Health Canada / Santé Canada

HC PROTECTED

Veterinary Drug Submission Fee Application Form

This form must be completed for every submission. In addition, please complete and submit only the section(s) which are necessary. One form may be used for multiple strengths of a single dosage form. However, individual Drug Submission Application Forms are still required to be submitted for each formulation strength.

- For a New Drug Submission complete Section 1.
- For a Supplement to a New Drug Submission complete Section 2.
- For an Abbreviated New Drug Submission or Supplement to an Abbreviated New Drug Submission complete Section 3.
- For a DIN Application complete Section 4.
- For a Preclinical (Investigational) New Drug Submission complete Section 5.
- For a Notifiable Change or Protocol Review complete Section 6.
- For an Experimental Studies Certificate Application complete an ESC Fee Application Form.
- For an Emergency Drug Release complete an EDR Application and Fee Form.

Is this an application for a phased submission review? ☐ yes ☐ no	If this is an application for a fee reduction, please remit $1,000.

- Where the submission fee total is <$10,000, the full fee is due on filing.
- Where the submission fee total is >$10,000, 10% of the total fee is due on filing.

Identification

Product name		
Name of Manufacturer/Sponsor as per Drug Submission Application		
Address of Manufacturer/Sponsor		
Contact Person	Telephone	Fax
Billing address (if different)	Billing Contact Person	

Submission Information

Dosage Form	Route(s) of Administration
Strength(s) - A product with multiple strengths (eg. tablet) may be indicated	

Send completed form and remittance, made payable to "Receiver General for Canada", together with the submission to:

Submission and Knowledge Management Division
Veterinary Drugs Directorate
Holland Cross Complex
Ground Floor, Suite 14
11 Holland Avenue, Address Locator : 3000A
Ottawa, ON K1A 0K9

HPFB use only

HPFB use only						
Customer No.				Submission No.		
SO#						
INV #						
	10% or full fee		40%	CED Comp	MCED Comp	HSD Comp

Product Name: _____ **Submission No.:** _____ **File No.:** _____

Section 1: New Drug Submission **HC PROTECTED**

Component	Fee	x no.	Enter fee here	HPFB Use Only	
1. Efficacy & safety data (intended species) for one route, dosage form & indication in 1 species. For antiparasitic, several indications in 1 food species.	$15,980				
2. Efficacy & safety data (intended species) for one route & dosage form for an antiparasitic in 1 non-food species.	9,680				
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.	23,240				
4. Efficacy & safety data (intended species) for a growth promotion or production enhancement indication in 1 species.	31,470				
5. Comparative (pharmacodynamic, clinical or bioavailability) data for additional route. (In addition to route referred to in item 1, 2 or 3.	2,900				
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.)	480				
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.	21,790				
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.	29,050				
9. For food animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route.	2,900				
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.	14,520				
11. Chemistry & manufacturing for non-compendial medicinal ingredient. (A medicinal ingredient previously evaluated within the last 3 years, to which reference is made is not required to be re-evaluated).	4,840				
12. Chemistry & manufacturing for one strength of 1 dosage form	4,840				
13. Chemistry & manufacturing for an additional strength of 1 dosage form submitted with item 12.	2,420				
14. Change in manufacturer of a drug. (Applies only where a NDS does not include any of the above components.)	250				
HPFB use only Fee assessment verified by (print): _____ _____ _____ Signature Date	**Total Fee ▶**				

Product Name: _____ **Submission No.:** _____ **File No.:** _____

Section 2: Supplement to a New Drug Submission **HC PROTECTED**

Component	Fee	x no.	Enter fee here	HPFB Use Only	
1. Efficacy data for an additional indication in 1 species.	$12,590				
2. Efficacy & safety data (intended species) for one route & dosage form for an antiparasitic in 1 non-food species.	9,680				
3. Efficacy & safety data (intended species) for an indication in another species.	15,980				
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.	23,240				
5. Efficacy & safety data (intended species) for a growth promotion or production enhancement indication in 1 species.	31,470				
6. Efficacy & safety data (intended species) for the concurrent use of 2 drugs approved for the same species.	7,740				
7. Comparative (pharmacodynamic, clinical or bioavailability) data for an additional route. (In addition to route referred to in item 2 or 4.)	2,900				
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.)	480				
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.	2,900				
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.	14,520				
11. For food animals, toxicity studies for a change of an established ADI, MRL & withdrawal period.	7,260				
12. For concurrent use of 2 drugs in a food species, residue depletion studies to determine if extension to withdrawal periods is required.	5,810				
13. Chemistry & manufacturing for change in source of medicinal ingredient or its manufacturing process.	4,840				
14. Chemistry & manufacturing for change in formulation or dosage form.	2,420				
15. Chemistry & manufacturing for change in packaging or sterilization.	1,930				
16. Chemistry & manufacturing for extension of expiry date.	1,450				
17. Chemistry & manufacturing for concurrent use of 2 drugs.	1,450				
18. Chemistry & manufacturing for change in manufacturing site (parenteral or sterile).	480				
19. Change in manufacturer or brand name of a drug. (Applies only where a SNDS does not include any of the above components.)	250				
HPFB use only Fee assessment verified by (print): _____ _____ _____ Signature Date	**Total Fee ▶**				

Product Name: _____ **Submission No.:** _____ **File No.:** _____

Section 3: Abbreviated New Drug Submission or Supplement to an Abbreviated New Drug Submission **HC PROTECTED**

Component	Fee	x no.	Enter fee here	HPFB Use Only	
1. Any applicable component listed in Section 2.	See Section 2				
2. Comparative (pharmacodynamic, clinical or bioavailability) data for one route & dosage form.	$2,900				
3. 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.	2,900				
4. Chemistry & manufacturing for non-compendial medicinal ingredient. (A medicinal ingredient previously evaluated within the last 3 years, to which reference is made is not required to be re-evaluated.)	4,840				
5. Chemistry & manufacturing for 1 dosage form.	4,840				
6. Change in manufacturer or brand name of a drug. (Applies only where an abbreviated submission does not include any of the above components.)	250				
HPFB use only Fee assessment verified by (print): _____ _____ _____ Signature Date	**Total Fee ▶**				

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Section 4: DIN Application **HC PROTECTED**

Component	Fee	x no.	Enter fee here	HPFB Use Only	
1. Information (other than item 2 below) for DIN application, including the submission of labelling for a second review, if required.	$720				
2. Published references or other data.	500				
3. Change in manufacturer or brand name of a drug. (Applies only where a DIN application does not include any of the above components.)	250				
HPFB use only Fee assessment verified by (print): _____ _____ _____ Signature Date	**Total Fee ▶**				

Product Name: _____ **Submission No.:** _____ **File No.:** _____

Section 5: Preclinical (Investigational) New Drug Submission **HC PROTECTED**

Component	Fee	x no.	Enter fee here	HPFB Use Only	
1. Efficacy & safety data (intended species) & protocol for the conduct of clinical studies for one dosage form, route & indication in 1 species.	$4,840				
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.	3,870				
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.	14,520				
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.	21,790				
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.	29,050				
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.	7,260				
7. Chemistry & manufacturing for 1 dosage form with a non-compendial medicinal ingredient. (A medicinal ingredient previously evaluated within the last 3 years, to which reference is made is not required to be re-evaluated. In that case, the fee for item 8 would apply.)	4,840				
8. Chemistry & manufacturing for 1 dosage form with a compendial medicinal ingredient.	2,420				
HPFB use only Fee assessment verified by (print): _____ _____ _____ Signature Date	**Total Fee ▶**				

Product Name: _____ **Submission No.:** _____ **File No.:** _____

Section 6: Notifiable Change or Protocol Review **HC PROTECTED**

Component	Fee	x no.	Enter fee here	HPFB Use Only	
1. Information & material to support an application for a Notifiable change.	$1,300				
2. Request for review of scientific information outside of a regular drug submission (i.e. review of a proposed trial protocol).	1,300				
HPFB use only Fee assessment verified by (print): _____ _____ _____ Signature Date	**Total Fee** ▶				