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Notice

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Guidance Document – Fees for the Review of Drug Submissions and Applications

This guidance document has been updated, including its Document Change Log, to reflect the recent amendments to the *Fees in Respect of Drugs and Medical Devices Regulations* (Regulations). The amendments included the exclusion of Emergency Use New Drugs (EUND) from the Regulations.

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GUIDANCE DOCUMENT

Fees for the Review of Drug Submissions and Applications

Published by authority of the
Minister of Health

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Health Products and Food Branch

Canada 

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p style="text-align: right;"><i>Health Canada</i></p>	<p>The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by:</p> <ul style="list-style-type: none"> • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. <p style="text-align: right;"><i>Health Products and Food Branch</i></p>
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Également disponible en français sous le titre : *Ligne directrice - Frais pour l'examen des présentations et demandes de drogues*

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

Document Change Log			
Date	Change	Location (Section, paragraph)	Nature of and/or Reason for Change
2013-06-10	Scope was changed to exclude Emergency Use New Drug (EUND) submissions from this guidance document	S.1.3	Regulatory amendment to the <i>Fees in Respect of Drugs and Medical Devices Regulations</i> (Fee Regulations) to exclude EUND submissions (NDS and ANDS)
	Submission and Information Policy Division changed to Office of Submissions and Intellectual Property	S.2.1	To reflect the office name change
2013-04-01	Fees were increased by 2%	Appendices 1 and 2	In accordance with s. 4 of the Regulations
2012-04-01	Fees were increased by 2%	Appendices 1 and 2	In accordance with s. 4 of the Regulations
	Fee Verification Period definition was revised and definition for Fiscal Year was inserted	S.1.5	For clarification
	Revised fifth paragraph under this section	S.2.2.3.	
	Revised wording in Table	S.2.2.5	
	Revised wording in the paragraphs	S.2.3.1, S.2.3.2.4, S.2.3.2.6, S.2.3.2.11	
	Rearranged paragraphs and moved the table to Appendix 3	S.2.3.1.1	
	Additional examples were added to these sections and some wording was changed.	S.2.3.2.2, S.2.3.2.3, S.2.3.2.4, S.2.3.2.5	
	Example was revised and an example was deleted.	S.2.3.2.8	
	Sentence inserted in the first paragraphs	S.2.4.2, S.2.4.3	
2011-04-01	Significant changes to this document include changes to the fee structure and the addition of information on remissions and deferrals		The guidance document was rewritten to reflect the new Fee Regulations.

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1. INTRODUCTION

This document provides guidance on the interpretation of the *Fees in Respect of Drugs and Medical Devices Regulations* with a focus on how the fees for the review of a new drug submission (NDS), a supplement to a new drug submission (SNDS), an abbreviated new drug submission (ANDS), a supplement to an abbreviated new drug submission (SANDS) and a drug identification number (DIN) application contained in Part 2, Division 1 of these regulations will be administered.

1.1 Policy Objectives

To ensure that the cost recovery system to defray the cost to government of applying the principles of risk assessment and risk management in the regulation of drugs reflects the current costs associated with the review of drug submissions and DIN applications, excluding natural health products and drugs for veterinary use only.

1.2 Policy Statements

Sponsors submitting drug submissions, supplements or applications will be charged a review fee. Fees are proportionate to the type and complexity of the examination, and for eligible sponsors, the actual gross revenue in respect of the sale of the drug for which the submission or application is made.

Sponsors that have not completed their first full fiscal year at the filing date of their submission, supplement or application are eligible for a fee payment deferral period of two years starting on that filing date.

Sponsors are eligible for a remission of a portion of the review fee when the applicable fee exceeds 10% of the actual gross revenue during the fee verification period for the drug product for which the submission, supplement or application has been made.

1.3 Scope and Application

This guidance document applies to sponsors submitting an NDS, SNDS, ANDS, SANDS or DIN application to Health Canada except if the NDS or ANDS is filed under C.08.002.01 or C.08.002.1 of the *Food and Drug Regulations*, respectively, i.e., Emergency Use New Drug (EUND) submissions. This guidance document does not apply to submissions or applications pertaining to drugs that are natural health products, or drugs that are for veterinary use only.

1.4 Background

Before a drug is authorized for sale in Canada, scientific evidence of its safety, efficacy and quality, as required by the *Food and Drugs Act* and regulations, must be provided for review by Health Canada to determine whether the benefits associated with the product outweigh the risks. In the early 1990s, Health Canada was given the authority under the *Financial Administration Act* to charge industry user fees in order to recover some of the costs related to service delivery for drugs, including the costs of review. However, the cost of service delivery has increased substantially since that time due to increasing volume and complexity of applications, along with costs of inflation and other costs of doing business.

The *Fees in Respect of Drugs and Medical Devices Regulations* aim to provide sufficient funding for Health Canada to meet service standards and support access to drugs for Canadians in a timely manner. They also address costs associated with inflation.

1.5 Definitions

Actual Gross Revenue - The amount earned by the sponsor during the fee verification period from sales in Canada of a drug that is subject to a submission, supplement or application.

Anticipated Gross Revenue - The amount the sponsor expects to earn during the fee verification period from sales in Canada of a drug that is subject to a submission, supplement or application.

Examination - The review of the original information submitted by a sponsor in support of a drug submission, supplement or application, as well as solicited and unsolicited information, for the purpose of determining whether the requirements of the *Food and Drugs Act* and regulations are met. If the requirements are met, a notice of compliance (NOC) and/or a DIN is issued. Examination is commonly known as review, and is referred to as such in this guidance document.

Fee Verification Period - The period beginning on the day the drug is first sold in Canada and ending three years after that day. In the case of an SNDS where no new DIN is issued, such as an SNDS for a new use, the fee verification period begins on the date that the NOC for the SNDS is issued unless the applicant can prove that the sale of the drug with the new use started at a later date.

Fiscal Year (or financial year) - The period determined by a business for calculating its annual ("yearly") financial statements for tax purposes or other annual reporting responsibilities.

Filing Date - Refers to the final central registry file date allocated to an application once it is deemed administratively complete by Health Canada that is (i.e.), once all elements and forms required for processing are completed and submitted to Health Canada. This date may differ from the date of original filing should the submission be considered administratively incomplete at the time of receipt.

Preliminary Examination - The examination of the original information submitted by a sponsor in support of a drug submission, supplement or application, as well as solicited and unsolicited information, to ensure the submission contains the requisite information for the type of submission, and that it is submitted in an acceptable format as outlined in the applicable guideline(s). If the information is found to be acceptable on preliminary examination, it is accepted for review. Preliminary examination is commonly known as screening, and is referred to as such in this guidance document.

1.6 Acronyms

ANDS	abbreviated new drug submission
DIN	drug identification number
DINA	drug identification number application for a pharmaceutical
DINB	drug identification number application for a biologic
DIND	drug identification number application for a disinfectant
DINF	drug identification number application for a Category IV Monograph
EUND	Emergency Use New Drug
LASA	look-alike-sound-alike
NAS	new active substance
NDS	new drug submission
NOC	notice of compliance
NOD	notice of deficiency
NON	notice of noncompliance
OSIP	Office of Submissions and Intellectual Property
SANDS	supplement to an abbreviated new drug submission
SDN	screening deficiency notice
SNDS	supplement to a new drug submission

2. GUIDANCE FOR IMPLEMENTATION

This section provides detailed information on how and where to submit fees; the fee payment schedule; fee structure; and fee remissions.

2.1 General Contact Information

For questions regarding your invoice payment or your account balance, contact Accounts Receivable by phone at 613-957-1052 or 1-800-815-0506; by fax at 613-957-3495; or by email at AR-CR@hc-sc.gc.ca. Please have your customer account or invoice number available.

For questions related to the interpretation of fees pertaining to your drug submission, supplement or application including invoice disputes, contact the Office of Submissions and Intellectual Property (OSIP formerly SIPD) by phone at 613-941-7283, by fax at 613-941-0825 or by email at cost.recovery@hc-sc.gc.ca.

2.2 Fee Payment Procedures

All payments must be in Canadian funds. Cheques must be made payable to the “Receiver General for Canada”.

2.2.1 Drug Submission/Application Fee Form

A Drug Submission/Application Fee Form must be included with every submission, supplement or application. The form outlines the fees in Schedule 1 to the *Fees in Respect of Drugs and Medical Devices Regulations*. It also includes sections on fee deferral requests and fee remission applications.

A Drug Submission/Application Fee Form is not required to accompany a response to a screening deficiency notice (SDN), a response to a Notice of Non-Compliance (NON), or a response to a Notice of Deficiency (NOD) unless requested by Health Canada.

The Drug Submission/Application Fee Form is located on the Health Canada website at: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/index-eng.php>.

2.2.2 Where to Submit Payment

Where to submit payment of the fee is dependent on the amount of the fee to be paid. Payments should be submitted as follows:

Payments for \$10,000 or less:

Payments for \$10,000 or less must be included with the drug submission, supplement or application and sent to:

Office of Submissions and Intellectual Property
Therapeutic Products Directorate
Health Canada
101 Tunney's Pasture Driveway,
Finance Building
Address Locator 021A1
Ottawa, Ontario
K1A 0K9

Payments over \$10,000:

Payments for more than \$10,000 should be made in response to an invoice and sent to:

Health Canada
Accounts Receivable
2932 Baseline Road
Qualicum Tower C
Address locator 3203B, Room B350
Ottawa, Ontario
K1A 0K9

2.2.3 Payment Schedule

The timing of payment of the drug submission, supplement or application fee is dependent on the amount of the fee to be paid. Payments are due as follows:

Fees of \$10,000 or less:

- 100% of the fee must be submitted at the time the drug submission, supplement or application is filed. However, if an application for a fee remission accompanies the submission, supplement or application, only the remission processing fee must be submitted upon filing; the sponsor will receive an invoice for the review fee (see section 2.4 of this guidance document).

Note: When submissions, supplements or applications are not accepted into review, the sponsor will receive a remission of 90% of the fees paid.

Fees over \$10,000:

- 10% of the fee is due upon receipt of a notice that the drug submission, supplement or application has been found to be incomplete following screening;

- 75% of the fee is due upon receipt of a notice that the drug submission, supplement or application has been found to be complete following screening and has been accepted for review;
- 25% of the fee is due upon receipt of a notice that the review has been completed.

2.2.4 Deferred Payments

If the sponsor has not completed its first full fiscal year on the filing date of the drug submission, supplement or application, a two-year deferral of payment is granted from that filing date. At the end of the two-year period the sponsor must pay all of the applicable fees. In order to qualify for the deferral period, a statement, signed by the individual responsible for the sponsor's financial affairs, specifying the commencement date of the sponsor's fiscal year must be submitted with the drug submission, supplement or application.

If it is determined, on the basis of any information available to Health Canada, that the statement submitted by the sponsor is inaccurate, a notification will be sent indicating that the payment cannot be deferred, and the fee will be payable in accordance with the payment schedule outlined in section 2.2.3 of this guidance document.

2.2.5 Withdrawn or Cancelled Submissions

If Health Canada withdraws a submission or if the sponsor submits a written request to cancel a submission, the total fee will be based on when the submission was withdrawn or cancelled. Refer to the summary table below:

Timing of Withdrawal or Cancellation	Total Applicable Fee for Submissions Filed
Before the screening has been completed	0%
After screening has been completed but before the submission is accepted into review (including after a decision to issue an SDN)	10%
During the review but before a decision is made to issue an NOC, NOD, NON, NOD-Withdrawal or NON-Withdrawal or upon issuance of a NOD-Withdrawal	75%
After decision is made to issue a NON, NON withdrawal, a	100%

rejection letter for a Category IV Monograph or labelling standard, an NOC or a DIN	
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2.3 Fee Structure

Every fee in this guidance document is to be increased annually by 2%, rounded upwards to the nearest dollar, beginning April 1, 2012. An annual adjustment factor is necessary to ensure that service standards continue to be met. Each year, a Notice of Intent will be published in *Canada Gazette, Part I* setting out the revised fees. Additionally, Health Canada will review the costs associated with service delivery every three years and will propose new or amended fees to reflect the results of those reviews, if necessary.

Appendices 1 and 2 outline the fees for the review of drug submissions, supplements or applications and for remission processing, respectively. These appendices will be updated as required to reflect the annual inflation cost of 2%, as well as any penalties incurred by Health Canada. The fee to be paid for a drug submission, supplement or application is the one in effect at the time of filing. The appendices will be dated and available with previous versions on the Health Canada website for ease of reference.

2.3.1 Fees for Drug Submission Review

Appendix 1 contains the fees for each submission class as outlined in Schedule 1 to the *Fees in Respect of Drugs and Medical Devices Regulations*. The fee structure is hierarchical. Only the largest of all the possible applicable fees applies; therefore, only **one fee** should be checked on the fee form submitted with the submission, supplement or application.

2.3.1.1 Grouping of Products

As with applications under Division 8 applications, under Division 1 of the *Food and Drug Regulations* may be grouped together resulting in one fee if the following conditions apply:

- the applications are filed concurrently;
- the reason for filing is the same for all applications;
- all products in the group have the same trade name, manufacturer and active ingredient(s).

A grouping can consist of products with different strengths, dosage forms and/or routes of administration.

Appendix 3 provides **examples** of groupings that may or may not be acceptable in accordance with the conditions listed above.

2.3.2 Submission Class Descriptions and Examples

The following descriptions provide further explanation of terms used in relation to the *Fees in Respect of Drugs and Medical Devices Regulations*.

2.3.2.1 New Active Substance

The New Active Substance (NAS) fee applies to a submission in support of a drug, excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph. For biologics, this submission class does not include an NDS in support of a subsequent entry biologic or an SNDS in support of changes to the manufacturing process of biologics.

2.3.2.2 Clinical or Non-Clinical Data and Chemistry and Manufacturing Data

The clinical or non-clinical data, **and** chemistry and manufacturing data fee applies to submissions based on clinical or non-clinical data, and chemistry and manufacturing data for a drug that does not include an NAS.

This fee applies to the following submission types:

- NDS
- SNDS
- ANDS
- SANDS
- DIN application for a pharmaceutical (DINA)
- DIN application for a biologic (DINB)

Following are some examples:

- NDS for a non-NAS [for example (e.g.), an enantiomer, a new salt]
- new dosage form requiring clinical studies
- new strength requiring clinical studies
- new formulation requiring clinical studies
- DIN with clinical and chemistry and manufacturing data (formerly known as DIN Form and Supporting Data)

- SNDS switch from prescription to nonprescription status (or vice versa) that involves a change in indication, dose or strength and requires chemistry and manufacturing data
- includes subsequent entry biologics

2.3.2.3 Clinical or Non-Clinical Data Only

The clinical or non-clinical data only fee applies to submissions based only on clinical or non-clinical data for a drug that does not include a NAS.

This fee applies to the following submission types:

- NDS
- SNDS
- SANDS
- DINA
- DINB

Following are some examples:

- new indication or change in indication
- changes to dosing and administration
- removal of contraindications or warnings and precautions
- pre-clinical study to support a mechanism of action resulting in an explicit or implicit claim
- a switch from prescription to nonprescription status (or vice versa) that involves a change in indication or dose and that does not require chemistry and manufacturing data
- change in product monograph format where the change includes presentation of additional or re-analysed data that is not in previous format

2.3.2.4 Comparative Studies

The comparative studies fee applies to submissions based on comparative studies with or without chemistry and manufacturing data for a drug that does not include a NAS. It excludes superiority and non-inferiority studies since they are clinical studies. It also excludes pharmaceutical equivalence studies since they are captured by the chemistry and manufacturing fee.

This fee applies to the following submission types:

- NDS
- SNDS
- ANDS
- SANDS
- DINA
- DINB

Following are some examples:

- change in formulation, new strength or new dosage form requiring a bridging study
- ANDS or SANDS for a generic product
- comparative bioavailability, pharmacokinetic and pharmacodynamic data

2.3.2.5 Chemistry and Manufacturing Data Only

The chemistry and manufacturing data only fee applies to submissions based only on chemistry and manufacturing data for a drug that does not include a NAS.

The fee applies to the following submission types:

- NDS
- SNDS
- ANDS
- SANDS
- DINA
- DINB

Following are some examples:

- a change to a manufacturing site for a modified release product with a waiver for comparative clinical data
- pharmaceutical equivalence for generic injectables, solutions, etc.
- data to support a bioequivalence waiver

2.3.2.6 Published Data Only

The published data only fee applies to submissions based only on published clinical or non-clinical data for a drug that does not include a NAS. The evidence to support the

safety and efficacy of the product or the requested change to a current product should be limited to published data. Published data must be from a peer-reviewed, recognized journal. A published thesis would not be acceptable. The sponsor should discuss with Health Canada if a summary of the published data would be acceptable.

This fee applies to the following submission types:

- NDS
- SNDS
- ANDS
- SANDS
- DINA
- DINB

Following are some examples:

- a generic submission for the addition of a strength that is currently marketed by other generics but unavailable from the innovator and is within the dosing regimen of the innovator, where all other requisite data in support of the submission may be cross-referenced to a previously approved submission for that generic product
- DIN applications for which products with identical claims, dosing and strengths are already approved and on the Canadian market, and where safety and efficacy have been clearly established for those products
- published information to support a waiver of bioequivalence data
- a supplement for an update to the PM that has provided published references as the only supporting data

2.3.2.7 Switch from Prescription to Nonprescription Status

The switch from prescription to nonprescription status applies to submissions based only on data that support the modification or removal of a medicinal ingredient listed in Schedule F to the *Food and Drug Regulations*. This fee is limited to switches from prescription to nonprescription status when an identical claim is made for an existing drug.

This fee applies to the following submission types:

- SNDS
- SANDS

2.3.2.8 Labelling Only

The labeling only fee applies to submissions of labelling material that do not include supporting clinical or non-clinical data or chemistry and manufacturing data.

This fee applies to the following submission types:

- NDS
- SNDS
- ANDS
- SANDS
- DINA
- DINB

Some examples include:

- DIN applications that do not include supporting clinical, non-clinical or chemistry and manufacturing data (formerly known as DIN Form)
- DIN applications that include standardized/published test methods, or *in vitro/in vivo* photostability data
- SNDS to remove an indication or dosage form
- SANDS to add an indication for a generic product monograph to update to an innovator's product monograph
- an update to the new product monograph format limited to format changes only and does not include any data that was not previously reviewed by Health Canada
- SNDS for changes to labels or product monographs for which there is no new clinical data
- a submission requiring a Look-Alike-Sound-Alike (LASA) assessment

2.3.2.9 Administrative Submission

The administrative submission fee applies to submissions in support of only a manufacturer or product name change. It is only applicable to submissions and applications that do not require a scientific review to support the specified name change for the drug product (e.g., a change in name that implies a claim will not be accepted as an administrative change). A new DIN may or may not be required.

Note: If there have been unapproved changes to the label submitted then the submission will be refused as an administrative submission.

This fee applies to the following submission types:

- NDS (including disinfectants)
- SNDS (including disinfectants)
- ANDS
- SANDS
- DINA
- DINB
- DIN for disinfectants (DIND)

Following are some examples:

- a change to the name of the manufacturer following a company merger, buy-out or licensing agreement
- a change to the product name where there are no direct or indirect changes to claims (i.e., non-substantive claims), formulas or indications made; where the name change does not require a LASA review; or where there are no implied claims

2.3.2.10 Disinfectants

The disinfectant fee applies to submissions and applications that include data in support of a disinfectant with the exception of Administrative Disinfectants, Labelling Standard and Category IV Disinfectants where the relevant fee would apply.

This fee applies to the following submission types:

- NDS
- SNDS
- DIND

Examples of an NDS disinfectant would include a hard surface disinfectant or contact lens disinfectant.

2.3.2.11 Drug Identification Number (DIN) Applications - Labelling Standards

The DIN applications - labelling standards fee applies to applications attesting to compliance with a labelling standard or Category IV Monograph (DINF) for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data. It also does not include product name changes which are captured by the labeling only or administrative submissions fees.

This fee applies to the following submission types:

- DINA
- DINB
- DIND
- DINF

2.4 Fee Remission

2.4.1 General Information

A sponsor who files a drug submission, supplement or application may apply for a remission in fees. The applicable documentation (see section 2.4.3), the remission processing fee and a completed fee form indicating that the sponsor is applying for a fee remission must be included with the drug submission, supplement or application.

2.4.2 Remission Processing Fee

The remission processing fee is outlined in Appendix 2 and must be included with the drug submission, supplement or application upon filing. Remission requests will not be accepted retroactively. This fee is for the assessment of the information submitted with the application for remission of fees and the audited sales records, and is not considered part of the submission review fee. This fee will not be deducted from the fees payable for the submission review.

2.4.3 Eligibility for Remission and Required Documentation

Only the sponsor who filed the drug submission, supplement or application is eligible for a remission of fees when the fee for the drug submission, supplement or application is greater than 10% of the actual gross revenue from that drug in Canada during the fee verification period.

The sponsor must provide the following to support the remission application:

1. A statement signed by the individual responsible for the sponsor's financial affairs:
 - indicating the sponsor's anticipated gross revenue; and
 - certifying that the fee payable for the drug submission, supplement or application is greater than 10% of the anticipated gross revenue.
2. Information establishing that the fee payable is greater than 10% of the sponsor's anticipated gross revenue; for example:

- a marketing plan/product plan;
 - sales history from similar products;
 - estimated market share (i.e., the product's market potential compared to the total market for similar products in Canada);
 - an analysis of the target population in terms of product demand;
 - average sale price/volume for each subpopulation in the targeted group;
 - a comparison to similar products of the same therapeutic class on the Canadian market or other similar markets (e.g., the United States, the European Union).
3. A Drug Submission/Application Fee Form indicating:
- that the sponsor is applying for a remission; and
 - the fee they propose to be charged (i.e., 10% of their anticipated gross revenue for that drug product).

The sponsor will be notified in writing if the application for remission of fees has been accepted or rejected.

2.4.4 Payment Schedule

If the application for remission is accepted by Health Canada, the fee for the review of a drug submission, supplement or application will be an amount equal to 10% of the anticipated gross revenue. In contrast to the remission processing fee which must be included upon filing of the drug submission, supplement or application, the review fee should not be included at the time of filing. Rather, the fee will become payable upon receipt of an invoice from Health Canada.

If the application for a fee remission is rejected, the sponsor will receive an invoice(s) for the full amount of the review fee.

2.4.5 Confirmation of the Actual Gross Revenue following the Fee Verification Period

Within 60 days of the end of the fee verification period, the sponsor must provide sales records in regard to the sales of the drug in Canada during the fee verification period. The sales records must be prepared in accordance with generally accepted accounting principles and certified by the person responsible for the sponsor's financial affairs. The records should include:

- a sales report from an automated accounting system showing the financial period covered and the actual gross revenue in Canadian funds; or
- a report from an auditor if no automated accounting system exists.

If it is determined at the end of the fee verification period that the amount paid by the sponsor was **less** than 10% of the actual gross revenue for that product, the sponsor must pay the lesser of:

- the difference between 10% of the actual gross revenue and the amount originally paid; and
- the difference between the fee payable under Appendix 1 and the amount originally paid.

Payment is due within 60 days after the day on which the fee verification period ended.

In contrast, if it is determined at the end of the fee verification period that the amount paid by the sponsor was **more** than 10% of the actual gross revenue for that product, the difference between the amount paid and 10% of the actual gross revenue will be remitted to the sponsor.

If it is determined, based on any information available to Health Canada, that the sales records provided by the sponsor were not adequate to determine the sponsor's actual gross revenues, Health Canada may require the sponsor to provide sales records that have been audited by a qualified independent auditor (i.e., a chartered accountant).

The difference between the amount of the fee paid and the full applicable fee will be immediately payable if the sponsor does not provide Health Canada with:

- the sales records within 60 days after the end of the verification period; or
- the audited sales records within 60 days of request.

2.5 Fees for the Sale of Drugs for the Purposes of Implementing the General Council Decision

Sponsors that are concurrently filing a submission, supplement or application with an application to sell a drug for the purpose of implementing the General Council Decision (i.e., applying for authorization under section C.07.003 of the *Food and Drug Regulations*) will be granted a fee deferral until the NOC and/or DIN, as applicable, is issued. The manufacturer will be granted remission of the whole amount of the fee to be paid if they subsequently receive an authorization under section 21.04 of the *Patent Act*.

APPENDIX 1
Fees for the review of drug submissions and applications - Effective 2013-04-01

#	Submission Class	Submission Description	Fee (\$)
1	New Active Substance	Submissions in support of a drug, excluding a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada, and that is not a variation of a previously approved ingredient such as a salt, ester, enantiomer, solvate or polymorph.	315,741
2	Clinical or non-clinical data and chemistry and manufacturing data	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance.	159,921
3	Clinical or non-clinical data only	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance.	74,639
4	Comparative studies	Submissions based on comparative studies (e.g. clinical or non-clinical data, bioavailability, pharmacokinetic and pharmacodynamic data) with or without chemistry and manufacturing data for a drug that does not include a new active substance.	45,113
5	Chemistry and manufacturing data only	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance.	21,329
6	Published data only	Submissions based only on published clinical or non-clinical data for a drug that does not include a new active substance.	17,687
7	Switch from prescription to nonprescription status	Submissions based only on data that support the modification or removal of a medicinal ingredient listed in Schedule F to the <i>Food and Drug Regulations</i> (i.e. identical claim for existing drug).	42,949
8	Labelling only	Submissions of labelling material (i.e. does not include supporting clinical or non-clinical data or chemistry and manufacturing data).	2,873
9	Administrative submission	Submissions in support of a manufacturer or product name change.	297
10	Disinfectants	Submissions and applications that include data in support of a disinfectant.	3,975
11	Drug identification number application – labelling standards	Applications attesting to compliance with a labelling standard or Category IV Monograph for a drug that does not include clinical or non-clinical data or chemistry and manufacturing data.	1,593

APPENDIX 2

Remission Processing Fee - Effective 2013-04-01

The remission processing fee is \$521.

APPENDIX 3

The table provides examples of products with varied brand names/active ingredients /strengths/dosage forms followed by an explanation of what groupings are acceptable.

Example	Brand Name	Active Ingredient	Strength	Dosage Form	Route
A	BrandName	active ingredient A	10 mg	tablet	oral
B	BrandName Plus	active ingredient A	10 mg	tablet	oral
		active ingredient B	100 mg		
C	BrandName Injection	active ingredient A	5 mg/ml	liquid	IV
D	BrandName Plus Extra Strength	active ingredient A	20 mg	tablet	oral
		active ingredient B	200 mg		
E	BrandName	active ingredient A	10 mg	tablet	oral
		active ingredient B	100 mg		
		active ingredient C	2 mg		
F	BrandName Anti-Inflammatory	active ingredient A	10 mg	tablet	oral
		active ingredient B	100 mg		
G	BrandName SPF30	active ingredient A	2%	cream	topical
		active ingredient B	5%		
H	BrandName SPF45	active ingredient A	4%	cream	topical
		active ingredient B	15%		
I	BrandName Wipes	active ingredient A	10 mg	liquid	topical

- A and C have the same brand name (other than indicators of dosage form) and the same active ingredients, therefore, they may be “grouped” under a single application fee.
- B and D have the same brand name (other than indicators of strength) and the same combination of active ingredients, therefore, they may be “grouped” under a single application fee.
- E has a different combination of active ingredients from the other possible “groups”, therefore, it must be submitted with its own application fee.
- F and I have different brand names from the other possible “groups” and from each other; therefore, they each must be submitted with their own application fee.

- G and H have the same Brand Name but different strengths therefore, they may be grouped.