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# Guidance on evaluation fees for human drugs and disinfectants



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Lignes directrices sur les frais d'évaluation des médicaments à usage humain et des désinfectants assimilés à une  
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## Foreword

Guidance documents provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied by industry. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They 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 always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy or quality of a therapeutic product. We must make sure that such requests are justifiable and that decisions are clearly documented.

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

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## Overview

Health Canada has recently updated the Guidance document on fees for the review of human and disinfectant drug submissions and applications. The revised guidance takes effect on March 19, 2021. This updated document replaces the [original guidance](#), which was adopted in May 1997.

## Background

As of March 18, 2021, Health Canada will make changes to the *Food and Drug Regulations* to facilitate the normalization of COVID-19 drugs. The changes affect the following sections:

- scope and application
- mitigation measures
- missed performance standards

We have revised this guidance to include the new fees and revised fee policy.

Previous changes to the guidance have included:

- updating the address for accounts receivable (November 20, 2015)
- making an administrative change to mitigation measures during an urgent public need (November 9, 2015)
- updating and adding examples to sections 2.3.2.8 and 2.3.2.9 to reflect labelling, packaging and brand names of drugs for human use amendments to the *Food and Drug Regulations* (June 13, 2015)

This guidance document came into effect on April 1, 2020, and should be used for submissions and applications submitted on or after April 1, 2020. For previous versions of this document, please email us at [publications-publications@hc-sc.gc.ca](mailto:publications-publications@hc-sc.gc.ca).

## Introduction

Before a human or disinfectant drug is authorized for sale in Canada, scientific evidence of its safety, efficacy and quality must be provided to Health Canada. This is a requirement of the *Food and Drugs Act* and *Regulations*. Health Canada reviews the evidence to determine whether the benefits associated with the product outweigh the risks.

We charge industry fees for these pre-market regulatory activities to recover some of the associated costs.

## Objective

This document provides guidance on how fees for the review of human and disinfectant drug submissions and applications will be administered. Fees are in accordance with the *Food and Drugs Act* and are stipulated in the:

- [Fees in Respect of Drugs and Medical Devices Order](#)
- [Regulations Amending and Repealing Certain Regulations Made under the Financial Administration Act](#)

## Policy statements

Sponsors submitting human or disinfectant drug submissions or applications will be charged a fee. Fees are in proportion to the type and complexity of the regulatory activity.

Unpaid fees are subject to collection procedures in accordance with the federal government's [directive on public money and receivables](#). Health Canada has the authority to withhold services, approvals or rights and privileges for unpaid fees.

New fees came into effect on April 1, 2020. For further details, see the page on [applicable fees](#).

In addition, Health Canada may:

- waive or reduce fees in specific circumstances (see the section on [mitigation measures](#)) for:
  - small businesses
  - certain products for urgent public health need
  - publicly funded health care institutions
  - federal, provincial or territorial governments
- submissions for a COVID-19 drug for which an application was previously filed under the [Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#) for the same product
- 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 the page on [missed performance standards](#))

Under the revised fee policy, we will also **no longer**:

- defer fees for sponsors that have not completed their first full fiscal year of business
- reduce fees for sponsors based on a product's gross revenue

However, we will honour existing terms and conditions previously granted on [fee deferrals and remissions](#).

## Scope and application

This guidance applies to sponsors submitting a:

- new drug submission (NDS)
- supplement to a new drug submission (SNDS)
- abbreviated new drug submission (ANDS)
- supplement to an abbreviated new drug submission (SANDS)
- drug identification number (DIN) application

Any other type of submission or application is excluded, as well as:

- an extraordinary use NDS filed under C.08.002.01
- an abbreviated extraordinary use NDS filed under C.08.002.1 of the *Food and Drug Regulations*
- a natural health product
- a drug for veterinary use only (see the [guidance related to the management of regulatory submissions](#))

# Invoicing, fee payment and mitigation measures

## Fee section template

Sponsors must complete the fee section of the Regulatory Enrolment Process (REP) Regulatory Transaction (RT) template. Please consult the [Regulatory Enrolment Process \(REP\) information page](#) for more information. Be sure this is included in your submission or application.

The RT template provides a link to the fees, and includes sections on fee mitigation measures. When filing your submission, do not include payment.

When Health Canada receives the required documents, we will conduct a preliminary examination. We will verify the classification and issue an invoice for the applicable fee.

For most submissions, we will issue an invoice when the submission is accepted into the Review 1 stage. However, for administrative or labelling standard submissions, we will issue an invoice when we make our final decision. Payment is due 30 days from the date of the invoice.

If we **reject** a submission or application during the preliminary examination period (it's considered deficient at the time of screening), we will issue a notice of rejection. We will also issue an invoice for 10% of the applicable fee at this time.

If a submission or application is **withdrawn** after a Screening Deficiency Notice has been issued, we will issue an acknowledgement of cancellation. We will also issue an invoice of 10% of the applicable fee.

The full fee will be invoiced if a submission or application is withdrawn after we have either:

- issued a Screening Acceptance Letter or
- reached a decision on an administrative or labelling standard submission

## Fee payment schedule

The following fee payment schedule applies:

- 0% before acceptance into review and no Screening Deficiency Notice has been issued
- 10% before acceptance into review but after a Screening Deficiency Notice has been issued
- 100% after a decision is made to issue a screening acceptance letter, or a final review decision is made for administrative or labelling standard submissions

Instructions on the payment of fees are further outlined in the [how to pay fees](#) page. All payments must be in Canadian funds. Cheques must be payable to the "Receiver General for Canada."

Sponsors wishing to dispute a particular fee should contact our [Food and Drugs Act Liaison Office \(FDALO\)](#).

## Mitigation measures

Requests can be made to waive or reduce fees for submissions or applications filed by:

- a small business
- a publicly funded health care institution
- any branch or agency of the Government of Canada or of a province or territory
- organizations sponsoring drugs for the purposes of implementing [Canada's Access to Medicines Regime under section C.07.003 of the Food and Drug Regulations](#)

Requests can also be made to waive or reduce fees for:

- products on the [list of drugs for an urgent public health care need](#) as per the *Access to Drugs in Exceptional Circumstances Regulations*
- a COVID-19 drug for which an application was previously filed under the interim order for the same product

Sponsors must apply for mitigation when they file. Indicate the type of mitigation being requested in the fee section of the REP RT template.

For submissions or applications received before April 1, 2020, refer to Appendix A of the archived [Guidance document Fees for the review of human drugs and disinfectant drug submissions and applications](#).

### Small business

Sponsors will be required to register as a small business and ensure that their registration information is up to date.

Sponsors who meet the criteria of a small business will be invoiced at the reduced fees (see below). However, if we determine that the sponsor does not qualify as a small business, then the full fee will be due. In this case, we will issue an additional invoice for the difference between the full fee payable and the original invoice.

For a submission or application that was reviewed for free, we will issue an invoice for the full amount.

A small business is any business, including its affiliates, that has:

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

Note that the definition is an OR statement so you must meet one of the 2 qualifications. The annual gross revenues must also include all revenues and are not limited to the health products being licenced.

Sponsors that meet the above definition are eligible for a 50% reduction on all human or disinfectant drug submissions or applications.

Sponsors are also eligible for a "one-time only" waiving of fees for their very first submission or application filed with Health Canada.

First submissions that are withdrawn before the final decision is made or that receive a negative decision are considered to be the first filed submission. This means that future submissions will not be reviewed for free.

Sponsors must indicate on the REP RT template that they are requesting small business mitigation. They must also indicate if this is their first submission ever filed.

Before submitting a submission or application, sponsors must first apply for small business status through the [Drug and Medical Device Small Business Application](#) process. Those who have not been granted small business status at the time of filing will be charged the full fee.

When registering, please provide the following information:

- name of company
- annual gross revenue for last completed fiscal year
- number of full-time or equivalent employees for last completed fiscal year
- previous fiscal year-end date
- affiliate status
- breakdown of the above information for each affiliated company
- contact information for all companies listed



Affiliated companies are those that:

- are controlled by the sponsor's company, which holds 50% or more of the affiliate's votes or shares
- control the sponsor's company, where the affiliate holds 50% or more of the sponsor's company's votes or shares
- share a parent company with the sponsor, where they are controlled by the same company that controls the sponsor's company

A company that has not yet completed a full fiscal year may estimate or project their annual gross revenue and number of employees. In these cases, Health Canada will follow up once the sponsor's fiscal year-end date has passed to verify their small business status.

At any time, Health Canada may ask the sponsor for additional information in order to verify their small business status. Information may include:

- records that identify the number of persons employed for the previous fiscal year
- financial statements
- tax returns
- corporate or management organization charts
- other official documents issued or certified by a business registration authority

#### 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 an institution that is funded by the Government of Canada or a provincial/territorial government and is either:

- licensed, approved or designated by a province/territory in accordance with the laws of the jurisdiction to provide care or treatment to persons or animals suffering from any form of disease or illness **or**
- owned or operated by the Government of Canada or a province/territory and provides health services

#### 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/territory. For example, the Department of National Defence or the Public Health Agency of Canada will not have to pay fees.

#### Organizations sponsoring drugs under Canada's Access to Medicines Regime

Fees will be automatically deferred for sponsors that file a submission or application at the same time as an application to sell a drug under section C.07.003 of the *Food and Drug Regulations*. Fees are deferred until a notice of compliance (NoC) and/or drug identification number (DIN) is issued.

Fees will be waived if sponsors subsequently receive an authorization under section 21.04 of the *Patent Act*.

For information on how to apply for this type of mitigation, please refer to the [Guidance on the application process for drugs for export to developing and least developed countries](#).

#### Urgent public health need

Fees may be waived for products on the [list of drugs for an urgent public health need](#) in accordance with the *Access to Drugs in Exceptional Circumstances Regulations*.

Submissions or applications are eligible to be reviewed for free if:

- the drug has the same medicinal ingredient, strength and route of administration, and is in a comparable dosage form to a drug on the list and
- a DIN or NoC has not previously been issued for the product

The full fee will be charged if additional dosage forms, strengths or routes of administration are included in the submission.

#### Interim order for the importation, sale and advertising of COVID-19 drugs

Pre-market evaluation fees will be remitted for submissions filed under the *Food and Drug Regulations* seeking approval for a COVID-19 drug. However, the application must have been previously filed under the interim order for the same drug, and not have been previously filed under the *Food and Drug Regulations*.

Once a drug receives an NOC, drug right to sell fees will apply.

COVID-19 drug submissions filed under the *Regulations* for which no interim order application was previously filed will be subject to fees.

Small business mitigation is available on all applicable fees for COVID-19 drug submissions.

## Credit for missed performance standard

Performance for all submissions or applications filed after April 1, 2020 will be tracked individually. Note that performance for all submissions or applications filed before April 1, 2020, will continue to be rigorously monitored and processed in the order in which they're received.

The [Performance Standards for Fees in Respect of Drugs and Medical Devices Order](#) defines the applicable standard for 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 "the period from date of acceptance to date of first decision," not including any review clock pauses.

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. In other words, the days during which the clock is paused will not count when measuring performance. Please see the [guidance document on the management of drug submission and application](#) for more information on pausing the clock during the review period.

If 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.

The following are not subject to a credit in the event of a missed performance standard:

- submissions or applications that are part of a joint review or reviewed along with a foreign regulatory authority
- applications for medical device combination products
- rolling submissions filed in accordance with subsection C.08.002(2.3) of the *Food and Drug Regulations*

For administrative and labelling standards submissions, the 25% credit will be applied automatically to the invoice. In other words, an invoice will be issued for 75% of the applicable fee.

# Applicable fees and fee groupings

## Applicable fees

The applicable fees are laid out in Schedule 1 of the [Fees in Respect of Drugs and Medical Devices Order](#). As of April 1, 2021, fees will be adjusted once a year to keep up with inflation. The annual adjustment will be equivalent to the Consumer Price Index from the previous year.

Every fall, Health Canada will publish a notice of intent in the [Canada Gazette](#) specifying the fee amounts that will take effect the following April 1. We will also update the [Canada.ca web site](#).

The fee is based on when the submission or application was filed. This is the date that Health Canada considers the submission or application has been completed to our standards.

The filing date and the date that we receive the submission or application are the same if the submission or application is accepted for preliminary examination as is, with no adjustments required.

However, the filing date will lag behind the date of receipt if we find that the submission or application is incomplete and the sponsor needs to provide additional information. For example, we receive a submission on March 15, 2021, but adjustments are required. If the submission is considered complete on April 5, 2021, then the fee in place on April 5 is the applicable fee.

Note: Submissions or applications are considered received on the next business day if they come in:

- after 5 pm Eastern Standard Time
- on a weekend
- on a statutory holiday

The fee structure for a drug submission or application review is hierarchical. Only the highest of all the possible applicable fees applies and will be charged.

If there's a change in the fee category while a submission or application is being reviewed, we will issue an invoice for the appropriate amount or apply a credit to the sponsor's account.

The following section provides additional descriptions and examples of the fee categories (in accordance with the [Fees in Respect of Drugs and Medical Devices Order](#)). Please refer to the following acronyms and their full names:

- 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 categories

### New active substance

These are 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<sup>1</sup>
- is not a variation of a previously approved medicinal ingredient, such as a salt, ester, enantiomer, solvate or polymorph

### Clinical or non-clinical data and chemistry and manufacturing data

These are submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance.

The fee applies to the following submission types:

- NDS
- SNDS
- DINA
- DINB

Examples include:

- NDS for a non-NAS, such as an enantiomer, a subsequent entry NDS, a new fixed-dose combination product
- new dosage form requiring clinical studies
- new strength requiring clinical studies
- new formulation requiring clinical studies
- submission based on clinical data from published data and chemistry and manufacturing data (for example, submission relying on third-party data)
- 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
- subsequent entry biologics

### Clinical or non-clinical data only

These are submissions based only on clinical or non-clinical data for a drug that does not include a new active substance.

This fee applies to the following submission types:

- NDS
- SNDS
- DINA
- DINB

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<sup>1</sup> A medicinal ingredient is not considered to be approved in a drug by reason of the Minister having issued or amended an authorization under the ISAD Interim Order in respect of a COVID-19 drug that contains the medicinal ingredient

Examples include:

- new indication or change in indication supported by clinical data, non-clinical data or published data only, not containing chemistry and manufacturing data
- changes to dosing and administration supported by clinical data, non-clinical data or published data only, not containing chemistry and manufacturing data
- any change to the text of the labelling that may increase the exposure levels of the drug, either by:
  - expanding the population that is exposed (related to market expansion) or
  - 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
- a switch from prescription to non-prescription status (or vice versa) that may 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
- a change in product monograph format where the change includes presentation of additional or re-analyzed data that is not in a previously approved format

### Comparative studies

These are submissions based on comparative studies (for example, 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.

This fee applies to the following submission types:

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

Examples include:

- a change in formulation, new strength or new dosage form requiring a bridging bioavailability study
- any other change in chemistry and manufacturing supported by comparative bioavailability, pharmacodynamic or clinical studies
- ANDS or SANDS for a generic product supported by comparative bioavailability, pharmacodynamic or clinical studies in comparison to a reference product
- any other submission containing comparative bioavailability and pharmacodynamics data, including food effect studies

### Chemistry and manufacturing data only

These are submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance.

This fee applies to the following submission types:

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

Examples include:

- 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
- ANDS or SANDS for a generic product supported by pharmaceutical equivalence data only (such as injectable solutions) in comparison to a reference product
- data to support a bioequivalence waiver

#### Clinical or non-clinical data only, in support of safety updates to the labelling

These are submissions based only on clinical or non-clinical data supporting safety updates to the labelling materials for a new drug that does not include a new active substance.

This fee applies to the following submission types:

- SNDS
- SANDS

An example includes:

- any change to the text of the labelling resulting in safety information or reduced exposure to the drug being added (such as contraindications or warnings and precautions), supported by clinical data, non-clinical data or literature references and not containing comparative or chemistry and manufacturing data

#### Labelling only

These are submissions for labelling material. They do not apply to submissions for 'labelling only (generic drugs),' 'labelling only (disinfectants)' or 'DIN applications, labelling standards.'

Labelling only submissions include data supporting:

- a brand name assessment
- standardized or published test methods
- in vitro or in vivo photostability or applications for a DIN supporting 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)

This fee applies to the following submission types:

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

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
- 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
- SNDS or SANDS to remove an indication, dosage form or strength, with no supporting data provided

- SNDS or SANDS for changes to mock-up labels or content changes to the product monograph with no supporting data provided
- an update to a new product monograph format limited to format changes only with no supporting data provided
- a submission requiring a brand name assessment
- significant changes exclusive to label design elements
- generic SNDS or SANDS proposing changes to the product monograph to be in line with the Canadian Reference Product (CRP), where the changes require label review, such as changes:
  - changes that require inner and outer labels and package mock-ups
  - changes to design elements of the labelling
  - changes to the brand name
  - product monograph changes that are based on a reference product other than the CRP, product monograph format updates, or removal of dosage form or strength

### Labelling only (generic drugs)

These are submissions supporting a change to the labelling to be consistent with the CRP that do not include any additional labelling updates requiring a labelling assessment.

This fee applies to the following submission types:

- SNDS
- SANDS

Examples include:

- SNDS or SANDS for generic products filed for changes to the product monograph to be in line with the CRP only where additional changes requiring label review are not being proposed (see the section on 'Labelling only fee' for examples)
- SNDS or SANDS for generic products adding new safety information to be in line with the CRP where additional changes requiring label review are not being proposed
- SNDS or SANDS for generic products adding new indications to be in line with the CRP where additional changes requiring label review are not being proposed

### Administrative submission (administrative processing)

These are submissions supporting 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 due to a licensing agreement being entered into by 2 manufacturers that do not require an assessment of labelling material or brand name, such as:
  - 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*

This fee applies to the following submission types:

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



Examples include:

- 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
- a change to the product name where there are no direct or indirect changes to claims (for instance, non-substantive claims), formulas or indications made and where the name change does not require a brand name assessment or where there are no implied claims

Note: If unapproved changes to the label have been submitted, the submission will not be eligible for processing under the administrative pathway.

#### Disinfectant, full review

These are submissions, other than those described for 'labelling only (disinfectants),' that include data in support of a disinfectant.

This fee applies to the following submission types:

- NDS
- SNDS
- DIND

An example includes:

- applications for a hard-surface disinfectant that includes supporting data

Not included are administrative, labelling only or labelling standard disinfectants, where the relevant fee would apply.

#### Labelling only (disinfectants)

These are submissions supporting either:

- changes to the labelling of disinfectants that do not require supporting data or
- safety updates for disinfectants that are new drugs or
- supporting 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

This fee applies to the following submission types:

- NDS
- SNDS
- DIND

An example includes:

- labelling material that deviates from the previously authorized labelling or product

#### DIN applications, labelling standards

These are applications involving changes to brand names for non-prescription drugs. Changes include an attestation of compliance with a labelling standard or category IV monograph for a drug. They do not include clinical or non-clinical data or chemistry and manufacturing data.

This fee applies to the following submission types:

- DINA
- DINB
- DIND
- DINF

Examples include:

- non-prescription or disinfectant products only
- applications for non-prescription or disinfectant products attesting to compliance with a labelling standard or category IV monograph (DINF) for a drug where clinical or non-clinical data or chemistry and manufacturing data are not included

Not included are product name changes, which are covered by labelling only or administrative submission fees.

## Fee groupings

Applications under Division 1 of the *Food and Drugs Regulations* may be grouped together resulting in 1 fee if the following conditions apply:

- 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 they wish to group applications by listing concurrently filed applications on each cover letter.

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

The following table gives examples of products with varied brand names, active ingredients strengths and dosage forms. An explanation for acceptable product groupings is also provided.

**Table 1: Sample product groupings**

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:

- same brand name (other than indicators of dosage form) and active ingredients
- may be "grouped" under a single application fee

B and D:

- same brand name (other than indicators of strength) and active ingredients
- may be "grouped" under a single application fee

E:

- different combination of active ingredients from the other possible "groups"
- must be submitted with its own application fee

F and I:

- different brand names from the other possible "groups" and from each other
- each must be submitted with its own application fee

G and H:

- same brand name but different strengths
- may be grouped

## Who to contact

Health Canada is available Monday to Friday from 8 a.m. to 4 p.m. (EST) and closed on statutory holidays. We will respond to your emails within 10 business days.

Please send your queries to:

Office of Submissions and Intellectual Property

Email: [cost.recovery@hc-sc.gc.ca](mailto:cost.recovery@hc-sc.gc.ca)

### **For 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 ON K1A 0K9

Email: [ar-cr@hc-sc.gc.ca](mailto:ar-cr@hc-sc.gc.ca)

Phone: 613-957-1052 or 1-800-815-0506

Fax: 613-957-3495

## References

1. [Fees in Respect of Drugs and Medical Devices Fees Order](https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-124/FullText.html)  
<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-124/FullText.html>
2. [Guidance document: Management of drug submissions and applications](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/management-drug-applications-2019/document.html)  
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/management-drug-applications-2019/document.html>
3. [Guidance document: Management of disinfectant drugs applications](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/disinfectants/summary.html)  
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/disinfectants/summary.html>