Health Canada Santé Canada

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Veterinary Drugs Directorate (VDD)
Health Products and Food Branch (HPFB)
Veterinary Drug Submission Application and Fee Form

This form must be completed with every submission or application. One form may be used for multiple strengths of a single dosage form.

Do not use this form for the following applications:

For an Experimental Studies Certificate (ESC) application, complete the Veterinary Drug Experimental Studies Certificate Application Form.

For an Emergency Drug Release (EDR) request, complete an Emergency Drug Release Request Form and Fee Form.

For Veterinary Health Products (VHPs), please contact vhp-psa@hc-sc.gc.ca for the appropriate forms and process.

1. Manufacturer or Sponsor Information

Brand or Proprietary or Product Name	
Company Name	

2. Billing Information

Contact Name and Title		
Company Name		
Mailing Address	Street/Suite	
	City/Town	
	Province/State	
	Country	
	Postal/Zip Code	
Telephone Number		
Email		
Fax Number		

Canada

3. Fees for the Review of Veterinary Drug Submissions, Supplements and Applications

Submission Type:

- ○ Section 1: New Drug Submission
- ○ Section 2: Supplement to a New Drug Submission
- ○ Section 3: Abbreviated New Drug Submission or Supplement to an Abbreviated New Drug Submission
- ○ Section 4: DIN Application
- ○ Section 5: Preclinical Submission (Investigational New Drug Submission)
- ○ Section 6: Notifiable Change or Protocol Review

Please complete and attach the applicable section(s) below.

Do not send fee payment with your submission, supplement or application. Health Canada will verify the fee and issue an invoice accordingly.

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Section 1: New Drug Submission

Component Fee	Fee (Apr 1, 2024 – Mar 31, 2025)	Quantity	Total Fees
1. Efficacy & safety data (intended species) for one route, dosage form & indication in 1 species. For antiparasitic, several indications in 1 food species.	$50,015		$0.00
2. Efficacy & safety data (intended species) for one route & dosage form for an antiparasitic in 1 non-food species.	$30,298		$0.00
3. Efficacy & safety data (intended species) for one route, dosage form & indication in 2 species; or one route, dosage form & 2 indications in 1 species.	$72,735		$ 0.00
4. Efficacy & safety data (intended species) for a growth promotion or production enhancement indication in 1 species.	$98,491		$ 0.00
5. Comparative (pharmacodynamic, clinical or bioavailability) data for additional route. (In addition to route referred to in item 1, 2 or 3).	$9,079		$0.00
6. Comparative (pharmacodynamic, clinical or bioavailability) data for each additional strength. (1 study to support strengths may be included with a NDS, under items 1, 2 or 3, without payment of this fee.)	$1,505		$ 0.00
7. For food animals, toxicity, metabolism & residue depletion studies to establish an ADI with a SF of 1,000, a MRL & a withdrawal period for one dosage form, dosage & route in 1 species.	$68,199		$ 0.00
8. For food animals, toxicity, metabolism & residue depletion studies to establish an ADI with a SF of <1,000, a MRL & a withdrawal period for one dosage form, dosage & route in 1 species.	$90,918		$ 0.00
9. For food animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route.	$9,079		$0.00
10. For food animals (once an ADI and a SF of ≤ 1,000 has been established), metabolism & residue depletion studies to establish a MRL & a withdrawal period for one dosage form, dosage and route in an additional species.	$45,446		$ 0.00
11. Chemistry & manufacturing for non-compendial medicinal ingredient.	$15,150		$ 0.00
12. Chemistry & manufacturing for one strength of 1 dosage form.	$15,150		$ 0.00
13. Chemistry & manufacturing for an additional strength of 1 dosage form submitted with item 12.	$7,578		$ 0.00

14. Change in manufacturer's name. (Applies only where a NDS does not include any of the above components.)	$786		$ 0.00
	Total Fee:	$0.00	

Section 2: Supplement to a New Drug Submission

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Component Fee	Fee (Apr 1, 2024 – Mar 31, 2025)	Quantity	Total Fees
1. Efficacy data for an additional indication in 1 species.	$39,406		$ 0.00
2. Efficacy & safety data (intended species) for one route & dosage form for an antiparasitic in 1 non-food species.	$30,298		$ 0.00
3. Efficacy & safety data (intended species) for an indication in another species.	$50,015		$ 0.00
4. Efficacy & safety data (intended species) for one route, dosage form & indication in 2 species; or one route, dosage form & 2 indications in 1 species.	$72,735		$ 0.00
5. Efficacy & safety data (intended species) for a growth promotion or production enhancement indication in 1 species.	$98,491		$ 0.00
6. Efficacy & safety data (intended species) for the concurrent use of 2 drugs approved for the same species.	$24,225		$ 0.00
7. Comparative (pharmacodynamic, clinical or bioavailability) data for an additional route. (In addition to route referred to in item 2 or 4.)	$9,079		$0.00
8. Comparative (pharmacodynamic, clinical or bioavailability) data for each additional strength. (1 study to support strengths may be included with a SNDS, under item 1, 2 or 3 without payment of this fee.)	$1,505		$ 0.00
9. For food animals, residue depletion studies to establish a new withdrawal period for a change in the dosage or route of an approved dosage form in 1 species.	$9,079		$ 0.00
10. For food animals, metabolism & residue depletion studies to establish a MRL & a withdrawal period for one dosage & route of an approved dosage form in an additional species.	$45,446		$ 0.00
11. For food animals, toxicity studies for a change of an established ADI, MRL & withdrawal period.	$22,724		$ 0.00
12. For concurrent use of 2 drugs in a food species, residue depletion studies to determine if extension to withdrawal periods is required.	$18,187		$ 0.00
13. Chemistry & manufacturing for change in source of medicinal ingredient or its manufacturing process.	$15,150		$ 0.00
14. Chemistry & manufacturing for change in formulation or dosage form.	$7,578		$ 0.00
15. Chemistry & manufacturing for change in packaging or sterilization.	$6,043		$ 0.00

16. Chemistry & manufacturing for extension of expiry date.	$4,541		$ 0.00
17. Chemistry & manufacturing for concurrent use of 2 drugs.	$4,541		$ 0.00
18. Chemistry & manufacturing for change in manufacturing site (parenteral).	$1,505		$ 0.00
19. Change in product name. (Applies only where a SNDS does not include any of the above components.)	$786		$ 0.00
	Total Fee:		$ 0.00

Section 3: Abbreviated New Drug Submission or Supplement to an Abbreviated New Drug Submission

Component Fee	**Fee(Apr 1, 2024 – Mar 31, 2025)**	**Quantity**	**Total Fees**
1. Comparative (pharmacodynamic, clinical or bioavailability) data for one route & dosage form.	$9,079		$ 0.00
2. For food animals, residue depletion studies to confirm that the withdrawal period(s) for each species falls within the conditions of use for the Canadian reference product.	$9,079		$ 0.00
3. Chemistry & manufacturing for non-compendial medicinal ingredient.	$15,150		$ 0.00
4. Chemistry & manufacturing for 1 dosage form.	$15,150		$ 0.00
5. Change in manufacturer's name (ANDS); Change in product name (SANDS). (Applies only where an abbreviated submission does not include any of the above components.)	$786		$ 0.00
	Total Fee:		$ 0.00

Section 4: DIN Application

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Component Fee	**Fee(Apr 1, 2024– Mar 31, 2025)**	**Quantity**	**Total Fees**
1. Information (other than item 2 below) for DIN application, including the submission of labelling for a second review, if required.	$2,257		$ 0.00
2. Published references or other data.	$1,569		$ 0.00
3. Change in manufacturer or brand name of a drug. (Applies only where a DIN application does not include any of the above components.)	$786		$ 0.00
	Total Fee:		$ 0.00

Section 5: Preclinical Submission (Investigational New Drug Submission) **Protected B** when completed

Component Fee	Fee (Apr 1, 2024 – Mar 31, 2025)	Quantity	Total Fees
1. Efficacy & safety data (intended species) & protocol for the conduct of clinical studies for one dosage form, route & indication in 1 species.	$15,150		$ 0.00
2. Efficacy data & protocol for the conduct of clinical studies for one route & indication with a dosage form for which a NOC has been issued for use in that species.	$12,114		$ 0.00
3. For food animals, toxicity, metabolism & residue depletion studies to establish a temporary ADI, MRL & a withdrawal period for one dosage form, dosage & route in 1 species.	$45,446		$ 0.00
4. For food animals, toxicity, metabolism & residue depletion studies to establish an ADI with a SF of 1,000, a MRL & a withdrawal period for one dosage form, dosage & route in 1 species.	$68,199		$ 0.00
5. For food animals, toxicity, metabolism & residue depletion studies to establish an ADI with a SF of <1,000, a MRL & a withdrawal period for one dosage form, dosage & route in 1 species.	$90,918		$ 0.00
6. For food animals (once a ADI and a SF of ≤1,000 has been established), metabolism studies to establish a withdrawal period for one dosage form, dosage & route in an additional species.	$22,724		$ 0.00
7. Chemistry & manufacturing for 1 dosage form with a noncompendial medicinal ingredient.	$15,150		$0.00
8. Chemistry & manufacturing for 1 dosage form with a compendial medicinal ingredient.	$7,578		$ 0.00
	Total Fee:		$ 0.00

Section 6: Notifiable Change or Protocol Review

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Component Fee	**Fee (Apr 1, 2024 – Mar 31, 2025)**	**Quantity**	**Total Fees**
1. Information & material to support an application for a Notifiable Change.	$4,072		$ 0.00
2. A protocol that is filed with the Minister and may support a New Drug Submission, Abbreviated New Drug Submission, Supplement to a New Drug Submission or Abbreviated New Drug Submission, Preclinical Submission or information filed for the purpose of obtaining an Experimental Studies Certificate.	$4,072		$ 0.00
	Total Fee:		$ 0.00

4. Mitigation measures

The following mitigation measures are available. Sponsors must certify that they meet the criteria as outlined in the *Food and Drug Regulations*.

Small Business

☐ We certify that we meet the definition of a small business at the time of this filing and have applied for small business status for our company with Health Canada and have received confirmation prior to submitting this submission/application. We understand that failure to hold a valid small business status with Health Canada at the time of submitting this submission/application will result in the full fee being charged.

☐ We have not previously filed a submission/application in respect of a drug with Health Canada. We are filing our first drug submission/application.

Publicly Funded Health Care Institution

☐ We certify that our institution is funded by the Government of Canada or the government of a province or territory and that it is

a) licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness; or
b) owned or operated by the Government of Canada or the government of a province and that provides health services.

Government Organization

☐ We certify that our organization is a branch or agency of the Government of Canada or of a province or territory.

5. Certification

I, the undersigned, certify that:

1. The information and material included in this form is accurate and complete.
2. No information is false or misleading and no omissions have been made that may affect its accuracy and completeness.

Name of Authorized Signing Official	Signature	Date		
		YYYY	MM	DD
Title	Telephone No.	Email		