Health Canada Santé Canada

# Guidance Document

## Fees for the Review of Human and Disinfectant Drug Submissions and Applications


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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, Ontario K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca



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## Document change log

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| **Version** | Guidance Document: Fees for the Review of Human and Disinfectant Drug Submissions and Applications | **Replaces** | Guidance Document: Fees for the Review of Drug Submissions and Applications |
| **Date** | April 1, 2020 (posted November 4, 2019) | **Date** | June 13, 2015 (posted November 6, 2015) |

| Date | Change | Location (Section, paragraph) | Nature of and/or Reason for change |
|---|---|---|---|
| April 1, 2020 (posted November 4, 2019) | Content was updated. | All | As of April 1, 2020, new fees along with a revised fee policy will come into force requiring significant changes to the guidance document. |
| November 20, 2015 | Administrative Change | 2.2.2 | As of November 9, 2015, the Accounts Receivable address has changed. |
| June 13, 2015 (posted November 6, 2015). | Content was updated and examples were added. | S.2.3.2.8<br>S.2.3.2.9 | Changes were made to reflect amendments to the Food and Drug Regulations: Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use) which came into force on June 13, 2015, for prescription products and those administered or obtained through a health professional. |

## 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.

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.

Please note that this guidance document is in effect as of April 1, 2020 and should be used for submissions and applications submitted on or after April 1, 2020. Previous versions of this guidance document are available upon request (hc.publications-publications.sc@canada.ca).

## Table of Contents

# 1. Introduction

Before a human or disinfectant 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 to Health Canada to determine whether the benefits associated with the product outweigh the risks. Health Canada has charged industry fees for these pre-market regulatory activities since 1995 in order to recover some of the associated costs.

## 1.1 Objective

This document provides guidance on how fees for the review of human and disinfectant drug submissions and applications will be administered in accordance with the Food and Drugs Act and as stipulated in the Fees in Respect of Drugs and Medical Devices Order and the Regulations Amending and Repealing Certain Regulations Made under the Financial Administration Act.

## 1.2 Policy statements

Sponsors submitting human or disinfectant drug submissions or applications will be charged a fee. Fees are proportionate to the type and complexity of the regulatory activity. Note that unpaid fees are subject to collection procedures as per the Government of Canada Directive on Public Money and Receivables (https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32505). Should fees not be paid, Health Canada has the authority to withhold services, approvals or rights and privileges.

As of April 1, 2020, new fees will be in effect. See Section 2.4 Applicable fees for further details. Further, as of April 1, 2020, Health Canada:

- Will offer fee mitigation in specific circumstances. Fees may be waived or reduced for small businesses, certain products for urgent public health need, publicly funded health care institutions and federal, provincial or territorial governments. See Section 2.2 Mitigation measures for further details.
- Will charge a reduced fee or credit a portion of the fee to the sponsor's account in the event that a performance standard is missed. See Section 2.3 Missed performance standards for further details.
- Will no longer consider deferring fees for sponsors that have not completed their first full fiscal year of business nor will it reduce fees for sponsors based on a product's gross revenue. However, existing terms and conditions previously granted on fee deferrals and remissions will be honored. See Appendix A for further details.

## 1.3 Scope and application

This guidance applies to sponsors submitting a:

- New Drug Submission
- Supplement to a New Drug Submission
- Abbreviated New Drug Submission
- Supplement to an Abbreviated New Drug Submission
- Drug Identification Number Application

Any other type of submission or application not explicitly listed above is excluded along with drugs that are:

- An Extraordinary Use New Drug Submission filed under C.08.002.01 or an Abbreviated Extraordinary Use New Drug Submission filed under C.08.002.1 of the Food and Drug Regulations
- A natural health product
- A drug for veterinary use only (see Management of Regulatory Submission Guidance)

# 2. Guidance

This section provides detailed information on invoicing and fee payment, mitigation measures, credit for missed performance standards, and applicable fees.

## 2.1 Invoicing and fee payment

Sponsors must complete a Drug Submission Application Fee Form for Human and Disinfectant Drugs (Fee Form) (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fees.html)[1] and include it when filing every submission or application. The form outlines the fees and includes sections on fee mitigation measures. Payment should not be included when filing the submission.

Upon receipt of the required documents, Health Canada will conduct a preliminary examination, verify and adjust the fee if required, and issue an invoice. For most submissions this will mean an invoice is issued when the submission is accepted into Review 1. However, for Administrative or Labelling Standard submissions, the invoice will be issued at the time of final decision. Regardless of when the invoice is issued, payment is due 30 days from date of issuance**.**

Should a submission or application be **rejected** during the preliminary examination period (i.e., found to be deficient at screening), Health Canada will issue a notice of rejection and an invoice for 10% of the applicable fee. Invoices will be issued at the time of rejection. Note that in the event a submission or application is **withdrawn** after a Screening Deficiency Notice has been issued, Health Canada will issue an acknowledgement of cancellation along with an invoice of 10% of the applicable fee. However, if a submission or application is withdrawn after Health Canada has issued a screening acceptance letter or reached a decision on an Administrative or Labelling Standard submission, the invoice for 100% of the applicable fee will still be payable.

[1] Updated fee forms available as of March 2020

| Timing of Withdrawal | % of Fee Applicable |
|---|---|
| Before acceptance into review and no Screening Deficiency Notice has been issued | 0% |
| Before acceptance into review, but after a Screening Deficiency Notice has been issued | 10% |
| After a decision is made to issue a screening acceptance letter, or a final review decision is made for Administrative or Labelling Standard submissions | 100% |

Instructions on the payment of fees are further outlined in the document How to Pay Fees (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/cost-recovery/pay-fees.html). All payments must be in Canadian funds. Cheques must be made payable to the "Receiver General for Canada".

Sponsors wishing to dispute a particular fee should contact Health Canada's Food and Drugs Act Liaison Office (FDALO) (https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/food-drugs-act-liaison-office.html).

## 2.2 Mitigation measures

Fees can be requested to be waived or reduced for submissions or applications filed:

- By a small business
- For products on the List of Drugs for an Urgent Public Health Care Need as per the Access to Drugs in Exceptional Circumstances Regulations
- By a publicly funded health care institution
- By any branch or agency of the Government of Canada or of a province or territory
- By organizations sponsoring drugs for the purposes of implementing the Canada's Access to Medicines Regime under section C.07.003 of the Food and Drug Regulations

To be considered for mitigation, sponsors must apply at the time of filing by indicating on the Fee Form the type of mitigation requested. In the case of small businesses, sponsors will be required to register as a small business and ensure that their registration information is kept up to date.

### 2.2.1 Small business

Sponsors who meet the criteria of a small business will be invoiced at the reduced fees described below. However, should Health Canada subsequently determine that the sponsor does not qualify as a small business the full fee is then due. Therefore, an additional invoice will be issued for the difference between the full fee payable and the original invoice. In the case where the submission or application was reviewed for free, an invoice will be issued for the full amount due.

A small business is defined as any business, including its affiliates, that:

- has fewer than 100 employees OR
- has between $30,000 and $5 million (CAD) in annual gross revenues

Sponsors that meet the above definition are eligible for a 50% reduction on all human or disinfectant drug submissions or applications, as well as a "one-time only" waiving of fees for their very first submission or application filed with Health Canada. However, should that first submission be subsequently withdrawn prior to final decision, or receive a negative decision, it is still considered the first filed submission. As such, no future submission will be reviewed for free.

Sponsors must indicate that they are requesting small business mitigation on the Fee Form, as well as indicate if this is their first submission ever filed. Sponsors must formally register (https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees.html) as a small business prior to submitting a submission or application. Sponsors who have not registered as a small business will be charged the full fee. Sponsors must provide the following information when registering:

- Name of company
- Annual gross revenue for their last completed fiscal year
- Number of full-time or equivalent employees for their last completed fiscal year
- Fiscal year end date
- Affiliate Status
- Breakdown of the above information for each affiliated company
- Contact information for all companies listed

Affiliated companies are defined as those that:

- Are controlled by the sponsor's company whereby the sponsor's company holds 50% or more of the affiliate's votes or shares
- Control the sponsor's company whereby the affiliate holds 50% or more of the sponsor's company's votes or shares
- Share a parent company with the sponsor whereby they are controlled by the same company that controls the sponsor's company

In the event that a company has not yet completed a full fiscal year, it is permissible to use estimates/projections with respect to annual gross revenue and number of employees. In this situation Health Canada will follow-up once the sponsor's fiscal year end date has passed to verify their small business status.

Note that at any point in time, Health Canada may request additional information from the sponsor to verify their small business status. This may include (but is not limited to):

- Records that identify the number of persons employed for the previous fiscal year
- Financial statements
- Tax returns
- Corporate and/or management organization charts
- Other official documents issued or certified by a business registration authority

### 2.2.2 Urgent public health need

Fees may be waived for products on the List of Drugs for an Urgent Public Health Need (https://www.canada.ca/en/health-canada/services/drugs-health-products/access-drugs-exceptional-circumstances/list-drugs-urgent-public-health-need.html) as per the Access to Drugs in Exceptional Circumstances Regulations. If a submission or application is filed for a drug with the same medicinal ingredient, strength and route of administration, and is in a comparable dosage form to a drug on the list, it is eligible to be reviewed for free as long as no Drug Identification Number or Notice of Compliance has previously been issued for the product. However, if additional dosage forms, strengths or routes of administration are included in the submission the full fee will be charged.

### 2.2.3 Publicly funded health care institutions

Fees will be waived for all drug submissions or applications filed by publicly funded health care institutions. For example, hospitals filing submissions for radiopharmaceutical diagnostic isotopes will not have to pay a fee. A publicly funded institution is defined as an institution that is funded by the Government of Canada or a provincial government, and 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 a province and/or territory and provides health services.

### 2.2.4 Government organizations

Fees will be waived for submissions or applications filed by a branch or agency of the Government of Canada or of a province or territory. For example, the Department of National Defence or the Public Health Agency of Canada will not have to pay fees.

### 2.2.5 Canada's access to medicines regime

Fees will be automatically deferred for sponsors that concurrently file a submission or application with an application to sell a drug under section C.07.003 of the Food and Drug Regulations until such time as a Notice of Compliance and/or Drug Identification Number is issued. Further, sponsors fees will be waived entirely if they subsequently receive an authorization under section 21.04 of the Patent Act.

Please refer to the Guidance Document: Canada's Access to Medicines Regime: Application Process for Drugs for Export to Developing and Least Developed Countries (https://www.canada.ca/en/health-canada/services/canada-access-medicines-regime/documentation/health-canada-guidance-documents.html) for information on how to apply for this type of mitigation.

## 2.3 Missed performance standards

Performance for all submissions or applications filed after April 1, 2020, will be tracked individually.[2] The Performance Standards for Fees in Respect of Drugs and Medical Devices Order (https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/performance-fees-drugs-medical-devices.html) defines the applicable standard associated with each activity and fee. Performance standards for drugs may differ for the same fee category depending on whether the drug is regulated under Division 1 or Division 8 of the Food and Drug Regulations. Most standards reflect the time to complete Review 1, Iteration 1, which is defined as "the period from date of acceptance to date of first decision" not including any review clock pauses.[3]

In the event that a submission or application is not reviewed within the established performance standard, sponsors will be credited 25% of the fee originally paid. Health Canada will credit the sponsor's account within 30 days. Note that submissions or applications that are part of a joint review or reviewed in parallel with a foreign regulatory authority or applications for medical device combination products are not subject to a credit in the event of a missed performance standard.

In the case of Administrative and Labelling Standards Submissions, the 25% credit will be applied automatically on the invoice (i.e., an invoice will be issued for 75% of the applicable fee).

## 2.4 Applicable fees

The applicable fees are laid out in Schedule 1 of the Fees in Respect of Drugs and Medical Devices Order. Beginning on April 1, 2021, fees will increase annually to keep up with inflation by an amount equivalent to the Consumer Price Index from the previous year. Health Canada will publish a Notice of Intent in Canada Gazette (http://www.gazette.gc.ca/accueil-home-eng.html) every fall specifying the fee amounts that will take effect the following April 1st. Health Canada's web site will be updated accordingly (https://canada-preview.adobecqms.net/en/health-canada/services/drugs-health-products/drug-products/fees.html).

Note that the fee payable is based on the filing date of the submission or application. That is, the date Health Canada deems the submission or application to be administratively complete with all elements completed to Health Canada's standards. The filing date and the date Health Canada receives the submission or application will be the same if the submission or application

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[2] Note that performance for all submissions or applications filed prior to April 1, 2020, will continue to be rigorously monitored and will be processed in the order in which they are received.

[3] In the event that the review clock has been paused, the duration of the pause will be deducted from the total review time when calculating performance. That is, the days during which the clock is paused will not count when measuring performance. Please see the Management of Drug Submission and Application Guidance for more information regarding pausing the clock during the review period (Effective date April 1, 2020).

is accepted for preliminary examination as is, with no adjustments required. However, the filing date will lag behind the date of receipt in the event that Health Canada finds the submission or application to be administratively incomplete and must ask the sponsor for additional information. For example, if a submission is received on March 15, 2021 but adjustments are required, and is only deemed administratively complete on April 5, 2021, then the fee in place on April 5 is the applicable fee.

Note that a submission or application that is received after 5:00pm Eastern Standard Time, on a weekend, or on a statutory holiday is considered received on the next Health Canada business day.

The fee structure for a drug submission or application review is hierarchical. Only the highest of all the possible applicable fees applies; therefore, only **one fee** should be checked on the Fee Form submitted with the submission or application.

Should a change in fee category occur during the review of a submission or application, an invoice will be issued for the appropriate amount, or a credit will be applied to the sponsor's account.

The following table provides additional descriptions and examples of the fee categories as per the Fees in Respect of Drugs and Medical Devices Order.

**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
**NAS** New Active Substance
**NDS** New Drug Submission
**SANDS** Supplement to an Abbreviated New Drug Submission
**SNDS** Supplement to a New Drug Submission

| Fee Category | Additional Description and Examples |
|---|---|
| **2.4.1 New active substance** | |
| Submissions in support of a drug, other than 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. | N/A |

| Fee Category | Additional Description and Examples |
|---|---|
| **2.4.2 Clinical or non-clinical data and chemistry and manufacturing data** | |
| Submissions based on clinical or nonclinical data and chemistry and manufacturing data for a drug that does not include a new active substance.<br><br>This fee applies to the following submission types:<br>• NDS<br>• SNDS<br>• ANDS<br>• SANDS<br>• DINA<br>• DINB | • NDS for a non-NAS [for example (e.g.), an enantiomer, a subsequent entry NDS, a new fixed-dose combination product]<br>• New dosage form requiring clinical studies<br>• New strength requiring clinical studies<br>• New formulation requiring clinical studies<br>• Submission based on clinical data from published data and chemistry and manufacturing data (e.g., submission relying on third-party data)<br>• A switch from prescription to non-prescription status (or vice versa) that may or may not involve a change in indication, dose or strength, supported by clinical data, non-clinical data or published data and chemistry and manufacturing data<br>• Includes subsequent entry biologics |
| **2.4.3 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.<br><br>This fee applies to the following submission types:<br>• NDS<br>• SNDS<br>• ANDS<br>• SANDS<br>• DINA<br>• DINB | • New indication or change in indication supported by clinical data, non-clinical data or published data only, not containing chemistry and manufacturing data<br>• Changes to dosing and administration supported by clinical data, non-clinical data or published data only, not containing chemistry and manufacturing data<br>• Any change to the text of the labelling that has the potential to increase the exposure levels of the drug, either by expanding the population that is exposed (i.e., related to market expansion), or by increasing individual exposure, such as a new indication, removal of contraindications or warnings and precautions supported by clinical data, non-clinical data or published data, and not containing chemistry and manufacturing data<br>• A switch from prescription to non-prescription status (or vice versa) that may |

| Fee Category | Additional Description and Examples |
|---|---|
| | or may not involve a change in indication or dose, supported by clinical data, non-clinical data or published data only, not containing chemistry and manufacturing data<br>• Change in product monograph format where the change includes presentation of additional or re-analysed data that is not in previously approved format |
| **2.4.4 Comparative studies** | |
| Submissions based on comparative studies (e.g., clinical or non-clinical data, bioavailability data and data on the pharmacokinetics and pharmacodynamics of the drug) with or without chemistry and manufacturing data for a drug that does not include a new active substance.<br><br>This fee applies to the following submission types:<br>• NDS<br>• SNDS<br>• ANDS<br>• SANDS<br>• DINA<br>• DINB | • Change in formulation, new strength or new dosage form requiring a bridging bioavailability study<br>• Any other change in chemistry and manufacturing supported by comparative bioavailability, pharmacodynamic, or clinical studies<br>• ANDS or SANDS for a generic product supported by comparative bioavailability, pharmacodynamic, or clinical studies in comparison to a reference product<br>• Any other submission containing comparative bioavailability and pharmacodynamics data, including food effect studies |
| **2.4.5 Chemistry and manufacturing data only** | |
| Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance.<br><br>This fee applies to the following submission types:<br>• NDS<br>• SNDS<br>• ANDS<br>• SANDS<br>• DINA<br>• DINB | • Any change in chemistry and manufacturing supported by chemistry and manufacturing data only, including those that include a waiver for bioavailability, pharmacodynamics, or clinical studies, that does not contain any clinical, non-clinical or comparative data<br>• ANDS or SANDS for a generic product supported by pharmaceutical equivalence data only (such as injectable solutions) in comparison to a reference product<br>• Data to support a bioequivalence waiver |

| Fee Category | Additional Description and Examples |
|---|---|
| **2.4.6 Clinical or non-clinical data only, in support of safety updates to the labelling** | |
| Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance.<br><br>This fee applies to the following submission types:<br>• SNDS<br>• SANDS | • Any change to the text of the labelling resulting in addition of safety information or reduced exposure to the drug, such as addition of contraindications or warnings and precautions, supported by clinical data, non-clinical data or literature references, and not containing comparative or chemistry and manufacturing data |
| **2.4.7 Labelling only** | |
| Submissions, other than those described in item 2.4.8, 2.4.11 or 2.4.12, of labelling material, that include data in support of the following: brand name assessment, standardized or published test methods, in vitro or in vivo photostability or applications for a drug identification number in support of changes to brand names of non-prescription drugs (but not including examination of other supporting clinical or non-clinical data, comparative data, or chemistry and manufacturing data).<br><br>This fee applies to the following submission types:<br>• NDS<br>• SNDS<br>• ANDS<br>• SANDS<br>• DINA<br>• DINB | • DIN applications that do not include supporting clinical, non-clinical or chemistry and manufacturing data (formerly known as DIN Form)<br>• DIN applications that include standardized/published test methods, or in vitro/in vivo photostability data<br>• NDS or ANDS that do not include supporting clinical, non-clinical or chemistry and manufacturing data, such as those for administrative submissions that also contain a component requiring label review, such as a new brand name<br>• SNDS or SANDS to remove an indication, dosage form or strength, with no supporting data provided<br>• SNDS or SANDS for changes to mock-up labels, or content changes to the product monograph with no supporting data provided<br>• An update to a new product monograph format limited to format changes only with no supporting data provided<br>• A submission requiring a Brand Name Assessment<br>• Significant changes exclusive to label design elements<br>• Generic SNDS or SANDS proposing changes to the Product Monograph to be in line with the Canadian reference product (CRP), that also make changes |

| Fee Category | Additional Description and Examples |
|---|---|
| | requiring label review, such as changes that require inner and outer labels and package mock-ups, changes to design elements of the labelling, change to brand name, PM changes that are based on a reference product other than the CRP, PM format updates, or removal of dosage form or strength |
| **2.4.8 Labelling only (generic drugs)** | |
| Submissions in support of a change to the labelling to be consistent with the CRP that do not include any additional labelling updates requiring a labelling assessment.<br><br>This fee applies to the following submission types:<br>• SNDS<br>• SANDS | • SNDS or SANDS for generic products filed for changes to the Product Monograph to be in line with the CRP only, that do not propose any additional changes requiring label review (see Labelling only fee for examples)<br>• SNDS or SANDS for generic products adding new safety information to be in line with the CRP, that do not propose any additional changes requiring label review<br>• SNDS or SANDS for generic products adding new indications to be in line with the CRP, that do not propose any additional changes requiring label review |
| **2.4.9 Administrative submission[4]** | |
| Submissions in support of a change in the manufacturer's name or brand name, including the following: changes in ownership of the drug, request for an additional brand name or changes resulting from a licensing agreement being entered into by two manufacturers that do not require an assessment of labelling material or brand name (e.g., post-authorization label changes filed by licensees to remain identical to licensor's drug and post-authorization chemistry and manufacturing updates for drugs listed in Schedule C or D of the Food and Drugs Act). | • A change to the name of the manufacturer following a company merger, buyout or licensing agreement where there are no significant changes to the graphics or design elements on the labels or packages<br>• 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 Brand Name Assessment; or where there are no implied claims |

[4] https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/guidance-administrative-processing-human-disinfectant-drugs.html

| Fee Category | Additional Description and Examples |
|---|---|
| This fee applies to the following submission types:<br>• NDS (including disinfectants)<br>• SNDS (including disinfectants)<br>• ANDS<br>• SANDS<br>• DINA<br>• DINB<br>• DIND<br>• DINF | **Note:** If there have been unapproved changes to the label submitted then the submission will not be eligible for processing under the administrative pathway. |
| **2.4.10 Disinfectant – full review** | |
| Submissions, other than those described in item 2.4.11, that include data in support of a disinfectant.<br><br>This fee applies to the following submission types:<br>• NDS<br>• SNDS<br>• DIND | • Applications for a hard surface disinfectant that includes supporting data<br>• Does not include Administrative, Labelling only or Labelling Standard Disinfectants where the relevant fee would apply |
| **2.4.11 Labelling only (disinfectants)** | |
| Submissions in support of changes to the labelling of disinfectants that do not require supporting data, submissions in support of safety updates for disinfectants that are new drugs or submissions in support of a change in the manufacturer's name or brand name that requires a review of labelling material due to deviations from the previously authorized labelling or drug.<br><br>This fee applies to the following submission types:<br>• NDS<br>• SNDS<br>• DIND | • Labelling material that deviates from the previously authorized labelling and/or product |

| Fee Category | Additional Description and Examples |
|---|---|
| **2.4.12 Drug identification number applications - labelling standards** | |
| Applications, including those that pertain to changes to brand names for non-prescription drugs, that include an attestation of compliance with a labelling standard or Category IV Monograph for a drug and that do not include clinical or non-clinical data or chemistry and manufacturing data.<br><br>This fee applies to the following submission types:<br>• DINA<br>• DINB<br>• DIND<br>• DINF | • Applies to non-prescription or disinfectant products only<br>• Applications for non-prescription or disinfectant products 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<br>• Does not include product name changes which are captured by the labelling only or administrative submission fees |

## 2.5 Grouping of products

Applications under Division 1 of the Food and Drugs 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 brand name, manufacturer and active ingredient(s)

Sponsors should clearly identify their request for grouping applications by listing concurrently filed applications on each cover letter.

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

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 | 200 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 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.

## 2.6 General contact information

Service hours are Monday to Friday from 8 a.m. to 4 p.m. (EST) and closed statutory holidays. Emails and fax will be responded to within 10 business days.

**Invoice Inquiries**
Office of Submissions and Intellectual Property
By email: hc.cost.recovery.sc@canada.ca
By fax: 613-941-0825

**Payment Inquiries**
Accounts Receivable
Chief Financial Officer Branch
Address Locator: 1918B
18th Floor, Room 1804B, Jeanne-Mance Building
161 Goldenrod Driveway, Tunney's Pasture
Ottawa, Ontario K1A 0K9
By email: hc.ar-cr.sc@canada.ca
By phone: 613-957-1052 or 1-800-815-0506
By fax: 613-957-3495

# Appendix A: Fee deferrals and remissions

Note that as of April 1, 2020, Health Canada will no longer offer deferrals to sponsors that have not completed their first calendar year of selling a drug, or remission fees based on individual product sales. Thus, the following information is specific to sponsors who have applied for or been granted a fee deferral or remission prior to April 1, 2020, as per Regulations Amending and Repealing Certain Regulations Made under the Financial Administration Act.

## 1.1 Deferred Payments

If a sponsor has not completed its first full fiscal year on the filing date of the drug submission 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 start date of the sponsor's fiscal year must accompany the drug submission or application at the time of filing.

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 full applicable fee at the time of filing will be payable.

## 1.2 Fee Remission

A sponsor who files a drug submission or application is eligible for a remission of fees when the fee for the drug submission or application is greater than 10% of the actual gross revenue from that drug in Canada during the fee verification[5] period.

### 1.2.2 Payment procedure

The sponsor will be notified in writing if the application for remission of fees has been accepted or rejected. If the application for remission is accepted by Health Canada, the fee for the review of a drug submission 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 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 for the full amount of the review fee.

[5] 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 Supplement to a New Drug Submission where no new Drug Identification Number is issued, such as an Supplement to a New Drug Submission for a new use, the fee verification period begins on the date that the Notice of Compliance for the Supplement to a New Drug Submission is issued unless the sponsor can prove that the sale of the drug with the new use started at a later date.

### 1.2.3 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; or
- Difference between the fee payable 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 credited 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
- Audited sales records within 60 days of request.