Health Canada Santé Canada

Guidance Document on Cost Recovery
Veterinary Drug Submission Evaluation Fees

Health Products and Food Branch

Veterinary Drugs Directorate

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Canada

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1 General Information Contacts

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Contacts
Head-Submission Office (613) 941-8841
VDD Screening and Information Officer (613) 941-9171

Drug Identification Number Applications (Not-New-Drugs)
Veterinary Products Consultant (613) 941-9269
Facsimile (613) 957-3861

Emergency Drug Release Requests
EDR Contact (613) 948-2381
Facsimile (613) 946-1125

Accounts Receivable
Health Canada
Financial Management Operations
Holland Cross Complex, Tower A
Address Locator : 3002B
Ottawa, Ontario K1A 0K9
Phone 1-800-815-0506 Fax 613-957-3495

2 Procedures

2.1 Invoices

When paying an invoice, all cheques should be in Canadian funds from a Canadian bank and made payable to the "**Receiver General for Canada**". As stated on the invoice, payment should be sent to Accounts Receivable. Payment may also be made by credit card by providing the card number, expiry date, cardholder's name, address and telephone number and written authorization to use the card.

Questions regarding your invoice or your account balance may be directed to the staff at Accounts Receivable by phone at 1-800-815-0506 or by fax at 613-957-3495. Please have your invoice number on hand.

If your question is related to the interpretation of the fee structure as it applies to your submission, please contact the Screening and Information Officer at the Veterinary Drugs Directorate.

Payment of invoices is due within 30 days from the date issued. Interest will be charged for the amount owing on invoices not paid by the due date. The interest charged on outstanding accounts will be calculated and compounded monthly, at the current bank rate plus three percent, and is payable on the outstanding amount ending the day on which payment is received.

2.2 Fee Form

The *Veterinary Drug Submission Fee Application Form* (HC/SC 4360E) requests a description of the components along with the relevant fees outlined in the *Veterinary Drug Evaluation Fees Regulations*. The front page of the application form must be completed for each veterinary drug submission or DIN application. It is only necessary to complete and send the section(s) pertaining to your submission/application. Fill in the appropriate boxes and total the components to indicate the total submission fee.

A completed form should accompany each submission. A completed form will include page 1, the relevant submission section page and the required fee. A new fee form is not required for a response to a screening deficiency or an Additional Data Letter. It is acceptable to submit photocopies of the fee application form.

The *Drug Submission Application Form* (HPB/DGPS 3011) must also accompany each drug submission and DIN application.

2.3 Payment Schedule

Cost recovery fees are in effect for evaluations of veterinary drug submissions and applications. The schedules outlined below apply to all New Drug and Not-New-Drug submissions, with the exception of Emergency Drug Release applications, which are invoiced after the application is received. Fee payment for phased submissions is outlined in Section 4.

a) Fees less than $10,000:

If the total fees for the submission or application are less than $10,000, the full amount is payable when the submission or application is filed. Payment should be sent with the relevant forms and supporting data to the Submission and Knowledge Management Division, Veterinary Drugs Directorate.

b) Fees greater than $10,000:

If the fees for the submission total over $10,000, they are payable in three stages: 10 percent should be paid at the time the submission is filed; 40 percent will be invoiced when the submission is accepted for review; and the remaining 50 percent will be invoiced for each individual component of the submission once its evaluation is completed. The evaluation is considered to be completed upon the issuance of a Notice of Compliance (NOC), Additional Data Letter (ADL), or Information Satisfactory Letter (ISL).

2.4 Submissions or Applications Rejected at Screening

The fees for each drug submission or application include both a screening fee and an evaluation fee. Screening determines whether all the required information is present and in an acceptable form. Manufacturers will receive prompt notification if deficiencies are identified. This will ensure that only submissions which are acceptable are waiting in order for review.

If a submission or application is rejected at screening, 10 percent of the sum of applicable submission fees will be retained to cover services rendered.

When a submission or application is determined to be unacceptable for review, a letter will be sent to the manufacturer advising of the deficiencies. Manufacturers will be given 30 days from the date of this letter to submit the missing information or modify their submission. Submissions that are not amended during this 30 day period will be rejected and the 10 percent screening fee will be retained. If more than 10 percent of the total fee has been paid, the excess will be refunded to the sponsor's account.

2.5 Withdrawn Submissions/Applications

If the sponsor submits a written request to cancel a submission, or a submission is withdrawn, the total fee for the submission will be based on the date of withdrawal. If a submission is withdrawn after screening has been completed but before the submission is picked up for review, only the screening fee will apply. Once the review of a component has commenced, the full fee for that component will apply.

3 Fee Structure

The regulations can be found in *The Canada Gazette* Part II, Volume 130, No. 6, page 1100. The fees for each of the submission components are outlined in Schedules I to VII in the fee regulations.

Schedule I	New Drug Submission
Schedule II	Supplement to a New Drug Submission
Schedule III	Abbreviated New Drug Submission and Supplement to an Abbreviated New Drug Submission
Schedule IV	Drug Identification Number (DIN) Application
Schedule V	Preclinical (Investigational) New Drug Submission
Schedule VI	Experimental Studies Certificate
Schedule VII	Emergency Drug Sale

Fees for Notifiable Changes and Protocol Reviews are described in Table VI.

Fees will not apply for the review of information submitted in response to an ADL. If the information requested in an ADL results in the filing of a submission component not previously filed; the manufacturer must submit payment, in the prescribed manner, upon filing of the new component.

Summary of Submission Evaluation Fees

The following tables, which summarize applicable fees, are presented as a guide. For the precise wording, refer to the text in Schedules I to VII of the *Veterinary Drug Evaluation Fees Regulations*.

TABLE I: Component Fees for NDS, SNDS, ABS, SABS and IND Submissions

	Submission Component	Submission Type	Fee
	A. Efficacy and Safety in the Intended Species		
1	Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in one animal species. (In the case of an antiparasitic drug, several indications in one food animal species.)	NDS, SNDS	$15,980
2	Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species.	NDS, SNDS	$9,680
3	Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in two animal species, or a single route of administration, dosage form and two indications in one animal species.	NDS, SNDS	$23,240
4	Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species.	NDS, SNDS	$31,470
5	Efficacy data to support an additional indication in one animal species.	NDS, SNDS, SABS	$12,590
6	Efficacy and safety data (in the intended species) to support the concurrent use of two drugs approved for the same animal species.	SNDS, SABS	$7,740
7	Efficacy and safety data (in the intended species) and protocol to support the conduct of clinical studies relative to a single dosage form, route of administration and indication in one species.	IND	$4,840
8	Efficacy data and protocol to support the conduct of clinical studies relative to a single route of administration and indication with a dosage form for which a notice of compliance has been issued for use in the species to be treated.	IND	$3,870
9	Comparative (pharmacodynamic, clinical or bioavailability) data to support an additional route of administration. (In addition to route referred to in item 1, 2 or 3.)	NDS, SNDS, ABS	$2, 900
10	Comparative (pharmacodynamic, clinical or bioavailability) data to support each additional strength. (One study to support strengths may be included under items 1, 2 or 3 without payment of this fee.)	NDS, SNDS, ABS	$480

	Submission Component	Submission Type	Fee
	B. Human Safety		
11	For food-producing animals, toxicity, metabolism and residue depletion studies to establish a temporary acceptable daily intake, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species.	IND	$14,520
12	For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species.	IND, NDS	$21,790
13	For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species.	IND, NDS	$29,050
14	For food-producing animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route of administration.	NDS, SNDS	$2,900
15	For food-producing animals, residue depletion studies to establish a new withdrawal period for a change in the dosage or route of administration of an approved dosage form in one species.	SNDS	$2,900
16	For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in an additional species.	IND, NDS, SNDS	$14,520
17	For food-producing animals, toxicity studies to support a change of an established acceptable daily intake, maximum residue limit and withdrawal period.	SNDS	$7,260
18	For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism studies to establish a withdrawal period for a single dosage form, dosage and route of administration in an additional species.	IND	$7,260
19	For the concurrent use of two drugs in a species of food-producing animals, residue depletion studies to determine if an extension to existing withdrawal periods is required.	SNDS	$5,810

	Submission Component	Submission Type	Fee
20	For food-producing 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.	ABS	$2,900

	Submission Component	Submission Type	Fee
	C. Chemistry and Manufacturing		
21	Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug. (A medicinal ingredient previously evaluated within the last 3 years, to which reference is made is not required to be re-evaluated.)	NDS, ABS	$4,840
22.	Chemistry and manufacturing data to support one strength of a single dosage form.	NDS, ABS	$4,840
23.	Chemistry and manufacturing data to support an additional strength of a single dosage form submitted at the same time as item 22.	NDS	$2,420
24.	Chemistry and manufacturing data to support a single dosage form containing 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 # 25 below would apply.	IND	$4,840
25.	Chemistry and manufacturing data to support a single dosage form containing a compendial medicinal ingredient.	IND	$2,420
26.	Chemistry and manufacturing data to support a change in the source of a medicinal ingredient or its manufacturing process.	SNDS	$4,840
27.	Chemistry and manufacturing data to support a change in formulation or dosage form.	SNDS	$2,420
28.	Chemistry and manufacturing data to support a change in packaging or in the sterilization process.	SNDS	$1,930
29.	Chemistry and manufacturing data to support an extension of the expiry dating.	SNDS, SABS	$1,450
30.	Chemistry and manufacturing data to support the concurrent use of two drugs.	SNDS, SABS	$1,450
31.	Chemistry and manufacturing data to support a change in the manufacturing site for parenteral dosage forms.	SNDS, SABS	$480
	Name Change		

Submission Component		Submission Type	Fee
32	Corporate or Drug Name change (each DIN).	NDS, ABS	$250

3.1 Calculating the Applicable Fee

More than one of the submission components listed in Column I of the *Veterinary Drug Evaluation Fees Regulations* may apply to the data package to be filed with a submission. The total fee for the submission evaluation will be the sum of the fees outlined in Column II corresponding to the applicable submission components from Column I.

The examples below illustrate how the fee components are used to calculate the total fee. The bold numbers beside the fees in these examples refer to the numbers in Table I rather than to specific component numbers for each submission type in the *Veterinary Drug Submission Fee Application Form* (HC/SC 4360E).

Investigational New Drug Submissions (IND)

Example 1: Single Indication, Single Dosage Form (non-compendial medicinal ingredient) and Single Route of Administration in Dogs.

This IND data package includes documentation regarding efficacy and species safety, a trial protocol and a chemistry and manufacturing package for drug substance (non-compendial) and dosage form. The fee will be the sum of the following submission components:

7 ($4,840) + **24** ($4,840) = $9,680

Example 2: Single Indication, Single Dosage Form (non-compendial medicinal ingredient) and Single Route for Growth Promotion in Cattle.

This IND includes information regarding efficacy and species safety, a trial protocol, toxicity data for a safety factor of 100, residue data and a complete **NDS chemistry and manufacturing package** for the drug substance (non-compendial) and dosage form. The fee will be the sum of the following submission components:

7 ($4,840) + **13** (29,050) + **21** ($4,840) + **22** ($4,840) = $43,570

New Drug Submissions (NDS)

Example 3: Product in Example 1 (IND), Single Indication in Dogs.

This NDS includes information on efficacy and species safety data and a complete chemistry and manufacturing package for the drug substance (non-compendial) and dosage form. The fee will be the sum of the following submission components:

1 ($15,980) + **21** ($4,840) + **22** ($4,840) = $25,660

Example 4: Product in Example 2 (IND), Growth Promotion Indication in Cattle.

This NDS includes information on efficacy and species safety data. Human Safety and Manufacturing requirements have already been completed at the IND stage. The fee will be for submission component **4** ($31,470) only.

Example 5: Three Conditions of Use, Single Dosage Form and Single Route for Swine (Active ingredient approved for dogs within the last 3 years).

This NDS includes information on efficacy and species safety data, toxicity data for a safety factor of 1,000 with residue data and complete manufacturing package for the dosage form. The fee will be the sum of the following submission components:

3 ($23,240) + **5** ($12,590) + **12** ($21,790) + **22** (4,840) = $62,460

Supplemental New Drug Submissions (SNDS)

Example 6: Product in Example 5 for Two Additional Conditions of Use in Cattle.

This SNDS includes information on efficacy and species safety data, metabolism and residue data. The fee will be the sum of the following submission components:

3 ($23,240) + **16** ($14,520) = $37,760

Additional examples are provided in Table II below.

TABLE II: Examples of Fees for Frequently Filed Submission Types

ACTIVITY OR SERVICE	ANIMAL SAFETY/ EFFICACY	HUMAN SAFETY	MANUFAC-TURING	TOTAL
	Submission Component Number(s) From Table I Are in Brackets			
NDS: New Entity/Food Species/1000 SF[1]	(1) $ 15,980	(12) $ 21,790	(21+22) $ 9,680	$ 47,450
NDS: New Entity/Food Species/100 SF	(1) 15,980	(13) 29,050	(21+22) 9,680	54,710
NDS: New Entity/Food Species/100 SF/GP[2]	(4) 31,470	(13) 29,050	(21+22) 9,680	70,200
NDS: New Entity/Non-Food Species	(1) 15,980	-	(21+22) 9,680	25,660
Abbreviated NDS: Food Species	(9) 2,900	(20) 2,900	(21+22) 9,680	15,480
Abbreviated NDS: Non-Food Species	(9) 2,900	-	(21+22) 9,680	12,580
S/NDS: Another Food Species	(1) 15,980	(16) 14,520	-	30,500
S/NDS: Another Non-Food Species	(1) 15,980	-	-	15,980
S/NDS: New Indication, Same Food Species	(5) 12,590	-	-	12,590
S/NDS: New Indication, Same Non-Food Species	(5) 12,590		-	12,590
Concurrent Use in Food Species	(6) 7,740	(19) 5,810	(30) 1,450	15,000
Concurrent Use in Non-Food Species	(6) 7,740	-	(30) 1,450	9,190
IND: New Entity/Food Species/Temporary ADI[3]	(7) 4,840	(11) 14,520	(24) 4,840	24,200
IND: New Entity/Food Species/1000 SF	(7) 4,840	(12) 21,790	(24) 4,840	31,470
IND: New Entity/Food Species/100 SF	(7) 4,840	(13) 29,050	(24) 4,840	38,730
IND: New Entity/Non-Food Species	(7) 4,840	-	(24) 4,840	9,680
ESC: Food Species/Original	-	-	-	2,900
ESC: Food Species/Repeat	-	-	-	480
ESC: Non-Food Species/Original	-	-	-	960
ESC: Non-Food Species/Repeat	-	-	-	480
DIN: Application	-	-	-	720
DIN: Drug Status Information	-	-	-	500
Corporate or Drug Name Change	-	-	-	250
EDR: Food Species	-	-	-	100
EDR: Non-Food Species	-	-	-	50

1. Safety Factor
2. Growth Promotant
3. Acceptable Daily Intake

Corporate or Drug Name Change:

This category includes changes to the name of the manufacturer or brand name of a drug, or to cross-referenced submissions. The term "Manufacturer" refers to the company which holds the DIN for the product, rather than the actual fabricator.

When a change to the manufacturer's name occurs because of a company merger or buy-out, a veterinary drug submission or DIN application is required for each product belonging to the company, and each submission/application will be charged the $250 fee. Proper documentation must be provided to show the legal change in company name, along with the proposed labelling for each product and its formulation.

When a sponsor is applying for a NOC based on cross-referencing another sponsor's previously approved submission, the written authorization of the company allowing the cross-reference is required. The *Drug Submission Application Form* (HPB/DGPS 3011), proposed labelling, and $250 fee must be included with the submission.

A manufacturer may wish to change the brand name of a product with no other changes to the labelling. A Change in Product Name is considered to be a NDS, and requires the *Drug Submission Application Form* (HPB/DGPS 3011), proposed labelling, and $250 fee.

TABLE III: DIN Application for Not-New-Drugs

	Application Component	Fee
1.	Information, other than that referred to in item 2, to support an application for a DIN, including the submission of labelling material for a second review, if required.	$720
2.	Published references or other data.	$500
3.	Documentation to support a change of manufacturer, a change to the name of a manufacturer or a change to the brand name of a drug. (Applies only where a DIN application does not include any of the above components.)	$250

The DIN fee of $720 only applies where the application does not include any other component. This fee allows for the submission of labelling material for a second review, if required. When published references or other data need to be reviewed for substantiating a new DIN application or modification of the current label information, an additional fee of $500 will apply. When a sponsor has submitted an NDS, SNDS or ABS, the DIN is issued with the Notice of Compliance and it is not necessary to submit a separate DIN application nor to pay an additional $720.

TABLE IV: Experimental Studies Certificate

	Certificate Component	Fee
1.	Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a non-food-producing animal.	$960
2.	Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that for a previously authorized experimental studies certificate for a drug to be administered to a non-food-producing animal.	$480
3.	Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a food-producing animal.	$2,900
4.	Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that for a previously authorized experimental studies certificate for a drug to be administered to a food-producing animal.	$480

The investigator must file the Experimental Studies Certificate Fee and Application Form, but the applicable fee may be submitted by either the investigator or the sponsoring manufacturer.

TABLE V: Emergency Drug Release

	EDR Component	Fee
1.	Information and material to support the sale of a drug to be used in the emergency treatment of a non-food-producing animal.	$ 50
2.	Information and material to support the sale of a drug to be used in the emergency treatment of a food-producing animal.	$100

An Emergency Drug Release Application and Fee Form is to be used when veterinary practitioners apply for Emergency Drug Releases.

One EDR is required for each animal patient, herd/farm or one site of fish. The amount to be released at one time depends on the nature of the condition being treated, single treatment or chronic treatment (maximum 6 months), and/or the nature of the drug.

Veterinary practitioners will be invoiced for their EDR requests.

TABLE VI: Notifiable Change or Protocol Review

	Component	Fee
1.	Information and material to support an application for a Notifiable Change.	$1,300
2.	Request for the review of scientific information outside of a regular drug submission (i.e. review of a proposed trial protocol).	$1,300

Applicable fees are to be submitted at the time of filing.

4 Phased Submissions

4.1 Description

The phased submission process allows a manufacturer to file for review a portion of the total information required for a new drug submission. Manufacturers may wish to take advantage of this process by filing data packages as they become available during the various stages of product development. An opinion from the Directorate on the data contained in the phased submission is available to the manufacturer much earlier on in the process.

4.2 Procedures

The phased submission filing process is available for New Drug and Abbreviated New Drug Submissions and Supplements to these submissions. One or more submission components contained in Schedules I, II and III to the *Veterinary Drug Evaluation Fees Regulations* may be contained in a phased submission. All the information required for an individual component, including the applicable fee, is to be submitted at the time of filing.

The quantitative formulation and draft labelling (information relevant to the component being submitted) should be included in the initial data package.

The chemistry and manufacturing data for a non-compendial medicinal ingredient should be submitted either at the same time or prior to the submission of the chemistry and manufacturing data in support of the dosage form. For abbreviated submissions, the chemistry and manufacturing data must be submitted as the first phase, since this information is needed to assess the pharmaceutical equivalence of the reference product and the subsequent-entry product.

a) Filing Requirements:

- A completed *Drug Submission Application Form* (HPB/DGPS 3011) is required. The quantitative formulation must be included, either on the form or separately.

- A draft label with information relevant to the component or components being submitted.

- A completed *Veterinary Drug Submission Fee Application Form* (HC/SC 4360E).

- The appropriate fee or fees as per the schedule of fees and regulations.

b) Fee Payment:

Where the total fee for the submission is less than $10,000; the fee for each component is payable at the time that each phase is filed.

Where the total fee for the submission is greater than $10,000; 10% is payable for each component on filing, 40% on acceptance of the submission and the remaining 50% when the review of each component is completed.

5 Application For Reduction of Fees

A sponsor who files a submission, supplement or application may apply for a reduction in the fees payable. A payment of $1,000 and the information supporting the request for a reduction must be included with the application. A request for a reduction of fees and the accompanying information should be included with the submission in a separate section which can be severed from the submission to facilitate separate review by the Veterinary Drugs Directorate. The sponsor should still include a completed fee form, indicating what the full fee would be and that the sponsor has applied for a reduction of this full fee.

5.1 Eligibility for Reduction

a) The applicant must present information to support the anticipated revenue from gross sales of the drug in Canada during the fee verification period. The fee verification period is the period beginning on the date that the drug is first sold in Canada and ending three years after that date. The information should provide an accurate measure of the current market situation for the proposed product. Information to support the anticipated revenue should include as a minimum:

- data from similar, previously marketed products;
- an analysis of the target population in terms of product demand;
- average sale price/volume for each subpopulation in the targeted group;

and

- a comparison to similar products of the same therapeutic class on the Canadian market.

b) the Drug Evaluation Fee must be greater than 10% of the total 3 year gross sales forecast; and

c) a fee for the assessment of the Application for Reduction of Fees of $1,000[1] must be submitted with the application and made payable to the " Receiver General for Canada". The cheque and accompanying information should be sent to the Submission and Knowledge Management Division, VDD.

The Application for Reduction of Fees will be reviewed during screening. The Submission and Knowledge Management Division, VDD will inform the applicant whether the Application for Reduction of Fees has been accepted or rejected.

If the reduction is granted, a fee equal to 10% of anticipated sales during the fee verification period will be charged. At the end of the fee verification period, audited sales records must be submitted to VDD. If the revenue stated in the audited sales records is greater than the anticipated sales, the balance payable will be due 60 days after the fee verification period ends.

Where the Application for Reduction in Fee was for a supplement to an existing drug product (e.g., new condition of use) the sponsor's audited sales report must clearly reflect the difference in sales over the fee verification period.

5.2 Calculation of Reduced Fee

The sponsor should calculate:

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1 This fee is for the review of the information submitted with the Application for Reduction of Fees and review of the audited sales reports, and is not considered part of the submission evaluation. This fee will not be deducted from the fees payable for the submission evaluation services.

(i) the total fee for the submission (sum of all applicable components)
(ii) the anticipated gross sales from the first 3 years sold in Canada
(iii) 10% of (ii).

If the application for reduction is accepted, the sponsor will pay 10% of the anticipated gross sales from the first three years sold in Canada, according to the timing and manner stated in sections 12 to 15 of the *Veterinary Drug Evaluation Fees Regulations*. Therefore, if the anticipated gross sales during the fee verification period is $100,000 or less, resulting in a reduced fee of $10,000 or less, then the fee must be paid immediately. If the reduced fee is greater than $10,000, the sponsor will be invoiced in the phases outlined in the fee regulations.

Example

A sponsor wishes to file a drug submission where the Veterinary Drug Evaluation Fee would normally be $50,000. Since the anticipated three year gross sales would only be $75,000, the sponsor wishes to apply for a reduction in fees. An Application for Reduction of Fees is sent with the submission, including a cheque for $1,000 and the information to support the anticipated revenue. If the Application for Reduction of Fees is granted, the submission review fee would be 10% of $75,000 (i.e. $7,500) which would be payable according to the timing set out in the fee regulations (in this case immediately because it is under $10,000). After the fee verification period ends, if the audited sales reports indicate that:

Scenario 1

the three year revenue was much higher than estimated (e.g. $700,000), then the sponsor will pay the original submission fee of $50,000 minus the $7,500 which was already paid, within 60 days after the day on which the fee verification period ended.

Scenario 2

the revenue was higher than estimated (e.g. $90,000), then the sponsor will pay the difference between the 10% actual revenue from sales ($9,000) and the 10% anticipated sales ($7,500), i.e. $1,500. The difference is payable 60 days after the day on which the fee verification period ended.

Scenario 3

the revenue was lower than estimated (e.g. $60,000). There is no provision for reimbursement of fees. A refund will not be made to the sponsor for the difference.

6 Appeals Procedure

A provision for appeals is an integral part of each HPFB cost recovery and client fee initiative. The following procedures may be followed for issues related to the *Veterinary Drug Evaluation Fees Regulations.*

6.1 Appeal Information and Status

Officers of the Submission and Knowledge Management Division, VDD will assist in the appeal/complaint process and provide status on ongoing appeals/complaints. Sections 6.2 and 6.3 outline the process for appeals related to the application of the *Veterinary Drug Evaluation Fee Regulations*.

6.2 Appeal Process: Step 1

The sponsor may appeal decisions regarding the application of the *Veterinary Drug Evaluation Fee Regulations*. The appeal must be received within 30 calendar days following issuance of the invoice. All appeals must be received in writing, by mail or facsimile and directed to the Chief, Submission and Knowledge Management Division (SKMD), Veterinary Drugs Directorate. The Division Chief will, within 30 days of receipt of the appeal, review the decision in question in consultation with other Division Chiefs and send the appellant a reply which will include the decision on the appeal and the rationale for the decision.

6.3 Appeal Process: Step 2

If the communication in Step 1 between the sponsor and the SKMD has not resolved the dispute, the sponsor may apply to the Director General, Veterinary Drugs Directorate, to request that the appeal be examined by an independent Appeal Committee.

The Appeal Committee will be made up of three members. The Chair person will be a Branch or Department Financial Officer, with one member nominated by the Branch and one by the Appellant. Any person who has previously been involved in the assessment of fees related to the submission will not be eligible to participate as a member of the Committee.

Appendix I

Glossary of Abbreviations

NDS	New Drug Submission
SNDS	Supplemental New Drug Submission
NC	Notifiable Change Submission
ABNDS	Abbreviated New Drug Submission
SABNDS	Supplemental Abbreviated New Drug Submission
NDS-P	Phased New Drug Submission
SNDS-P	Phased Supplemental New Drug Submission
IND	Investigational (Preclinical) New Drug Submission
ESC	Experimental Studies Certificate
EDR	Emergency Drug Release
DIN	Drug Identification Number Application ('not new drug')
NOC	Notice of Compliance
ADL	Additional Data Letter
ISL	Information Satisfactory Letter