottawa, Ontario K1A 0L2 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.
	PART 1 - Manufacturer/Sponsor and Drug Product Information
1-4	Health Canada Use Only
5	The type of submission being presented to Health Canada. Allowable entries are: • CTA (Clinical Trial Application) • CTA-A (Clinical Trial Application Amendment) • IND (Investigational New Drug Submission - veterinary drugs) • NDS (New Drug Submission) • SNDS (Supplemental New Drug Submission) • ANDS (Abbreviated New Drug Submission) • ABNDS (Abbreviated New Drug Submission - veterinary drugs) • SANDS (Supplemental Abbreviated New Drug Submission) • ABSNDS (Supplemental Abbreviated New Drug Submission - veterinary drugs) • NC (Notifiable Change) • DIN (Drug Identification Number submission - all types[5]) • ADMIN (Administrative manufacturer name/product name change/licensing agreements)
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 volumes.
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* or in any of the **Schedules** to the *Controlled Drugs and Substances Act* (CDSA).
8	The **brand name** or proprietary 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, IND, or NDS submissions, the proper or common name of the drug or the research code may be used. **If *after* filing a NDS, ANDS, ABNDS or DIN 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".

[5] **DIN SUBMISSIONS FOR PHARMACEUTICAL, BIOLOGICAL, HERBAL, HOMEOPATHIC AND DISINFECTANT DRUGS THAT ARE NOT SUBJECT TO DIVISION 8, PART C OF THE *FOOD AND DRUG REGULATIONS*, I.E., THAT ARE NOT CONSIDERED TO BE NEW DRUGS**

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*. Example: Ferrous Sulphate Tablets Immune Globulin Intravenous (human) 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. 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, leave Section 9 blank.
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 DIN/Notice of Compliance (NOC) is to be issued, **the company in whose name the DIN/NOC will be registered, (i.e., the DIN/NOC owner) and whose name must be included on the product label and Product Monograph/Package Insert.** **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.
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 not known, leave blank**.
11	Indicate the **full** name of the manufacturer/sponsor company 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. **If *after* filing a NDS, ANDS, ABNDS or DIN 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, or ABNDS must be submitted and cleared before changing the manufacturer/sponsor name for an already filed SNDS, SANDS, ABSNDS, or NC submission. **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.
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). Include the PO Box number (12) if a post office box is used.
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) if applicable, and language preference (20). 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**.
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.**
23	Enter the name of the company to which the drug submission contact belongs (i.e., is a staff member). 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) (if not already given in Section 23), 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) if applicable, and language preference (32).
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.
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 35. 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) if applicable, and language preference (44).
Block D	**Canadian Importer/Distributor:** 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. **For CTAs and CTA-As**, if the sponsor is not located in Canada, Appendix 1 must be completed and submitted. List each applicable importer authorized to import the new drug for the purposes of the trial outlined in the application. 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 is filed, Appendix 1 does not need to be re-submitted.
47	Enter the full name of the Canadian Importer/Distributor.
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/state (50), the country (51) and the postal or zip code (52). Include the PO Box number (48) if a post office box is used.
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.
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) 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, and the reason for the related submission (e.g. brief protocol description of a CTA, reason for supplement, etc.). Attach additional detailed pages as necessary.
	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. **For CTAs and CTA-As**, it is not necessary to fill in this Section if the drug product to be used in the clinical trial is marketed in Canada.

55	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. USP, 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. Leave blank if no compendial standard exists for the active ingredient. The strength of the active ingredient(s) should be expressed as follows: Discrete pharmaceutical forms (e.g. tablet) - g or mg / pharmaceutical form Powder for oral use - g or mg/mL, g or mg / dosage unit (e.g. /5mL) Liquid for parenteral use - mg/mL or % Liquid for oral use - g or mg/mL, g or mg / dosage unit (e.g. /5mL) Cream, ointment, lotion, etc. - mg or mL/g, g or mg/mL or % Also indicate whether or not the strength of the active ingredient is calculated as the strength of the base.
	Examples: **Ingredient** / **Standard** / **Strength** / **Unit** / **Per** / **Calculated as Base** Chloramphenicol / USP / 20 / mg / mL / Yes Magnesium (supplied as magnesium carbonate) / USP / 25 / mg / tablet / Yes Hydrocortisone acetate USP / / 1 / % / / No Hepatitis A Vaccine / / 1000 / HA / mL / No In the above examples the strength of the active moiety chloramphenicol is declared and is therefore calculated as the base; the strength of the active moiety magnesium (supplied as magnesium carbonate) is declared and again is calculated as the base. In the case of hydrocortisone acetate it is the strength of the salt that is declared and therefore the strength is not calculated as the base. Where the number of active ingredients exceeds seven, attach a separate list of ingredients presented in the same format. **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 completed and provided for each formulation and strength.**
56	List the non-medicinal ingredient(s) in a similar manner to the active ingredients in Section 55 except that there is no requirement to indicate whether the ingredient is calculated as the base or not. List the preservative(s) first in Section 56A, the colouring agent(s) in Section 56B, and the remaining non-medicinal ingredient(s) in Section 56C. **For CTAs and CTA-As**, it is not necessary to fill in this Section if the drug product to be used in the clinical trial is marketed in Canada.
57	Identify the proposed dosage form (pharmaceutical form) of the drug product, e.g. tablet, capsule, cream, powder for solution, etc. **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 completed and provided for each dosage form.**
58	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.
59	Record the appropriate therapeutic and pharmacological classification for the drug, e.g. calcium channel blocker, biological response modifier, histamine H_2-receptor antagonist.
60	Indicate the proposed route(s) of administration, e.g. oral, intravenous, topical.
61	Indicate whether the drug product is a biologic/radiopharmaceutical, pharmaceutical, natural health product, 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.

62	Indicate whether the drug is intended for human or veterinary use or as a disinfectant. 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.
63	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.
64	Specify the proposed dosage of the drug product, including the maximum daily dose, e.g. 1 tablet, four times daily.
65	Confirm that the draft labels for use in Canada (including the package insert if there is one) are included in the submission. Confirm that approved foreign labelling is included in the submission. **For CTAs and CTA-As**, labels should not be submitted unless requested by the appropriate Directorate.
66	Complete only if the subject drug submission is a SNDS, SANDS (all human drug types), ABSNDS (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.
67	Complete only if the subject submission is a Notifiable Change to a new drug. With reference to the Health Canada policy "Changes to Marketed New Drugs", identify the applicable change to which the subject submission refers.
68-70	**Complete Sections 68-70 for veterinary products only**
68	Specify the species and subtypes for which the drug product is intended, e.g. poultry (species) - laying hens (subtype).
69	Indicate whether or not the drug is intended for use in food-producing animals.
70	Indicate the proposed withdrawal time for each species identified in Section 68.
71	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.
72-73	The signature of the authorized signing official (72) and the date the form is signed (year/month/day) (73).
74-76	The name of the position held by the authorized signing official (74) and his/her telephone and fax numbers (75-76).
77	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 company must be filed with the submission application (see Appendix 2).
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 located outside of 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. A separate HC/SC 3011 and accompanying Appendix 1 should be provided for each protocol.
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.
Appendix 3	Complete **Appendix 3 - CLINICAL TRIAL APPLICATION INFORMATION** for Clinical Trial Application and Clinical Trial Application Amendments only. A separate HC/SC 3011 and accompanying Appendix 3 should be provided for each protocol.
78	Specify the protocol number of the clinical trial, if assigned.
79	Specify the clinical trial protocol title.
80	Indicate whether the clinical trial is anticipated to include pediatric population (0-18 years), females, and/or males. Check all that apply.
81	Specify what phase of clinical trial is being submitted.

82	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 "Not Applicable". If it is not yet known if a Research Ethics Board has refused, check "Not known at this time".
83	A completed Clinical Trial Site Information Form should be enclosed for each proposed clinical trial site known at the time of the application. For all clinical trial site information which becomes available after the time of application, a completed Clinical Trial Site Information Form should be provided to the appropriate Directorate.
84	Indicate if the Investigator's Brochure is enclosed in the submission.
85	If human- and/or animal-sourced excipients are being used in the product, confirm that required information is enclosed. If no human- or animal-sourced excipients are used, check "Not Applicable".
86	If the product has not yet received a Notice of Compliance (NOC) and/or a Drug Identification Number (DIN), indicate if quality (chemistry & manufacturing) information is enclosed. If the product has received a NOC and/or a DIN, check "Not Applicable".
87-88	Print the name of the Senior Medical Officer or Scientific Officer in Canada (87), and his/her telephone number (88). 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.
89-90	The signature of the Senior Medical Officer or Scientific Officer in Canada (89), and the date the form is signed (year/month/day) (90).
91-92	Print the name of the Senior Executive Officer (91), and his/her telephone number (92). **For institutional/ investigator-initiated clinical trials**, the appropriate Department Head may sign in lieu of the Senior Executive Officer.
93-94	The signature of the Senior Executive Officer (93), and the date the form is signed (year/month/day) (94).