Health Canada Santé Canada

Guidance document:

The management of drug submissions and applications

Date adopted	2020-11-26
Effective date	2025-10-01
Revised date	2025-10-01

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.

Également disponible en français sous le titre :
Ligne directrice : Gestion des présentations et des demandes de drogue

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Publication date: October 2025

Cat.: H164-277/2025E-PDF
ISBN: 978-0-660-74660-9
Pub.: 240651

Document change log

Date	Change	Nature of and reason for change
October 1, 2025	Added public health emergency drugs	Regulatory amendments
	Updated contact information (physical and email addresses)	Administrative
	Removed cost recovery hold	Administrative
August 2, 2022	Removed the submission certification requirement for: response to SDN response to NOD response to NON	Policy change
	Defined the duration of a "response to clarification request"	Administrative
	Updated email addresses, removed physical addresses and added Pharmaceutical Drugs Directorate contact information (formerly Therapeutic Products Directorate	Administrative
	Increase in performance standard for a post-authorization Division 1 change (PDC-prescription) for prescription pharmaceuticals and those administered or obtained through a health professional in the Pharmaceutical Drugs Directorate includes a screening and review component Separated post-authorization Division 1 change (PDCs) into: PDC-prescription PDC-non-prescription PDC-disinfectant	Policy change

Date	Change	Nature of and reason for change
July 7, 2021	Included joint reviews with other regulatory authorities in pause-the-clock mechanism	Policy change
November 26, 2020	Made changes to reflect the new names of the bureaus in the Marketed Health Products Directorate (MHPD)	Administrative
	Made changes to reflect the new Medical Devices Directorate (MDD)	Administrative
	Corrected the email address for questions about the classification of products at the device-drug interface to drug.device.classification-drogue.instrument@hc-sc.gc.ca	Administrative
November 8, 2019	Deleted: notifiable changes safety (90 days) and safety (120 days) New fee categories for: labelling only (generic) and safety updates to labelling (each with a 120-day performance standard) Labelling only (disinfectants) with a 90-day performance standard Eliminated fee categories for: published data and Rx to OTC switch Revised performance standard for:	New fees along with a revised fee policy on April 1, 2020, will require significant changes to the guidance document

Date	Change	Nature of and reason for change
	labelling only for Division 1 (180 to 120 days) and for Division 8 (60 to 120 days) DINA, DINF and DIND labelling standard (45 to 60 days) Added: screening 1, 2 and review 2 timelines for existing and new fee categories where none previously existed information on the pause-the-clock mechanism	
July 25, 2019	Reorganized and reformatted information to reflect current procedures (with no change to existing practices)	Administrative
	Added: a section on the classification of a therapeutic product an appendix indicating the individual responsible for signing decision documents an appendix listing relevant guidance and policy documents	New information to help sponsors prepare and file drug submissions and applications
	Deleted: update notices final data safety information advance notice letters issuance of acknowledgment letters upon receipt of information by OSIP	Sections deleted from the previous version because no longer used or applicable

Date	Change	Nature of and reason for change
	Other changes: Amended the existing 15-day standard timeline for response to a clarification request during scientific review based on the type and performance standards of the submission or application Reorganized the target performance standards table (Appendix 3) to delete replication of classes or types of submissions and applications filed	Administrative
December 19, 2013 (posted December 19, 2013)	Replaced references to Schedule F with references to the Prescription Drug List	Changes to reflect an amendment to the Food and Drug Regulations that replaced Schedule F with the Prescription Drug List

Foreword

Guidance documents are meant to 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. 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 are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the relevant sections of the regulations and other applicable guidance documents.

Sponsors should refer to the most up-to-date versions of the guidance documents. The guidance documents are a starting point only to help sponsor.

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1 Overview

1.1 Purpose

This guidance document gives direction and guidance when managing information submitted in accordance with the Food and Drugs Act and its regulations. This guidance is for sponsors and Health Canada staff from the following directorates and divisions:

- Medical Devices Directorate (MDD)
- Pharmaceutical Drugs Directorate (PDD)
- Marketed Health Products Directorate (MHPD)
- Business Facilitation and Modernization Directorate (BFMD)
- Biologic and Radiopharmaceutical Drugs Directorate (BRDD)
- Office of Submissions and Intellectual Property (OSIP) within MHPD
- Non-Prescription Drug Evaluation Division (NDED) of the Natural and Non-prescription Health Products Directorate (NNHPD)

1.2 Scope and application

This guidance document applies to the following drug submission and application types:

- clinical trial application (CTA) and amendments to a clinical trial application (CTA-A)
    - applies only to clinical trials filed under Division 5 of the Food and Drug Regulations
    - for clinical trials filed under the Natural Health Products Regulations, consult the Guidance document: Clinical trials for natural health products
- new drug submission (NDS)
- supplement to a new drug submission (SNDS)
- abbreviated new drug submission (ANDS)
- supplement to an abbreviated new drug submission (SANDS)
- extraordinary use new drug submission (EUNDS)
- supplement to an extraordinary use new drug submission (EUSNDS)
- abbreviated extraordinary use new drug submission (EUANDS)
- supplement to an abbreviated extraordinary use new drug submission (EUSANDS)
- supplement to a new drug submission - confirmatory (SNDS-c)
- supplement to an abbreviated new drug submission - confirmatory (SANDS-c)
- new drug submission for disinfectant products (NDS-D)
- supplement to a new drug submission for disinfectant products (SNDS-D)

This guidance document also applies to the following:

- application for a drug identification number (DIN) for a pharmaceutical product, including non-prescription products attesting to a labelling standard (DINA)
- application for a DIN for a category IV monograph product (DINF)
- application for a DIN for a biological product (DINB)
- application for a DIN for a disinfectant product (DIND)
- notifiable change (NC) (for human biologic or radiopharmaceutical drug quality changes)

- post-authorization Division 1 change for a pharmaceutical product (PDC) (includes prescription, non-prescription or disinfectant PDCs)
    - consult the Guidance document: Post-drug identification number (DIN) changes
- post-authorization Division 1 change for a biologic drug product (PDC-B)
    - consult the Guidance document: Post-notice of compliance (NOC) changes: Quality
- development safety update reports (DSUR)
    - when provided to PDD, BRDD and NNHPD as a standalone document and not as part of a submission

Note: This guidance document does not apply to blood establishment submissions and submissions for annual updates of influenza vaccines. For information on managing these submission types, consult:

- Guidance document: Blood Regulations
- Guidance document: Annual update of seasonal influenza vaccines

1.2.1 Post-market pharmacovigilance monitoring documents

The following documents are not within the scope of this guidance but are part of post-market pharmacovigilance monitoring:

- annual summary report in any format, including:
    - periodic benefit-risk evaluation report (PBRER-PV)
    - periodic benefit-risk evaluation report – confirmatory (PBRER-C)
    - periodic safety update report (PSUR-PV)
    - periodic safety update report - confirmatory (PSUR-C)
- issue-related summary report (IRSR-PV)
- notification of foreign action (NFA-PV)
- patient safety/advertising ad-hoc post-market request (PSA-PV)
- post-authorization commitments (PA-PV)
- post-authorization act and regulations (REG-PV)
- risk communication (RC-PV)
- stand-alone submission of a risk management plan (RMP-PV)
    - such as RMPs that are not provided with a drug submission or application applicable to this guidance

Send:

- these types of documents to the Office of Submissions and Intellectual Property (OSIP)
    - OSIP will notify the appropriate Health Canada division or directorate
- content-related questions on post-market pharmacovigilance monitoring to the Regulatory Project Management Office in the MHPD

Contact us

1.3 Policy objectives

The objective of this guidance document is to ensure that submission and application information as well as procedures related to a drug review are applied consistently. It gives specific direction and guidance on:

- processes and procedures to be followed for managing a drug submission or application
- ways to share information, such as through pre-submission meetings
- related guidance documents, policies and other relevant information
- performance standards for processes

1.4 Background

The first major revision to this guidance document was in 1993. It was then updated as follows:

- in 2013, to reflect an amendment to the Food and Drug Regulations that replaced Schedule F with the Prescription Drug List
- in July 2019, to reflect the most current information, processes and procedures to be used by sponsors and Health Canada staff in managing a drug submission or application
- in November 2019, to reflect new fee categories and performance standards as a result of the Fees in Respect of Drugs and Medical Devices Order coming into force on April 1, 2020

1.5 Accessing your application

1.5.1 Drug Submission Tracking System - industry access

You may access information on your own submissions or applications using the Drug Submission Tracking System - Industry Access (DSTS-IA). You will be assigned a user name and password.

Information available through this system includes:

- submission or application details such as dossier ID, control number (appears as submission number), submission type, submission class, file number, lead reviewing bureau, filing date
- drug product information (product name, manufacturer, active ingredients)
- status history (such as Screening 1 or Review 1, status dates, target dates)
- document history (document type, issued or received) and document date
- review (assessment) history such as type of review (for example, clinical, chemistry and manufacturing, label), the status (for example, pending, active) and dates

To obtain a DSTS-IA account or information about industry access, you should email OSIP at client.information@hc-sc.gc.ca.

1.5.2 Status requests

To check the status of your submission or application, you should first access the DSTS-IA. If you have further questions about the status, you may contact the appropriate office or person:

- Office of Regulatory Affairs for BRDD **or**
- regulatory project manager for PDD and NNHPD

Contact us

For CTAs and CTA-As, status updates will not be provided given the short performance standards for review.

2 Pre-application and filing

2.1 Classification of therapeutic products

To file information for a proposed therapeutic product, you should know how your product is classified (for example, as a drug, biologic, medical device or combination product).

Classification refers to the process of interpreting which regulatory framework under the Food and Drugs Act (act) applies to a product. For example, it may be needed to determine whether a therapeutic product is regulated as a device or a drug, and if it's a drug, to which sub-type it belongs (biologic, pharmaceutical, natural health product).

In most cases, the distinction between drugs and devices is clear and these products can be easily classified according to their definitions found in section 2 of the act. Most classifications are made by the appropriate program area upon submission of required information, or application for market authorization. But as new technologies and products emerge, it can be more difficult to identify the appropriate framework under which these products should be regulated.

When needed, the Therapeutic Products Classification Committee (TPCC) may be consulted. The TPCC primarily provides recommendations on the classification of a product as either a drug (pharmaceutical, biologic, or natural health product), medical device, or combination product. When appropriate, other regulatory areas of Health Canada may be asked to participate in the committee's discussion.

Classifications are based on available evidence at a point-in-time, and may be additionally influenced based on the full review of a submission of required information, or application for market authorization. Relevant acts and regulations are the central frameworks for product classification at Health Canada. Classification and subject matter experts from Health Canada's regulatory areas help to determine how a product is classified, taking into consideration:

- the definitions found in the act (section 2 on interpretation and application)
- inclusion and exclusion criteria of the implicated regulatory frameworks **and**
- criteria outlined in various classification guidance documents depending on the interface or product type

For more information, consult:

- Classification of products under the Food and Drugs Act
- Classification of health products at the device-drug interface
- Guidance document: Factors influencing the classification of products at the device-drug interface

For questions about the classification of products at the device-drug interface, email us at drug.device.classification-drogue.instrument@hc-sc.gc.ca.

2.1.1 Combination products

Health Canada regulates a number of product types, including where multiple products may be co-packaged or have a combined use. A subset of combined-use products may be classified as a drug-device combination product (DDCP). DDCPs are health products that combine drugs and medical devices as a single entity.

You may request a classification for a drug-device combination product that has not been previously classified by emailing the Health Product Classification Unit: drug.device.classification-drogue.instrument@hc-sc.gc.ca.

Or, you may file a submission or application to a review centre, bureau or office (review area) based on your own classification and identification of the primary component. You will be notified if you filed the submission or application incorrectly. The review area that received your submission or application will

consult with the appropriate expert area for the ancillary component as required, to ensure it is safe, effective and of high quality before licensing the primary component.

Submissions and applications for a drug-device combination product are:

- handled in accordance with the policy for drug and medical device combination products
- subject to the Medical Devices Regulations, the Natural Health Products Regulations or the Food and Drug Regulations based on the principal mechanism of action by which the claimed effect or purpose is achieved

Both principal and ancillary components must meet acceptable standards of safety, efficacy and quality.

Send your submission or application to the relevant review area as follows:

- for a drug-device combination product where a drug is the primary component: to the Office of Submissions and Intellectual Property (OSIP)
- for a drug-device combination product that's classified as a drug, subject to the Natural Health Products Regulations: to the Natural and Non-prescription Health Products Directorate (NNHPD)
  - refer to the policy on natural health products management of applications
- for a combination product where a medical device is the primary component: to the Medical Devices Directorate
  - consult the Guidance document: Management of applications for medical device licences

Contact us

2.1.2 Other regulations that influence the classification of a drug

Once a product has been classified as a drug and not a device at the level of the Food and Drugs Act, further classification is required to determine if the product is a:

- pharmaceutical or biologic drug subject to the Food and Drug Regulations **or**
- natural health product, a subset of drugs under the act and subject to the Natural Health Products Regulations (NHPR)

This further classification is guided by the following:

- definition for a natural health product in section 1 of the NHPR
- exclusion of prescription drugs in section 2(2) **and**
- inclusive and exclusive lists of substances set out in Schedules 1 and 2 to the NHPR

Personal care products may share characteristics of both a "cosmetic" and a "drug", as currently defined under the Food and Drugs Act. They could fall under the Cosmetic Regulations, the Food and Drug Regulations or the Natural Health Products Regulations.

Learn more about the criteria used to determine the appropriate regulatory regime that applies to a given product at the cosmetic-drug interface:

- Guidance document: Classification of products at the cosmetic-drug interface

If you have questions about which regulatory framework may apply to a particular health product or about the classification of products at the drug-medical device interface, e-mail us at drug.device.classification-drogue.instrument@hc-sc.gc.ca.

2.2 Submission and application pathways and policies

These pathways and policies do not apply to clinical trial applications (CTAs) or amendments to clinical trial applications (CTA-As).

Some submission and application pathways and policies are strictly for specific submission and application types or classes. Sponsors should consult existing guidance and policy documents to become familiar with the requirements of each submission and application type or class.

References

2.2.1 Priority review

Sponsors who want a priority review of a new drug submission (NDS) or supplement to a new drug submission (SNDS) should request this before filing the submission.

Requests for priority review status should be sent to OSIP to the attention of the director of the appropriate centre, bureau or office.

Contact us

You may file your NDS or SNDS once we have reviewed your priority review request. If your drug submission was granted priority review, you must clearly state this in your cover letter and file the submission within 60 calendar days.

For more information on priority review requests and submissions, including performance standards, consult:

- Guidance for industry: Priority review of drug submissions

2.2.2 Notice of compliance with conditions (NOC/c)

Sponsors who want to be given advance consideration to file a submission under the NOC/c policy should request a pre-submission meeting with the appropriate review work area. (Refer to the following section on this page for more information.)

You should file your submission as an NDS, SNDS, abbreviated new drug submission (ANDS) or supplement to an abbreviated new drug submission (SANDS). If your drug submission was deemed eligible for advance consideration, you must clearly state this in your cover letter and file the submission within 60 calendar days.

If we issued an NOC/c, you should file the results from confirmatory trials outlined in the letter of undertaking as an SNDS-c or SANDS-c.

For more information on eligibility, procedural requirements and the performance standards, consult:

- Guidance document: Notice of compliance with conditions (NOC/c)

2.2.3 Extraordinary use new drug

Submissions eligible under the criteria set out in C.08.002.01 (1) of the Food and Drug Regulations may be filed as:

- an extraordinary use new drug submission (EUNDS)
- a supplement to an extraordinary use new drug submission (EUSNDS)
- an abbreviated extraordinary use new drug submission (EUANDS) or
- a supplement to an abbreviated extraordinary use new drug submission (EUSANDS)

These submissions have the same performance standards as the corresponding NDS, SNDS, ANDS or SANDS.

For submission requirements, consult:

- Guidance document: Submission and information requirements for extraordinary use new drugs (EUNDS)

2.2.4 Public health emergency drug

Submissions eligible for modified requirements under the criteria set out in C.08.001.1 of the Food and Drug Regulations may be filed as an NDS or SNDS.

For submission requirements, consult:

- Guidance on the Food and Drug Regulations for public health emergency drugs

2.2.5 Biosimilar biologic drug

Biosimilar biologic drugs, like all new drugs, are subject to Part C, Division 8 of the Food and Drug Regulations for authorization and oversight. Submissions for biosimilar biologic drug products should be filed as an NDS or SNDS and have the same performance standards as the corresponding NDS or SNDS.

For submission requirements, consult:

- Guidance document: Information and submission requirements for biosimilar biologic drugs

2.2.6 Administrative processing

Eligible drug submissions and applications will be processed under the administrative pathway. We screen the information submitted in your submission or application to ensure it is complete and of suitable quality for the intended purpose.

For more information, consult:

- Guidance document: Administrative processing of submissions and applications involving human or disinfectant drugs

2.3 Pre-submission or pre-application meeting

You may request a pre-submission or pre-application meeting with the appropriate directorate within Health Canada. These meetings may be conducted in person or by videoconference.

A pre-submission or pre-application meeting is held to answer any questions or concerns you may have before you file a:

- drug submission or application
  - for example, NDS, SNDS, ANDS, SANDS, DINA
- clinical trial application
- request for a combination product classification
  - for example, medical device-drug, drug-drug
- request for a priority review
- request for advanced consideration of a submission under the NOC/c policy
- submission for an EUNDS
- submission for a public health emergency drug
- submission relying on third-party data
- response to a notice of deficiency (NOD) or notice of non-compliance (NON)

A pre-submission or pre-application meeting also gives an opportunity for Health Canada to:

- discuss the data in support of the proposed submission or application
- become familiar with the submission or application before it's filed
- identify potential problems or issues and manage disputes early in the submission or application process
- learn about the studies being used to establish the drug's safety and efficacy
- offer feedback on the regulatory requirements
- discuss the potential eligibility of the submission for priority review or NOC/c consideration
- improve the quality of information being submitted
- re-align resources within the directorate to accommodate the arrival of the submission or application

Note: While the data may be discussed at the meeting, its acceptability is only considered during the scientific review of the proposed submission or application.

For clinical trial consultation meetings, make sure that the requested feedback relates to clinical trial information and not market authorization requirements. For example, a meeting request to discuss pivotal clinical trials for market authorization may require a pre-NDS meeting and not a pre-clinical trial application (CTA) meeting.

Consult section 2.2. in:

- Guidance document for clinical trial sponsors: Clinical trial applications

For pre-submission meetings for priority review requests or requests for advance consideration of a submission under the NOC/c policy, consult:

- Guidance to industry: Priority review of drug submissions
- Guidance document: Notice of compliance with conditions

For pre-submission meetings relying on third-party data, consult:

- Guidance document: Drug submissions relying on third-party data (literature and market experience)

2.3.1 Meeting requests

For pre-CTA meeting requests, submit your request as follows:

- use the Common Electronic Submissions Gateway (eCTD dossiers)
- email the appropriate directorate (non-eCTD dossiers)

For pre-CTA meeting requirements, consult section 2.2.1 in:

- Guidance document for clinical trial sponsors: Clinical trial applications

For other pre-submission and application meeting requests, contact the appropriate review work area.

Contact us

You should send an administrative cover letter and your meeting request to the director of the appropriate review area as early as possible. We recommend that this be done 3 or more months in advance of the proposed meeting date. Send these in an acceptable submission format (refer to the following section on filing with Health Canada).

Learn more about Filing submissions electronically.

Submit your meeting request in a separate document (not in the cover letter) and include the following information:

- purpose of meeting
    - for example, pre-NDS, pre-phase 3, pre-response to an NOD or NON
- details about the product to be discussed
    - for example, active ingredient, dosage form and therapeutic classification, including whether the drug is first in class
- enough information about the product to help Health Canada assess whether the meeting is needed
- questions to be addressed during the meeting
- submission or application information (such as control number, product name) and a copy of the NOD or NON if the meeting concerns a response to an NOD or NON
- 3 meeting date suggestions, with afternoons or mornings indicated
- suggestions for review expertise that may be needed for meeting
    - for example, clinical, chemistry or biopharmaceutics reviewers, biostatisticians
- if the drug submission will rely on third-party data
    - consult the Guidance document: Drug submissions relying on third-party data

If necessary, you will be contacted by a regulatory project manager (RPM) or senior regulatory affairs officer (SRAO) in 1 of the following directorates to discuss the meeting request:

- Pharmaceutical Drugs Directorate (PDD)
- Natural and Non-prescription Health Products Directorate (NNHPD)
- Biologic and Radiopharmaceutical Drugs Directorate (BRDD)

If we determine that a meeting is needed, we will confirm possible meeting dates, the overall content of the pre-submission or application package and number of participants. We may decline the meeting request if the information listed in this section has not been provided.

If we believe that a meeting is not needed, we will respond with our reasons in a reasonable time period.

2.3.2 Meeting packages

You will be asked to submit a pre-submission or pre-application meeting package in an acceptable file format at least 1 month before the meeting.

Refer to the following section for information on formats.

For information on the pre-clinical trial applications consultation information package, consult section 2.2.2 in:

- Guidance document for clinical trial sponsors: Clinical trial applications

If you are making a presentation, you should submit your slide deck 1 week before the meeting.

Pre-submission or pre-application meeting packages should be as concise as possible and contain the following information, where applicable:

- cover letter
- proposed meeting agenda
- brief slide presentation
- brief summary of the drug product
- identification of the indications for which approval is sought
- proposed strengths and dosages
- summary of the clinical development plan for the drug, including clinical trials that have been completed in Canada (if any) and trials that are ongoing (if any)

- summary of the development of the product, including any changes in production process, dosage form and testing methods and a description of the manufacturing process
- summary of the safety and efficacy data relating to the drug (for example, draft of the product monograph)
- overview of the market history of the product, including its foreign regulatory status
- list of specific issues or questions (grouped by discipline) that are to be discussed
- projected submission or application filing date

Note: We may request meeting packages in hard copy.

2.3.3 Post-meeting requirements

After the pre-submission or pre-application meeting, meeting minutes should be drafted and sent to us no later than 2 weeks after the meeting. Submit the final meeting minutes in an acceptable file format.

Refer to the following section for information on formats.

For information on the pre-clinical trial applications consultation meeting records, consult section 2.2.3 in:

- Guidance document for clinical trial sponsors: Clinical trial applications

When filing your submission or application, you should reference the following information in the cover letter:

- control number of the pre-submission or pre-application meeting
- confirmation that the submission or application reflects what was committed to at the meeting
- minutes of the meeting
- other pre-submission or pre-application correspondence with Health Canada

It is in your best interest to file a submission or application within a reasonable time period following the pre-submission or pre-application meeting.

2.4 Filing with Health Canada

Your submission or application must contain enough information to satisfy the regulatory requirements set out in Part C of the Food and Drug Regulations. All submitted information and subsequent information (solicited and unsolicited) should be included with the cover letter. Be sure to indicate the reason for filing the information and the date filed in the letter.

2.4.1 Acceptable formats for filing

We accept submissions and applications in the electronic common technical document (eCTD) electronic-only format and the non-eCTD electronic-only format via Common Electronic Submission Gateway (CESG) using the Regulatory Enrolment Process (REP).

For acceptable formats, refer to the appropriate section in Filing submissions electronically:

- Preparation of regulatory activities in eCTD format
- Preparation of regulatory activities in non-eCTD format

2.4.2 Filing formats and where to file for CTAs and CTA-As

The clinical trial application (CTA) or amendment to a clinical trial application (CTA-A) may be submitted in eCTD or non-eCTD format.

Refer to the appropriate section for the requirements in Filing submissions electronically.

Submit your CTA or CTA-A by email or by courier (on electronic media) to the appropriate directorate:

- Pharmaceutical Drugs Directorate: oct.smd-dgp.bec@hc-sc.gc.ca
- Biologic and Radiopharmaceutical Drugs Directorate: brdd.cta-dec.dmbr@hc-sc.gc.ca

Contact us

If you file by email, note the following email restrictions:

- The maximum email size accepted by the corporate mail server is 20 megabytes (MB).
    - As individual files larger than 10 MB have been rejected by our mail server, we recommend that you split files larger than 10 MB into 2 or more files.
- The regulatory transaction must be provided as a zipped file, in accordance with the requirements for non-eCTD electronic-only formats.
    - The submissions should **not** be password-protected.
- The subject line of the email should state: "CTA(-A) [product name], [protocol number]".
- Emails received after 3 pm EST will be considered received the following day.

For more information, consult sections 2.3.2 and 2.4.4 in:

- Guidance document for clinical trial sponsors: Clinical trial applications

3 Processing and screening

3.1 Processing submissions and applications

All information received by the Office of Submissions and Intellectual Property (OSIP) is processed and sent to the appropriate review work area within 10 calendar days of receipt. Exceptions are clinical trial applications (CTAs) and amendments to clinical trial applications (CTA-As), which are submitted to the appropriate directorate:

- Pharmaceutical Drugs Directorate: oct.smd-dgp.bec@hc-sc.gc.ca
- Biologic and Radiopharmaceutical Drugs Directorate: brdd.cta-dec.dmbr@hc-sc.gc.ca

Contact us

For details on processing CTAs and CTA-As, consult section 2.5 in:

- Guidance document for clinical trial sponsors: Clinical trial applications

During the 10-day processing period and depending on the type of submission or application, OSIP will:

- assign a control number
- enter the initial information into the drug submission tracking system (DSTS)
    - for example, medicinal ingredient, dosage form, brand name, date received
- verify that the information submitted is administratively complete
    - for example, the submission contains all necessary certification forms and the REP Product Information (PI) and REP Regulatory Transaction (RT) templates, including a completed fees section
    - the information meets the requirements of section 5 of the Patented Medicines (Notice of Compliance) Regulations, where applicable
- verify that the data protection provisions in section C.08.004.1 of the Food and Drug Regulations do not prevent the filing of the submission

At this stage in processing, the information package may be placed on:

- Process Hold – Initial **or**
- Patent Form V Hold **or**
- Data Protection Refused Hold

When a submission or application in the Drug Submission Tracking System – Industry Access is placed in 1 of these 3 administrative holds, the filing date (previously referred to as “CR Date”) is not final.

Learn more about the different types of administrative holds.

When the hold is resolved or the information package is considered administratively complete, then the:

- information package becomes a submission or application
- filing date is entered into the DSTS
- remainder of the submission or application information is entered into the DSTS, if applicable, **and**
- appropriate review area is notified that the submission or application has been processed and can be assigned to a regulatory project manager (RPM) or senior regulatory affairs officer (SRAO) for screening

3.1.1 Cancellation or withdrawal letter during processing period

Sponsors who wish to cancel their submission or application during the processing period should send a signed letter requesting the cancellation to OSIP in the same format as the original submission or application.

The status of the submission or application will be changed to “Cancel Admin” in the DSTS, as the scientific review has not started.

For CTAs and CTA-As, you should send a signed letter requesting the withdrawal of an application or amendment to the Office of Regulatory Affairs in the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) or Office of Clinical Trials in the Pharmaceutical Drugs Directorate (PDD). The status of the application or amendment will be changed to “Withdrawn” in the DSTS.

Submissions and applications that are cancelled or withdrawn do not affect a refiling.

For more information, refer to the following sections:

- Refiling after a cancellation by a sponsor
- Refiling after a withdrawal by a sponsor

3.1.2 Submissions and applications for administrative processing

Submissions and applications for administrative processing are to be submitted to Health Canada when the manufacturer's name or product name has changed due to a merger, buy-out, other corporate restructuring or when establishing a new licensing agreement.

They may be processed administratively, only if the original cross-referenced drug product has received market authorization from Health Canada and has an active drug identification number (DIN).

These types of submissions and applications may be filed for:

- NDSs and ANDSs, including their applicable supplements
- NCs (quality changes for biologics and radiopharmaceuticals) **and**
- applications for a DIN and post-authorization Division 1 changes, such as:
    - PDCs for prescription, non-prescription and disinfectant products
    - PDC-Bs

To be eligible for administrative processing, these submissions and applications should not contain scientific data or require regulatory review. All aspects of the product, except for the manufacturer and product name, must be identical to those previously authorized for that product. Any deviations from the previously authorized product are not accepted under the administrative pathway.

For more information on administrative processing, consult:

- Guidance document: Administrative processing of submissions and applications: Human or disinfectant drugs

Solicited information in a clarification request should be submitted within 5 business days from the date of the request. If the response to a clarification request is not satisfactory or not submitted within the specified time, Health Canada may send a:

- deficiency notice (response should be submitted within 45 days from the date of the request) **or**
- rejection letter

3.2 Screening

3.2.1 During the screening 1 period

The screening period begins when the submission or application is received at the relevant centre, bureau or office.

The RPM or SRAO will:

- verify that the type and class of the submission or application has been filed correctly given the intended purpose
- ensure requisite information for the type and class has been provided **and**
- verify the fee is appropriate

Note: In the Natural and Non-prescription Health Products Directorate (NNHPD), label reviewers also conduct the screening of some submissions.

Screening 1 period performance standards

For information on the screening process of CTAs and CTA-As, consult section 2.5.1 in:

- Guidance document for clinical trial sponsors: Clinical trial applications

3.2.2 Cancellation letter

Sponsors who wish to cancel their submission or application during the screening period before it has been accepted into scientific review should send a signed letter requesting the cancellation to OSIP. It should be in the same format as the original submission or application. The status of the submission or application will be changed to "Cancel Admin" in the DSTS, as the scientific review has not started.

The SRPM or SRAO will issue the cancellation acknowledgment letter.

Submissions and applications that are cancelled by the sponsor do not affect a refiling.

For more information, refer to the following sections:

- Refiling after a cancellation by a sponsor
- Refiling after a withdrawal

3.2.3 Screening acceptance letter

If the information submitted by the sponsor is acceptable at screening and requests for information or clarification are not required, then the:

- submission or application or response to solicited information is accepted for scientific review and a screening acceptance letter (SAL) is sent to the sponsor
- appropriate databases are updated **and**
- relevant review division is notified

Once the submission or application is accepted for scientific review, the RPM or SRAO continue to be the sponsor's point of contact.

3.3 Solicited information

Solicited information during the screening process is any information that Health Canada requests during the screening of a submission or application. Examples include clarification requests and screening deficiency notices.

For information on the screening process of CTAs and CTA-As, consult section 2.5. 1 in:

- Guidance document for clinical trial sponsors: Clinical trial applications

3.3.1 Clarification requests during the screening 1 period

A clarification request is issued when Health Canada wants a sponsor to expand on, clarify or re-analyze information in the submission or application during the screening period. For example, a clarification request could be made to locate misplaced documents.

A clarification request should not be made to request missing documents or data, or new data, such as new clinical or pre-clinical information, bioavailability studies or chemistry and manufacturing data not previously submitted.

Health Canada will email the request. Sponsors must respond in writing. The screening process does not stop if we receive a complete response within the requested timeframe.

3.3.2 Response to a clarification request during the screening 1 period

When responding to a clarification request, sponsors should clearly identify in the cover letter the:

- name of the drug
- dossier ID
- control number of the relevant submission or application and
- purpose of the correspondence
    - for example, “response to a screening clarification request”

Submit your response in a question-and-answer format and reference the applicable sections in the submission or application.

For acceptable formats, refer to the appropriate section in Filing submissions electronically:

- Preparation of regulatory activities in eCTD format
- Preparation of regulatory activities in non-eCTD format

For questions on filing submissions or applications electronically, you may contact BFMD.

Contact us

Submit the solicited information within 15 calendar days from the date of the request or as indicated in the clarification request. A response is complete if:

- all clarifications or questions identified in the clarification request have been addressed **or**
- the sponsor provided a sound scientific rationale as to why the requested information is not necessary

Note: The duration that a sponsor has to respond to a clarification request does **not** include the day that the clarification request is issued. It does include all other days, including weekends and statutory holidays. For example, if a clarification request is issued on April 1 and you have 15 calendar days to respond, the deadline to submit the request is April 16.

For submissions and applications that are administratively processed, you should submit information solicited in a clarification request within 5 business days from the date of the request.

If a clarification request is inquiring about the location of data in the submission or application, you should only include the location of the data or an explanation as to why the data is missing.

To clarify any items in the clarification request or the reason for issuing it, you should contact the RPM or SRAO.

There is no limit on the number of clarification requests that may be solicited for 1 submission. However, a particular issue will only be addressed once. Acknowledgement letters are not sent when we receive information in response to a clarification request.

During the screening of a submission or application, if a response to a clarification request is not satisfactory or is not submitted within the specified time to respond, we will send a deficiency notice or rejection letter for administrative processing. For all other submission or application types, we will send a screening deficiency notice.

3.3.3 Screening deficiency notice

If deficiencies are identified during the screening of material relating to a submission or application, we will send the sponsor a screening deficiency notice (SDN) identifying the deficiencies. This may also include submissions where the drug is filed as a DIN application but is considered a new drug or where the monograph attestation does not reflect the submission content. The status of the submission or application will change to "inactive 45" in the DSTS. An SDN may be sent to the sponsor without a clarification request having been issued.

The solicited information is to be submitted within 45 calendar days from the date the SDN was sent.

To clarify any items in the SDN or the reason for issuing it, you should contact the RPM or SRAO.

3.3.4 Response to screening deficiency notice

When responding to an SDN, you should clearly identify in the cover letter the following:

- name of the drug
- dossier ID
- control number of the relevant submission or application **and**
- purpose of the correspondence (for example, "response to SDN")

Your response should be in a question-and-answer format and referenced to the applicable sections of the submission or application. It should not contain unsolicited information unless otherwise specified in the SDN.

Refer to the section on unsolicited information.

You should send all requested information along with the up-to-date documents and an updated cover letter in a single package to OSIP for processing. OSIP will process this information and send to the appropriate review area within 10 calendar days. When OSIP begins to process the response to the SDN, it will change the status of the submission to "process" in the DSTS. If the response is administratively incomplete, it will change the status to "Process Hold".

Once OSIP verifies that the response is administratively complete, it will notify the RPM or SRAO that it has processed the response.

Acknowledgment letters are not sent when responses to SDNs are received.

When the information requested in the SDN is received at the relevant centre, bureau or office, a new screening 1 period begins (with the associated performance standards). The requested material and information will be screened to ensure it is complete.

3.3.5 Acceptance letter following the response to a screening deficiency notice

If the response to the SDN is acceptable, a screening acceptance letter (SAL) is sent to the sponsor. The review 1 period begins immediately.

3.3.6 Screening rejection letter

A screening rejection letter (SRL) is issued by the SRPM or SRAO. (Note: In NNHPD, the SRPM, SRAO or manager issue screening rejection letters.) This is done when a sponsor does not provide a response to the SDN within 45 calendar days or if the information is incomplete, deficient or contains unsolicited information. An SRL instead of an SDN is sent for a notifiable change (NC), supplement to a new drug submission (SNDS) or supplement to an abbreviated new drug submission (SANDS) if the proposed changes are Level III changes only.

For more information, consult the following guidance documents:

- Post-notice of compliance (NOC) changes: Safety and efficacy document (for pharmaceutical, biologic and radiopharmaceutical drugs for human use only)
- Post-notice of compliance (NOC) changes: Quality document

To clarify items in the SRL or the reason for it being issued, you should contact the RPM or SRAO.

If an SRL has been issued, you may:

- ask for the decision to be reconsidered **or**
- refile the submission or application

4 Review

4.1 The review process

The review 1 period begins immediately after the screening acceptance letter (SAL) is issued. Health Canada will evaluate the submission or application as per the performance standards.

The reviewer examines and analyzes the information submitted to ensure the product meets the requirements set out in the applicable sections of the Food and Drug Regulations.

The regulatory project manager (RPM) or senior regulatory affairs officer (SRAO) coordinates the review timelines and is the sponsor's initial point of contact.

Visit:

- Performance standards
- Contact us

For information on the scientific review process of clinical trial applications (CTAs) and amendments to clinical trial applications (CTA-As), consult section 2.5.2 in:

- Guidance document for clinical trial sponsors: Clinical trial applications

4.1.1 Screening solicited and unsolicited information

During the scientific review process, we may screen solicited and unsolicited information submitted by the sponsor to ensure that:

- a cover letter is provided with the information and includes the control number of the submission or application
- the purpose of the correspondence is clearly stated as solicited or unsolicited **and**
- the information is in an acceptable format (for example, question-and-answer, side-by-side comparison), is referenced to the applicable section in the electronic submission or application and is complete for the intended purpose

Refer to the following sections on this page:

- Solicited
- Unsolicited information

4.1.2 Cancellation letter during the scientific review

You must send a signed letter if you wish to cancel your submission or application during the review stage to the Office of Submissions and Intellectual Property (OSIP). The letter must be submitted in the same format as the original submission or application before a decision is made to issue any of the following:

- notice of compliance (NOC)
- notice of deficiency (NOD)
- notice of non-compliance (NON)
- notice of compliance with conditions - qualifying notice (NOC/c-QN)
- notice of deficiency - withdrawal (NOD-W) **or**
- notice of non-compliance - withdrawal (NON-W)

The status of the submission or application will be changed to "Cancel Science" as the scientific review has started.

The senior RPM or SRAO will issue a cancellation acknowledgment letter.

Submissions or applications that are cancelled by a sponsor do not affect refiling.

Learn more about refiling.

4.1.3 Pause-the-clock during the scientific review

Pause-the-clock allows the review clock to be paused under specific circumstances. When there is a pause, the target date is shifted to account for the amount of time the clock has been paused.

The review clock can pause only during the review period (for example, review 1 and review 2) for cost-recovered submissions and applications. Administrative submissions and applications are excluded.

Pauses may occur under 2 circumstances:

- a sponsor requests an extension to respond to a clarification request, including pre-market testing information in accordance with the Guidance for sponsors: Lot Release Program for Schedule D (biologic) drugs **or**
- Health Canada wishes to seek advice from an external advisory committee

1. Sponsor requests an extension to respond to a clarification request

You should submit the extension request as soon as possible in the form of a letter and written rationale. The clock will pause if:

- the request is beyond the number of days allocated to respond to a clarification request:
  - 15 days for submissions with a 180- to 300-day performance standard
  - 10 days for submissions and applications with a 91- to 179-day performance standard
  - 5 days for submissions and applications with a 0- to 90-day performance standard
- the request is a minimum of 5 days but not beyond 90 days (applies to each clarification request)
- Health Canada approves the extension in writing to the sponsor

The review clock pauses once Health Canada approves the extension and after the standard clarification response time has elapsed. The target date is then changed. Note: There may be situations when we would not approve an extension or grant an extension to an existing pause.

The review clock resumes at the end of the approved extension period.

If the response to a clarification request is not satisfactory or not submitted within the specified time to respond, an NOD or NON is issued.

For example, if we issue a clarification request with a 10-day response time for a submission with a 91- to 179-day performance standard, the following happens:

- if an 8-day extension is requested beyond the standard 10-day response time and the extension request is approved, the review clock will pause for 8 days beginning on day 11 and the response is due on day 18
- if a 2-day extension is requested beyond the standard 10-day response time, and the extension request is approved, the review clock will not pause

2. Health Canada seeks advice from an external advisory committee

If an external advisory committee is required during the review period (this need will be identified as early as possible in the review), we will:

- notify you if a pause is required
- include the nature of the questions for the committee in the notification

The review clock resumes once we receive the committee's final recommendations. We will confirm the revised target date at this time.

Note: Expert advisory panels and committees are convened in accordance with our policy on external advisory bodies.

4.2 Solicited information

Solicited information during the scientific review is any information that we request. Examples of solicited information during a scientific review include clarification on a statistical analysis contained in the information package, the rationale for interim pivotal trials or changes to the proposed labelling material.

4.2.1 Clarification requests

A clarification request is issued when Health Canada wants the sponsor to expand on, clarify or re-analyze existing information in the submission or application during the scientific review. For example, a clarification request could be made to locate misplaced documents.

A clarification request should not be made to request missing documents or new data, such as new clinical or pre-clinical information, bioavailability studies or chemistry and manufacturing data not previously submitted.

Health Canada will email the request and sponsors must respond in writing. The review process does not stop if we receive a complete response within the requested timeframe.

When responding to a clarification request, you should clearly identify the:

- name of the drug
- dossier ID
- control number of the relevant submission or application and
- purpose of the correspondence
  - for example, "response to a clarification request"

Submit your response in a question-and-answer format and reference the applicable sections in the submission or application.

For acceptable formats, refer to the appropriate section in Filing submissions electronically:

- Preparation of regulatory activities in eCTD format
- Preparation of regulatory activities in non-eCTD format

For questions on filing submissions or applications electronically, you may contact BFMD.

Contact us

Submit the solicited information within 15 calendar days from the date of the request or as indicated in the clarification request. A response is complete if:

- all clarifications or questions identified in the clarification request have been addressed **or**
- the sponsor provided a sound scientific rationale as to why the requested information is not necessary

Note: The period during which you must respond to a clarification request **does not** include the day that the clarification request is issued. It **does** include all other days, including weekends and statutory holidays. For example, if a clarification request is issued on April 1 and you have 15 calendar days to respond, the deadline to submit the request is April 16.

If a clarification request is inquiring about the location of data in the submission or application, you should only include the location of the data or an explanation as to why the data is missing.

To clarify any items in the clarification request or the reason for issuing it, you should contact the RPM or SRAO.

There is no limit on the number of clarification requests that may be solicited for 1 submission. However, a particular issue will only be addressed once. Acknowledgment letters are not sent for information received in response to a clarification request.

4.2.2 Response to a clarification request

For acceptable formats, refer to the appropriate section in Filing submissions electronically:

- Preparation of regulatory activities in eCTD format
- Preparation of regulatory activities in non-eCTD format

The timeline to respond is between 2 and 15 calendar days and is based on the type of and performance standard for a submission or application:

- 180- to 300-day performance standard: 15-day response time
- 91- to 179-day performance standard: 10-day response time
- 0- to 90-day performance standard: 5-day response time
- CTAs and CTA-As: 2-day response time

These are guidelines only and can be adjusted to be longer or shorter based on the complexity of the request, communications with the sponsor or the particular review circumstances.

Note: During review of a clinical assessment package, the solicited information in a clarification request should be submitted within 2 business days from the date of the request.

For more information, consult:

- Guidance for industry: Priority review of drug submissions

The review of the submission or application will not be interrupted if a complete response is submitted within the given time period.

If the response to a clarification request submitted during the scientific review is not satisfactory or not submitted within the specified time, we may send the following to a sponsor:

- notice of deficiency (NOD)
- not satisfactory notice (NSN) **or**
- notice of non-compliance (NON)

4.2.3 Notice of deficiency (NOD) - NDS, SNDS, ANDS and SANDS, EUNDS, EUSNDS, EUANDS, EUSANDS, NDS-D, SNDS-D, SNDS-c, SANDS-c, or an application for a DIN (DINA, DINB, DIND)

A notice of deficiency (NOD) is sent when:

- deficiencies or significant omissions that preclude continuing the review are identified **or**
- during the review of an application for a DIN (DINA, DINB, DIND), the product is identified as a new drug and the sponsor is asked to file a new drug submission (NDS) or an abbreviated new drug submission (ANDS)

When an NOD is issued, all scientific review streams stop and the status changes to “Inactive 45” or “Inactive 90” in the DSTS (depends on the type of submission or application), even if the review in the other streams has not been completed. Deficiencies identified to date from all review streams are included in the NOD and only 1 NOD is sent for a submission or application.

The difference between an NOD and an NON is that the review of the submission or application is not complete when an NOD is issued.

To clarify items in the NOD or the reason for it being issued, you should contact the regulatory project manager (RPM) or senior regulatory affairs officer (SRAO).

For an NDS, SNDS, ANDS, SANDS, EUNDS, EUSNDS, EUANDS, EUSANDS, NDS-D, SNDS-D, SNDS-c, and SANDS-c, the response to an NOD is to be submitted within 90 calendar days (or the time that was agreed to by the review area and the sponsor) from the date the NOD was sent.

For applications for a drug identification number (DIN), the response to an NOD is to be submitted within 45 calendar days (or the time that was agreed to by the review area and the sponsor) from the date the NOD was sent.

4.2.4 Response to NOD

A response to an NOD is to be submitted in the same format as the original submission or application. Solicited information must include a copy of the NOD and should be submitted in a question-and-answer format and reference the applicable sections of the submission or application.

Sponsors who decide it is not necessary to file the solicited information must provide a sound scientific rationale as to why the requested information is not necessary.

You should send all requested information along with up-to-date documents, including an updated cover letter, in a single package to OSIP for processing. OSIP will process this information and send to the appropriate review area within 10 calendar days. When OSIP begins to process the response to an NOD, the status of the submission will be changed to “Process”. If OSIP determines that the response to the NOD is administratively incomplete, it will change the status to “Process Hold”.

Once OSIP verifies that the response to an NOD is administratively complete, it will notify the appropriate review area that the response has been processed.

When the response to the NOD is received, a new screening 1 period begins.

Note: Acknowledgment letters are not sent when a response to an NOD is received.

4.2.5 Acceptance of a response to an NOD

When the response to an NOD is screened and found acceptable for scientific review, a screening acceptance letter (SAL) is sent to the sponsor. Then, a new review 1 period begins.

The RPM or SRAO is the initial point of contact.

Following review of the response to the NOD, the sponsor may be sent a:

- notice of deficiency withdrawal (NOD-W)
- notice of compliance (NOC) **or**
- notice of non-compliance (NON)

4.2.6 Notice of deficiency withdrawal letter (NOD-W)

An NOD-W is sent to the sponsor if the:

- response to an NOD contains unsolicited information, is incomplete or is deficient (found during the screening process)
- sponsor does not submit the solicited information within the assigned time period
    - Health Canada interprets this as a request to withdraw the submission or application
- submission or application is still deficient (found during the scientific review of the response to the NOD)

You may withdraw a submission or application without having an impact on refiling.

Learn about refiling.

You may file a request for reconsideration after an NOD-W letter has been issued.

Learn about reconsideration of decisions.

4.3 Unsolicited information

When you file unsolicited information, you should use the same format as the original submission or application (eCTD or non-CTD electronic only). Your cover letter should indicate the type of information being provided, the reason for filing and the date of filing. Send this information to OSIP for processing. The RPM or SRAO will be notified that unsolicited information has been received.

Unsolicited information may only contain the types of information indicated in this section. All other types of information are not acceptable and you will be asked to remove them from your submission.

For submissions filed in the eCTD format, you must submit a new eCTD sequence to withdraw the unsolicited information as follows:

- assign operations attribute "delete" on leaves provided as "new" **or**
- assign operation attribute "replace" on leaves provided as replace
    - use file reuse to reinstate the previous document as the current submission content

If you require assistance, email us at ereview@hc-sc.gc.ca.

If you wish to include the unsolicited information in a future drug submission or application, you will need to resubmit the information. Your submission or application will be assigned a new control number.

All unsolicited information for a CTA or CTA-A should be submitted as CTA-notifications to either ORA in BRDD or OCT in PDD, unless otherwise directed.

For more information, consult:

- Guidance document for clinical trial sponsors: Clinical trial applications

4.3.1 Safety information

4.3.1.1 Information that may be submitted during the submission process

You may submit negative safety findings or risk information collected from animal studies or clinical experience at any time. This information should support additions or changes to the wording in the "contraindications", "warnings and precautions", and "adverse reactions" sections of the product monograph.

If you are revising the product monograph as a result of the unsolicited safety data, the revised monograph must appropriately reference the original monograph, include the proposed changes and accompany any unsolicited data being submitted. A mock-up label is also required if changes to the monograph result in changes to the label. The new information will not affect the performance standards for reviewing your submission.

When submitting negative safety information, be sure to include in the cover letter the following:

- name of the drug
- dossier ID
- control number of the relevant submission or application
- purpose of the correspondence
- statement that the information is unsolicited

4.3.1.2 Information that will not be accepted once submission is accepted for review

Unsolicited final reports of safety studies that do not require changes to the "contraindications", "warnings and precautions" and "adverse reactions" sections of the product monograph will not be accepted for scientific review. You may, however, file this information in response to an NOD or NON, or include this data when you file an SNDS.

For more information, consult:

- Guidance document: Post-notice of compliance (NOC) changes: Safety and efficacy

4.3.2 Foreign regulatory information

4.3.2.1 Assessment reports

We will accept assessment reports prepared by other regulatory authorities within 120 days of receiving the original submission or application. Assessment reports submitted outside the 120-day time period may not be used or considered. We will not accept reports that have been summarized.

4.3.2.2 Correspondence

We will accept copies of correspondence between the sponsor and other regulatory authorities at any time, but we will not accept summaries of the correspondence. Supporting data or appendices should not be included with the correspondence, but should be available if requested.

4.3.3 Reports from an expert or expert advisory committee

We will only accept reports from an expert or expert advisory committee at the time of filing or if submitted in a response to an NOD or NON.

4.3.4 Changes in name of sponsor or product during processing, screening or review

During the review of a submission or application for a new product that has not yet been issued a drug identification number (DIN), if the name of the sponsor or product changes, you should submit the applicable items to OSIP:

- letter stating the nature of the change
- Regulatory Enrolment Process (REP) Regulatory Transaction (RT) XML file, for submissions and applications
    - If the new manufacturer name does not have a company identifier, it is necessary to complete a REP Company (CO) XML file before filling out the updated RT XML file. The CO XML file is processed separately from submission and application documents. For any questions about the CO XML file, contact the Client Information Unit at client.information@hc-sc.gc.ca.
- revised product monograph, package insert and labels, including mock-up labels
- brand-name assessment and mock-up labels for a product name change
- labels and packages certification form
- revised Certified Product Information Document (CPID)
- letter of authorization from the originating sponsor if the product is being transferred from 1 sponsor to another

If a product has already received market authorization (has been issued a DIN) and the name of the sponsor or product changes during the review of a subsequent submission or application, you must file a submission or application to make the necessary changes.

For information on the requirements for sponsor and product name changes, consult:

- Guidance document for industry: Review of drug brand names

- Frequently asked questions – Guidance document for industry – Review of drug brand names
- Guidance document: Questions and answers: Plain language labelling regulations for prescription drugs
- Guidance document: Questions and answers: Plain language labelling regulations for non-prescription drugs
- Guidance document - Administrative processing of submissions and applications: Human or disinfectant drugs

4.3.5 Efficacy data

Efficacy data will not be accepted at any point during the review unless it is solicited in an NOD or NON. You may file efficacy data as a supplement to a new drug submission, where applicable.

For more information, consult:

- Guidance document: Post-notice of compliance (NOC) changes: Safety and efficacy

If you committed to providing additional efficacy data in a letter of undertaking prepared in response to an NOC/c qualifying notice, you should submit this data as an SNDS-c or SANDS-c.

4.3.6 Stability data

You should only submit updated stability information relating to the quality of the drug substance or drug product when requested.

4.4 Finalizing the review process

4.4.1 Finalizing the submission or application

After the review is completed and a decision has been recommended (either negative or positive), we will prepare and send 1 of the following decision documents.

4.4.2 Notice of compliance (NOC) - NDS, SNDS, ANDS, SANDS, EUNDS, EUSNDS, EUANDS, EUSANDS, NDS-D, SNDS-D, SNDS-c, SANDS-c

This section does not apply to CTAs and CTA-As.

If a submission for a Division 8 product complies with the Food and Drug Regulations, you may receive:

- a DIN, in the form of a Drug Notification Form (DNF), in accordance with sub-section C.01.014.2(1) of the Food and Drug Regulations **and**
- an NOC once the requirements of the Patented Medicines (Notice of Compliance) Regulations and the data protection provisions in section C.08.004.1 of the Food and Drug Regulations have been met **or**
- a notification that the submission has been placed on Intellectual Property - Hold until the requirements of the Patented Medicines (Notice of Compliance) Regulations have been met or the term of market exclusivity for an innovative drug in accordance with the data protection provisions in section C.08.004.1 of the Food and Drug Regulations has expired

Before receiving an NOC, submissions may also be placed on Switch Hold or Regulatory Hold.

Learn more about types of holds.

4.4.3 No objection letter (NOL) - application for a DIN (DINA, DINB, DIND), NC, PDC, PDC-B, CTA, CTA-A

When the scientific review of an application for a DIN (DINA, DINB, and DIND) has been completed and found to be in compliance, you will receive:

- a DIN, via a Drug Notification Form (DNF), in accordance with subsection C.01.014.2(1) of the Food and Drug Regulations **or**
- an NOL for DINAs and DINDs **or**
- an approval letter for DINBs

An NOL will also be sent by the responsible review area for NCs, PDCs, PDC-Bs, CTAs or CTA-As when the submission or application has been found to be in compliance.

4.4.4 Not satisfactory notice (NSN) - NC, PDC, PDC-B, CTA, CTA-A

If deficiencies are identified during the review of an NC, PDC, PDC-B, CTA or CTA-A, the review area will send an NSN specifying the deficiencies to the sponsor. The review of the submission will stop on the date the NSN is sent.

You should contact the RPM or SRAO to clarify items in the NSN or the reason for issuing it.

If an NSN has been issued, you may refile the submission or application.

Learn about refiling.

If an NSN has been issued, you may file a request for reconsideration.

Learn about reconsideration of decisions.

4.4.5 Notice of compliance with conditions qualifying notice (NOC/c-QN)

This section does not apply to CTAs and CTA-As.

When it has been determined that data submitted for review qualifies under the NOC/c policy, the appropriate directorate will contact the sponsor to discuss the details of the submission, commitments and its potential consideration under the NOC/c policy. Following these discussions, we will issue an NOC/c–QN if appropriate.

The NOC/c-QN indicates that the submission qualifies for an NOC under the NOC/c policy. This notice also outlines the:

- additional clinical evidence to be provided in confirmatory studies
- post-market surveillance responsibilities and
- requirements related to advertising, labelling or distribution

The scientific review of the submission will stop on the date the qualifying notice is issued.

You should submit the appropriate information within 30 calendar days of receiving the NOC/c-QN. Responses to an NOC/c-QN should reference the submission control number and be sent to OSIP.

Once we receive a sponsor's response to an NOC/c-QN, we start the scientific review of the additional information provided. This stage is subject to a 30-calendar day performance standard.

If the information is acceptable, we will finalize (with the sponsor) the conditions associated with the NOC and the letter of undertaking (LOU).

For more information, consult:

- Guidance document: Notice of compliance with conditions (NOC/c)

If the information is not acceptable, we may issue an NON.

Note: Acknowledgment letters are not sent when we receive information in response to an NOC/c-QN.

4.4.6 Notice of non-compliance (NON) - NDS, SNDS, ANDS, SANDS, EUNDS, EUSNDS, EUANDS, EUSANDS or an application for a DIN (DINA, DINB, DIND)

This section does not apply to CTAs and CTA-As.

If after the scientific review, we find that a submission or application is incomplete or non-compliant with the requirements outlined in the Food and Drugs Act and its regulations, we will send an NON to the sponsor. (Note: The authorities are set out in sections C.01.014.2 (2), C.08.004 (1) and C.08.004.01 (1) of the Food and Drug Regulations.)

The NON will specify the issues that make the submission non-compliant.

After an NON is issued, the status of the submission or application status will change to "Inactive 45" or "Inactive 90" in the DSTS (depends on the submission or application type). Only 1 NON for each submission or application is sent.

If you wish to clarify items in the NON or the reason for it being issued, you should contact the RPM or SRAO.

For an NDS, SNDS, ANDS, SANDS, EUNDS, EUSNDS, EUANDS and EUSANDS, you must submit the solicited response to an NON within 90 calendar days (or the time agreed upon by both parties) from the date the NON was sent.

For applications for a DIN, you must submit the solicited information within 45 calendar days (or the time agreed upon by both parties) from the time the NON was sent.

4.4.7 Response to a notice of non-compliance (NON)

You must submit a response to an NON in the same format as the original submission or application. The response must include a copy of the NON, be submitted in a question-and-answer format and reference the applicable sections in the original submission or application.

If you decide you do not need to file the solicited information, you must provide a sound scientific rationale in order for us to consider the response to be complete.

You should send all the requested information and up-to-date documents, including an updated cover letter, in a single package to OSIP. OSIP will process this information and send it to the appropriate review area within 10 calendar days.

When OSIP begins to process the response to the NON, it will change the status of the submission to "Process". If OSIP determines that the response is administratively incomplete, it will change the status to "Process Hold".

Once OSIP verifies that the response is administratively complete, it will notify the appropriate area that the response has been processed.

When the response to the NON is received, the screening 2 period begins. Acknowledgment letters are not sent when responses to NONs are received.

4.4.8 Acceptance of a response to a notice of non-compliance (NON)

When the response to an NON is screened and found to be acceptable for review, we will send a screening acceptance letter (SAL) to the sponsor. A review 2 period begins immediately after we issue the SAL.

The RPM or SRAO is the initial point of contact for the sponsor.

4.4.9 Notice of non-compliance withdrawal letter (NON-W)

An NON-W is sent to the sponsor if the:

- response to an NON contains unsolicited information, is incomplete or is deficient (during the screening process)
- sponsor does not submit the solicited information (the response to an NON) within the assigned time period
    - Health Canada interprets this as a request to withdraw the submission or application **or**
- submission is still non-compliant (during the scientific review of the response to the NON)

Submissions or applications may be withdrawn without having an impact on refiling.

Learn about refiling.

You may file a request for reconsideration after an NON-W has been issued.

Learn about reconsideration of decisions.

4.4.10 Scientific review reports

Sponsors will receive review reports from Health Canada within 7 calendar days after an NOD, NOD/W, NON or NON/W has been issued for all submissions except DINAs/DINBs and DINDs. For DINAs/DINBs and DINDs, sponsors may request reports following receipt of an NOD, NON, NOD/W or NON/W.

Sponsors may also request review reports following receipt of an NOL, NOC or NSN.

Address your requests to the director of the review centre, bureau or office. Health Canada aims to provide requested review reports to the sponsor within 30 calendar days of receiving the request.

Contact us

5 Reconsideration of decisions, refiling

5.1 Reconsideration of decisions

Reconsideration is a dispute resolution process designed to ensure that negative decisions are made in accordance with existing scientific and regulatory standards. The process is designed to look at the information in specific submissions or applications rather than address complaints about perceived systemic issues.

Health Canada tries to identify, manage and resolve disputes at the level at which they take place. Dispute prevention and early resolution usually take place through direct communication between directorates and sponsors of submissions or applications.

If mechanisms for early dispute resolution are not successful, you may file a formal request for reconsideration of certain decisions.

For more information, consult:

- Guidance document: Reconsideration of decisions issued for human drug submissions and natural health products.

You may request a reconsideration after receiving a:

- rejection of priority review request
  - consult the Guidance for industry - Priority review of drug submissions
- rejection of request for advance consideration under the notice of compliance with conditions policy
- screening rejection letter (SRL)
- notice of deficiency-withdrawal (NOD-W)
- notice of non-compliance-withdrawal (NON-W) **or**
- not satisfactory notice (NSN) for a notifiable change (NC), PDC, PDC-B, clinical trials application (CTA) and amendments to a clinical trial application (CTA-A)

Issues not eligible for reconsideration are:

- decisions based on submissions or applications containing documented falsified information
- allegations of bias and complaints about the submission management process

You should address issues of this nature to the director of the relevant review area.

5.2 Refiled submissions and applications

A refiled submission and application is a new submission and is assigned a new control number and new filing date.

A refiled submission and application is subject to Health Canada's policies, procedures and guidance documents that are in effect at the time of refiling. You should update your submission or application accordingly. The performance standards, matters related to intellectual property and fees for the submission or application type and class will apply.

Send refiled submissions or applications to the Office of Submissions and Intellectual Property (OSIP), along with up-to-date documents (for example, updated cover letter, submission certification form). Indicate the directorate that received the previously filed submission or application.

For CTAs and CTA-As, send the refiled submission or application to the:

- Office of Regulatory Affairs (ORA) in the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) **or**
- Office of Clinical Trials (OCT) in the Pharmaceutical Drugs Directorate (PDD)

Before refiling a submission or application in an eCTD format, contact BFMD for technical advice on how to reference the new information with the original submission or application.

Contact us

A refiled submission or application is one that a sponsor files after the following has taken place:

- issuance of an SRL
- cancellation of a submission or application by a sponsor
- issuance of an NOD-W or NON-W **or**
- issuance of an NSN

5.2.1 Refiling after a screening rejection letter

If you wish to refile a submission or application that received a SRL, you must resubmit all information for the submission or application. It is not acceptable to reference the original submission or application.

5.2.2 Refiling after cancellation by the sponsor

If you wish to refile a submission or application after cancelling it at any point during the processing, screening or review 1 period or following an NOD, you must resubmit all the information for the submission or application. It is not acceptable to reference the original submission or application.

5.2.3 Refiling a CTA or CTA-A after withdrawal by the sponsor

If you withdraw an application, you must resubmit all the information for the application and, if applicable, the information to address any deficiencies previously identified. The refiled information is a new application.

5.2.4 Refiling after a notice of deficiency withdrawal

If you wish to refile a submission or application any time after an NOD-W has been issued, you must resubmit all the information for the submission or application along with the information to address the deficiencies identified in the NOD or related withdrawal letter. It is not acceptable to reference the original submission or application.

5.2.5 Refiling in 5 years or less after a not satisfactory notice

If you wish to refile a submission or application within 5 years or less after an NSN has been issued, you must resubmit all the information, including the information to address the deficiencies identified in the NSN.

You should:

- provide a rationale for why the refiled information should be reviewed
- reference the previous control number of the original submission or application
- certify that all other information previously submitted is still the same

You should incorporate into the appropriate sections of the refiled submission or application, whichever is appropriate:

- Level II changes (biologic and radiopharmaceutical drug quality changes) for Division 8 drugs
- Level III changes for Division 8 drugs **or**
- PDCs for Division 1 drugs

For more information, consult the relevant guidance document:

- Post-drug identification number (DIN) changes
- Post-notice of compliance (NOC) changes: Quality document
- Post-notice of compliance (NOC) changes: Safety and efficacy document (for pharmaceutical, biologic and radiopharmaceutical drugs for human use only)

You should also provide a complete summary of the changes that have been included and reference the supporting data in the submission or application.

To increase the efficiency of the scientific review, you should:

- identify the new and original information that is being resubmitted
- reference the original submission or application where applicable

5.2.6 Refiling 5 years or less after an NON-W, a cancellation after an NON is issued (before an NON-W)

If you wish to refile a submission or application in 5 years or less after an NON has been issued (before an NON-W) or after receiving an NON-W, you are only required to resubmit the information to address the issues identified in the NON or NON-W letter. You should:

- give a reason for why the refiled information should be reviewed
- reference the control number of the original submission or application
- certify that all other information previously submitted is still the same

You should incorporate into the appropriate sections of the refiled submission or application, whichever is appropriate:

- Level II changes (biologic and radiopharmaceutical drug quality changes only) for Division 8 drugs
- Level III changes for Division 8 drugs **or**
- PDCs for Division 1 drugs

For more information, consult the relevant guidance document:

- Post-drug identification number (DIN) changes
- Post-notice of compliance (NOC) changes: Quality document
- Post-notice of compliance (NOC) changes: Safety and efficacy document (for pharmaceutical, biologic and radiopharmaceutical drugs for human use only)

You should also provide a complete summary of the changes that have been included and reference the supporting data in the submission or application.

To increase the efficiency of the scientific review, you should:

- identify the new and original information that is being resubmitted
- reference the original submission or application where applicable

5.2.7 Refiling more than 5 years after receiving an NON-W, cancellation after an NON (before an NON-W) or an NSN is issued

If you wish to refile a submission or application more than 5 years after receiving an NON-W, cancellation after an NON (before an NON-W) or NSN, you must resubmit all information for the submission or application and up-to-date documents (for example, cover letter, submission certification form). It is not acceptable to reference the original information. You should identify and certify any information that was submitted in the original submission or application that is still the same.

6 Performance standards

6.1 Performance standards for pharmaceuticals, biologics and radiopharmaceuticals

The Office of Submissions and Intellectual Property (OSIP) has 10 days to process submissions or applications (except CTAs and CTA-As) before they are accepted into screening 1 and screening 2 review periods.

Submission		**Performance standards (in calendar days)**					
Type	**Class**	**Screening 1 (including response to NOD)**	**Review 1 (including response to NOD)**	**CR review[1]**	**Screening 2 response to NON**	**Review 2 response to NON**	**Review of response to NOC/c-QN**
CTA CTA-A[2]	1. Phase I - bioequivalence	7 (administrative target) 30 (default)		N/A	N/A	N/A	N/A
	2. All other Phase I, Phase II, Phase III	30 (default)		N/A	N/A	N/A	
NDS SNDS ANDS SANDS EUNDS[2] EUSNDS[2] EUANDS[2] EUSANDS[2]	1. **Priority** - NAS, Clin or Non Clin data and C&M, Clin or Non Clin data only	25	180	300	25	90	0
	2. **NOC/c** - NAS, Clin or Non Clin data and C&M, or Clin or Non Clin data only	25	200	300	25	90	30
	3. PHED - NAS, Clin or Non Clin data and C&M, or Clin or Non Clin data only, C&M only, Labelling only, Administrative, NC quality (biologics only)	Performance standards of the applicable submission class apply but may be accelerated[3]					
For NDS-D and SNDS-D disinfectants, refer to the next section	4. NAS	45	300	300	45	150	0
	5. Clin or Non Clin data and C&M	45	300	300	45	150	0
	6. Clin or Non Clin data only	45	300	300	45	150	0
	7. Clin or Non Clin data only, in support of safety updates to the labelling (SNDS/SANDS only)	25	120	120	7	75	0
	8. Comp data and C&M or Comp data only	45	180	180	45	150	0
	9. C&M data only	45	180	180	45	150	0

Submission		Performance standards (in calendar days)					
Type	**Class**	**Screening 1 (including response to NOD)**	**Review 1 (including response to NOD)**	**CR review[1]**	**Screening 2 response to NON**	**Review 2 response to NON**	**Review of response to NOC/c-QN**
	10. Labelling only	45	120	120	45	75	0
	11. Labelling only (generic) (SNDS/SANDS only)	45	120	120	45	75	0
	12. Administrative	45 Administrative screening		45	0	0	0
DINA, DINB (For DIND disinfectants, refer to the next section)	1. Labelling standard	60		60	0	0	0
	2. Clin or Non Clin data and C&M	45	210	210	45	150	0
	3. Clin or Non Clin data only	45	210	210	45	150	0
	4. Comp data and C&M or Comp data only	45	210	210	45	150	0
	5. C&M data only	45	210	210	45	150	0
	6. Labelling only	45	120	120	45	75	0
	7. Administrative	45 Administrative screening		45	0	0	0
DINF	1. Labelling standard	60		60	0	0	0
	2. Administrative	45 Administrative screening		45	0	0	0
NC[2]	1. NC quality (90 day) for biologics and radiopharmaceuticals	7	90	N/A	0	0	0
PDC[2]	1. Post-authorization Division 1 change for non-prescription pharmaceuticals	30		N/A	0	0	0
	2. Post-authorization Division 1 safety change for prescription pharmaceuticals	25	120	N/A	N/A	N/A	N/A
	3. Post-authorization Division 1 quality change for prescription pharmaceuticals	25	90	N/A	N/A	N/A	N/A

Submission		Performance standards (in calendar days)					
Type	**Class**	**Screening 1 (including response to NOD)**	**Review 1 (including response to NOD)**	**CR review[1]**	**Screening 2 response to NON**	**Review 2 response to NON**	**Review of response to NOC/c-QN**
	4. Administrative	45 Administrative screening		N/A	0	0	0
PDC-B[2]	1. Post-authorization Division 1 change (biologics)	45	210	N/A	45	150	0
	2. Administrative	45 Administrative Screening		N/A	0	0	0

[1]The cost recovery (CR) review column defines the applicable performance standard associated with each activity and fee as per the performance standards for the Fees in Respect of Drugs and Medical Devices Order. The performance standard is the period from the date of acceptance to date of first decision not including any review clock pauses. If a drug submission (not including combination products or those subject to a joint or parallel foreign review) is not reviewed within the established CR performance standard, sponsors are credited 25% of the original fee.

[2] Non cost-recovered submissions and applications

[3]Submissions for PHED are not subject to fee remission in the case of a rolling review.

For interpretation of performance standards, refer to the glossary and terminology sections.

6.2 Performance standards for disinfectants

For more information on disinfectants, consult:

- Guidance document: Management of disinfectant drug applications

Submission		Performance standards (in calendar days)					
Type	**Class**	**Screening 1 (including response to NOD)**	**Review 1 (including response to NOD)**	**CR review[1]**	**Screening 2 response to NON**	**Review 2 response to NON**	**Review of response to NOC/c-QN**
NDS SNDS	1. Clin or Non Clin data and C&M	45	300	300	45	150	30
	2. Clin or Non Clin data only	45	300	300	45	150	30
	3. Clinical or non-clinical data only, in support of safety updates to the labelling	45	90	90	45	60	0
	4. C&M data only	45	300	300	45	150	0

Submission		Performance standards (in calendar days)					
Type	**Class**	**Screening 1 (including response to NOD)**	**Review 1 (including response to NOD)**	**CR review[1]**	**Screening 2 response to NON**	**Review 2 response to NON**	**Review of response to NOC/c-QN**
	5. Labelling only	45	90	90	45	60	0
	6. Administrative	45 Administrative screening		45	0	0	0
DIND	1. Labelling standard	60		60	0	0	0
	2. Clin or Non Clin data and C&M	45	210	210	45	150	0
	3. Clin or Non Clin data only	45	210	210	45	150	0
	4. C&M data only	45	210	210	45	150	0
	5. Labelling only	45	90	90	45	60	0
	6. Administrative	45 Administrative screening		45	0	0	0
PDC[2]	1. Post-authorization Division 1 change (disinfectants)	30		N/A	0	0	0
	2. Administrative	45 Administrative screening		N/A	0	0	0

[1]The cost recovery (CR) review column defines the applicable performance standard associated with each activity and fee as per the performance standards for the Fees in Respect of Drugs and Medical Devices Order. The performance standard is the period from the date of acceptance to date of first decision, not including any review clock pauses. If a drug submission (not including combination products or those subject to a joint or parallel foreign review) is not reviewed within the established CR performance standard, sponsors are credited 25% of the original fee.

[2]Non cost-recovered submissions and applications

For an interpretation of performance standards, refer to the glossary and terminology sections.

Consult the Guidance document: Fees for the review of human or disinfectant drug submissions and applications.

7 Definitions, glossary, notes

7.1 Definitions

Biologic drug: A drug listed in Schedule D to the Food and Drugs Act.

Biosimilar biologic drug: The term biosimilar biologic drug (or biosimilar) is used by Health Canada to describe subsequent entry versions of a Canadian-approved innovator biologic with demonstrated similarity to a reference biologic drug. Biosimilars were previously referred to as subsequent entry biologics (SEBs) in Canada.

Control number (may also appear as submission number): The ID number assigned to submissions and applications in the Drug Submission Tracking System.

Dossier: A collection of all regulatory activities throughout the life cycle of a product.

Dossier identifier (dossier ID): A number created by Health Canada to uniquely identify the dossier for a specific drug product.

Drug: According to the Food and Drugs Act, a drug includes any substance or mixture of substances manufactured, sold or represented for use in:

- diagnosing, treating, mitigating or preventing a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals
- restoring, correcting or modifying organic functions in human beings or animals
- disinfecting premises where food is manufactured, prepared or kept

For the purposes of this guidance, drug refers to:

- prescription and non-prescription pharmaceuticals
- biologically-derived products such as vaccines, blood-derived products and products produced through biotechnology
- cells and some tissues
- disinfectants
- radiopharmaceuticals

Drug/medical device combination product: A therapeutic product that combines a drug component and a device component (which by themselves would be classified as a drug or a device), such that the distinctive nature of the drug component and device component is combined in a singular product.

Note: While drug/medical device combination products include some co-packaged products, this definition does not apply to co-packaged products classified as kits, which may also include a combination of drugs and medical devices.

Ethical drug: A drug that, in accordance with federal legislation, does not require a prescription, but is generally prescribed by a medical practitioner. Ethical products are unscheduled non-prescription professional-use products (such as magnetic resonance imaging contrast agents, hemodialysis solutions) and a few emergency use products (such as nitroglycerine).

Filing date: The date that the submission or application is deemed administratively complete by Health Canada. For example, the submission or application contains all necessary certification forms, the REP Product Information and REP Regulatory Transaction templates, including a completed fees section, and meets the requirements of section 5 of the Patented Medicines (Notice of Compliance) Regulations, where applicable.

This date may differ from the date of original receipt should the submission or application be considered administratively incomplete at the time of receipt. The filing date established for a submission or application is not affected by subsequent screening or review activities. In the Drug Submission Tracking System – Industry Access, the filing date was previously referred to as the "CR Date".

Note: A submission or application received after 5:00 pm Eastern Standard Time, during a weekend or on a statutory holiday, is considered to be received on the next business day.

Generic drug: A generic drug is a copy of a brand name drug. The generic drug is pharmaceutically equivalent to the brand name drug and contains the identical medicinal ingredients, in the same amounts and in a similar dosage form. Generic medications may have different non-medicinal ingredients than the brand name drug, but the company must show that these do not affect its safety, efficacy or quality. Generic drugs are approved as abbreviated new drug submissions (ANDSs).

Manufacturer or sponsor: For drug products, the manufacturer or sponsor is the name under which the drug submission is filed. Where a drug identification number (DIN) or notice of compliance (NOC) is to be issued, this is the company in whose name the DIN or NOC will be registered (the DIN or NOC holder) and whose name must be included on the product label and product monograph or package insert. For clinical trial applications (CTAs) and amendments to clinical trial applications (CTA-As), a sponsor is defined by Division 5, Part C of the Food and Drug Regulations as the individual, corporate body, institution or organization that conducts a clinical trial. The sponsor is not necessarily the company that makes the drug product.

For medical devices, the manufacturer is the person (includes a partnership, firm or association) who:

- sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person and
- is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf

Medical device: As stated in the Food and Drugs Act, is an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in either:

a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals
b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals
c) diagnosing pregnancy in human beings or animals
d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring
e) preventing conception in human beings or animals

Does not include an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by:

- pharmacological, immunological or metabolic means or
- chemical means in or on the body of a human being or animal

Non-prescription drug: A drug that can be bought without a practitioner's prescription (not included in the Prescription Drug List).

Prescription drug: A drug that is:

- set out in the Prescription Drug List, as amended from time to time, or
- part of a class of drugs that is set out in the Food and Drugs Act

Regulatory activity: A collection of all regulatory transactions throughout the process of a specific activity, such as, for example, a new drug submission (NDS), abbreviated new drug submission (ANDS) or drug identification number application (DINA).

Therapeutic product: A drug or device or any combination of drugs and devices.

7.2 Glossary

ANDS: abbreviated new drug submission

C&M: chemistry and manufacturing (quality)

Clin: clinical

Comp: comparative studies (bioavailability, clinical, pharmacodynamics or pharmacokinetic)

CTA: clinical trial application

CTA-A: clinical trial application – amendment

DDCP: drug-device combination product

DIN: drug identification number

DINA: application for a DIN

DINB: application for a DIN - biological product

DINF: application for a DIN - category IV product

DIND: application for a DIN - disinfectant product

EUNDS: extraordinary use new drug submission

EUSNDS: supplement to an extraordinary use new drug submission

EUANDS: abbreviated extraordinary use new drug submission

EUSANDS: supplement to an abbreviated extraordinary use new drug submission

NAS: new active substance

NC: notifiable change

NDS: new drug submission

NDS-D: new drug submission for a disinfectant product

NOC: notice of compliance

NOC/c-QN: notice of compliance with conditions - qualifying notice

NOD: notice of deficiency

NOL: no objection letter

NON: notice of non-compliance

NSN: not satisfactory notice

PDC: post-authorization Division 1 change (includes prescription, non-prescription, and disinfectant PDCs)

PDC-B: post-authorization Division 1 change for biologics

PHED: public health emergency drug

SANDS: supplement to an abbreviated new drug submission
SANDS-c: supplement to an abbreviated new drug submission – confirmatory

SNDS: supplement to a new drug submission

SNDS-c: supplement to a new drug submission - confirmatory

SNDS-D: supplement to a new drug submission for disinfectant products

7.3 Notes on terminology and types of administrative holds

7.3.1 Terminology for interpretation of performance standards

Class: Submission class based on information included in submission (except for a new active substance, which applies to a medicinal ingredient not previously approved in a drug for sale in Canada), corresponding to the fee class.

NOC/c: Submissions that have been accepted for advance consideration under the notice of compliance with conditions policy.

Priority: Submissions that have been accepted for priority status according to the priority review of drug submissions.

Process: The 10-day processing period where OSIP verifies that the information submitted to Health Canada as a response to an SDN, an NOD or an NON is administratively complete.

Process for an initial submission or application: The 10-day processing period where the Office of Submissions and Intellectual Property (OSIP) verifies that the information submitted to Health Canada in an initial submission or application is administratively complete.

Review 1: Period from date of acceptance to:

- an NOL or NSN issued for a CTA, CTA-A, NC, PDC (for prescription drugs only) or PDC-B **or**
- an NOD, NOD-W, NON, NOC/c-QN or NOC for all other submissions

Review 2: Period from date of acceptance of response to the date of an NON to an NOC or an NON-W letter.

Review of response to NOC/c-QN: Period from date of acceptance of response to an NOC/c-QN sent under the notice of compliance with conditions policy

Screening 1: Period from date of receipt to the date of acceptance, rejection, SDN or withdrawal for an unacceptable response to NOD screening.

Screening 2: Period from date of receipt of response to an NON to the date of acceptance or withdrawal for unacceptable response to NON screening.

Learn more about the performance standards.

7.3.2 Types of administrative holds

Not applicable to CTAs or CTA-As.

Data protection refused hold: Manufacturers who seek a notice of compliance (NOC) based on a direct or indirect comparison with an innovative drug will not be permitted to file the submission for 6 years from the date the NOC was issued for the innovative drug. They will be given a preliminary decision by letter informing them of the intent to reject their submission and granting a period in which to provide representations. If, following consideration of the representations, the Office of Submissions and Intellectual Property (OSIP) believes that the submission cannot be filed, a final decision will be issued and the submission will be deleted.

Intellectual property hold: When the scientific review of a submission for a Division 8 product is complete and the submission is found to be in compliance, the sponsor will be notified that the submission has been placed on intellectual property hold. This is done until, as applicable, the:

- requirements of the Patented Medicines (Notice of Compliance) Regulations have been met **and**
- term of market exclusivity for an innovative drug in accordance with the data protection provisions at section C.08.004.1 of the Food and Drug Regulations has expired

While on intellectual property hold, subsequent SNDSs, SANDSs, NCs and post-market vigilance data will be accepted into review. Once the regulations and provisions have been satisfied, the original NOC and subsequent NOCs or NOLs are sent to the sponsor.

Learn more about issues related to intellectual property:

- Guidance document: Patented Medicines (Notice of Compliance) Regulations
- Guidance document: Data protection under C.08.004.1 of the Food and Drug Regulations

Patent-form V hold: For submissions subject to the provisions of the Patented Medicines (Notice of Compliance) Regulations, Health Canada is required to ensure that all relevant patents have been addressed through the filing of a Form V – Declaration Re: Patent List. OSIP will notify the sponsor when patent requirements are not met and the original information will be placed on Form V Hold. Once all the Form V requirements have been met, the received date will be entered and the submission will be sent to the relevant review bureau or centre.

However, if the Form V requirements have not been met within the period outlined in OSIP's letter, the sponsor will be notified that the submission is cancelled and the submission status will be changed to "Cancel Process".

Process hold – initial: OSIP will place the original information on process hold - initial when:

- more information such as a certification form is required
- the electronic data is not in CTD structure **or**
- a validation report with error is issued

Once the reason for the process hold - initial is addressed, the submission continues through the standard submission processing route.

If the company does not provide the requested information within 10 days, a final letter is sent to them. This letter notifies them that the information initially provided is considered administratively incomplete and the submission will be cancelled. The status of the submission or application will be changed to "Cancel Process". The company may refile.

Process hold: A submission is placed on process hold when the response to an NOD, NON or SDN is administratively incomplete (for example, has missing or incomplete forms) or a validation report with error is issued.

If the company does not provide the requested information within 10 days, a final letter is sent to them. The letter notifies them that the response will not be accepted.

When the missing information is received by OSIP, the received date will be entered and the response forwarded to the working area that's reviewing the submission or application.

For CTAs and CTA-As, a submission will be placed on process hold when the submission is administratively incomplete (for example, has missing or incomplete forms or is missing documents). When the missing information is received by OCT in PDD or ORA in BRDD, the received date will be entered and the regulatory review (30-day regulatory default period) will begin.

Regulatory hold: When the scientific review of the submission is complete and there are outstanding regulatory requirements (for example, completion of an on-site evaluation related to the review of a biologic), the submission will be placed on regulatory hold. A submission may also be placed on regulatory hold when there are pending related regulatory amendments.

Switch hold: This hold occurs after the review of a submission for a switch from prescription to non-prescription status has been completed. If the submission met the regulatory requirements and demonstrated that practitioner involvement may not be required, the submission is placed on hold. It remains on hold pending the outcome of the proposal to remove the medicinal ingredient or medicinal ingredients for certain conditions of use from Prescription Drug List.

7.3.3 Issuance of decision documents

The following tables list the submission or application type or category (for example, Division 1 or Division 8 drugs) and the individual responsible for signing the decision document.

Table 1. Notice of deficiency (NOD)

Division number	PDD	NNHPD (NDED)	BRDD
Division 8 drugs	Director General	Director General	Director General
Division 1 drugs: • DINA (not applicable to a DINA for a labelling standard or a labelling standard to a category IV monograph) • DIND • DINB)	Director	Division manager	Director General

Table 2. No objection letter (NOL)

Type	PDD	NNHPD (NDED)	BRDD
CTA or CTA-A	Division manager	N/A	Senior Regulatory Affairs Officer
Notifiable changes (NC) (for human biologic or radiopharmaceutical drug quality changes)	N/A	N/A	Senior Regulatory Affairs Officer
Division 1 drugs: • DINA (not applicable to a DINF and a DINA for a labelling standard) • DIND • DINB) (approval letters signed by the director general are issue for all DIN-Bs)	Director	Division manager or reviewer	Director General
PDC-pharmaceuticals (prescription, non-prescription, disinfectant)	Director	Division manager or reviewer	N/A
PDC-biologics	N/A	N/A	Senior Regulatory Affairs Officer

Table 3. Not satisfactory notice (NSN)

Type	PDD	NNHPD (NDED)	BRDD
CTA or CTA-A	Director General	N/A	Director General
Notifiable changes (NC) (for human biologic or radiopharmaceutical drug quality changes)	N/A	N/A	Review Centre Director
PDC - pharmaceuticals (prescription, non-prescription, disinfectant)	Director	Division manager or reviewer	N/A
PDC - biologics	N/A	N/A	Review Centre Director

Table 4. Notice of deficiency-withdrawal (NOD-W)

Division number	PDD	NNHPD (NDED)	BRDD
Division 8 drugs	Director General	Director General	Director General
Division 1 drugs: • DINA • DIND • DINB)	Director	Division manager	Director General

Table 5. Notice of non-compliance (NON)

Division number	PDD	NNHPD (NDED)	BRDD
Division 8 drugs	Director General	Director General	Director General
Division 1 drugs: • DINA • DIND • DINB	Director	Division manager	Director General

Table 6. Notice of non-compliance – withdrawal (NON-W)

Division number	PDD	NNHPD (NDED)	BRDD
Division 8 drugs	Director General	Director General	Director General
Division 1 drugs: • DINA • DIND • DINB	Director	Division manager	Director General

Table 7. Notice of compliance (NOC)

Division number	PDD	NNHPD (NDED)	BRDD
Division 8 drugs	Director General • Manager (generics) • Director (administrative)	Director General	Director General

8 References

Health Canada has published numerous guidelines, policies and reference documents to help sponsors prepare and file drug submissions and applications. The following list of guidance documents and policies is not exhaustive. These documents should be read along with this guidance document.

8.1 General filing

- Filing submissions electronically
- Management of disinfectant drug applications
- Questions and answers - Prescription Drug List
- Regulatory requirements for drug identification numbers (DIN)
- Guidance on switching from prescription to non-prescription status
- Guidance document: Patented Medicines (Notice of Compliance) Regulations
- Guidance document: Classification of products at the cosmetic-drug interface
- Guidance document: Data protection C.08.004.1 of the Food and Drug Regulations
- Guidance on evaluation fees for human drugs and disinfectants
- Guidance document: Reconsideration of decisions sent for human drug and natural health products submissions
- Guidance document: Administrative processing of submissions and applications: Human or disinfectant drugs
- Regulatory Enrolment Process (REP)
- Development safety update report (DSUR) - International Conference on Harmonisation (ICH) Topic E2F

8.2 Other filing processes

- Guidance for industry - Priority review of drug submissions
- Guidance document: Notice of compliance with conditions (NOC/c)
- Guidance on the Food and Drug Regulations for public health emergency drugs (PHED)
- Guidance document: Drug submissions relying on third party data (literature and market experience)
- Guidance document - Submission and information requirements for extraordinary use new drugs (EUNDS) (PDF)

8.3 Labelling

- Non-prescription drugs: Category IV monographs
- Non-prescription drugs labelling standards - Drug product
- Guidance document for industry - Review of drug brand names
- Guidance document: Drug facts table for non-prescription drugs
- Guidance document: Electronic Canadian drug facts table (eCDFT) technical standards
- Guidance document: Questions and answers: Plain language labelling regulations for prescription drugs
- Guidance document: Questions and answers: Plain language labelling regulations for non-prescription drugs

8.4 Post-authorization changes

- Guidance document: Post-drug identification number (DIN) changes
- Guidance document: Post-Notice of Compliance (NOC) Changes: Framework Document (Pharmaceutical, biologic and radiopharmaceutical drugs for human use only)

- Guidance document: Post-notice of compliance (NOC) changes: Quality
- Guidance document: Post-notice of compliance (NOC) changes: Safety and efficacy (for pharmaceutical, biologic and radiopharmaceutical drugs for human use only)

8.5 Clinical trials

- Guidance document for clinical trial sponsors: Clinical trial applications
- Guidance document: Quality (Chemistry and Manufacturing) Guidance: Clinical trial applications (CTAs) for pharmaceuticals
- Guidance document: Part C, Division 5 of the Food and Drug Regulations "drugs for clinical trials involving human subjects" (GUI-0100) - Summary

8.6 Medical devices and combination products

- Policy on drug/medical device combination products
- Policy on drug/medical device combination products - Decisions
- Guidance document: Management of applications for medical device licences
- Guidance document: Classification of products at the drug-medical device interface
- Classification of health products at the device-drug interface (questions and answers)
- Applications for medical device investigational testing authorizations guidance document - Summary

8.7 Biologics

- Guidance document: Blood Regulations
- Guidance document: Annual update of seasonal influenza vaccines
- Guidance for sponsors: Lot Release Program for Schedule D (biologic) drugs
- Guidance document: Information and submission requirements for biosimilar biologic drugs
- Lot release - Guidance documents - Applications and submissions - Biologics, radiopharmaceuticals and genetic therapies

8.8 Pharmacovigilance monitoring

- Submitting risk management plans guidance document

9 Contact us

The following work areas review drug submissions and applications.

Biologic and Radiopharmaceutical Drugs Directorate (BRDD)

BRDD is the Canadian regulatory authority that regulates within the scope of this guidance document:

- clinical trials of biologics and radiopharmaceuticals
- biologic drugs for human use
- radiopharmaceutical drugs for human use

The Office of Regulatory Affairs within BRDD manages submissions and applications associated with the products that the directorate regulates. It:

- screens and validates submissions and applications
- coordinates and facilitates meetings with sponsors
- provides regulatory and policy guidance to sponsors
- receives and issues all regulatory correspondence for BRDD

Office of Regulatory Affairs
Biologic and Radiopharmaceutical Drugs Directorate
Health Products and Food Branch
Health Canada
100 Eglantine Dr
Tunney's Pasture
Address Locator: 0601C
Ottawa ON K1A 0K9

Tel: 613-957-1722
Email: brdd.ora@hc-sc.gc.ca

Learn more about the Biologic and Radiopharmaceutical Drugs Directorate.

Pharmaceutical Drugs Directorate (PDD)

PDD regulates human prescription pharmaceutical (for example, chemically synthesized) products.

Depending upon therapeutic class and the types of studies filed in support of a pharmaceutical submission, the safety and efficacy (clinical and pre-clinical) component may be reviewed by one or more of the four review Bureaus in the PDD, whose functions are described below. The quality (chemistry and manufacturing) component of all pharmaceutical submissions is reviewed by the Bureau of Pharmaceutical Sciences.

Director General's Office
Pharmaceutical Drugs Directorate
Health Products and Food Branch
Health Canada
Holland Cross, Tower "B"
6th Fl, 1600 Scott St
Address Locator: 3106B
Ottawa ON K1A 0K9

Telephone: 613-957-0368
Fax: 613-952-7756
Teletypewriter: 1-800-465-7735 (Service Canada)

Email: pharma_drug_enquiries-renseignements_medicaments_pharma@hc-sc.gc.ca

The Bureau of Metabolism, Oncology and Reproductive Sciences (BMORS) has 3 divisions:

- Division of Reproduction and Urology Drugs
- Division for Oncology Drugs
- Division of Metabolic and Musculoskeletal Drugs

Among its responsibilities, BMORS oversees the clinical, pre-clinical and labelling review of submissions of pharmaceutical drugs used for:

- diabetes
- menopause
- haematology
- osteoporosis
- contraception
- erectile dysfunction
- hormone replacement
- musculoskeletal anti-inflammatories
- oncology (includes hormone-based therapies)

Email: bmors.enquiries@hc-sc.gc.ca

The Bureau of Gastroenterology, Infection and Viral Diseases (BGIVD) has 3 divisions:

- Division of Anti-Infective Drugs
- Division of AIDS and Viral Diseases Drugs
- Division of Gastroenterology, Imaging, Ophthalmology, and Dermatology

Among its responsibilities, BGIVD oversees the clinical, pre-clinical and labelling review of submissions for:

- sterile diluents
- contrast agents
- ophthalmic drugs
- parenteral nutrition products
- antidotes and poison treatments
- immunosuppressant drugs for transplants and skin disorders
- drugs to treat gastrointestinal disorders, conditions, and diseases
- drugs to treat dermatological disorders, conditions and diseases limited to the skin
- antimicrobial drugs (antibacterials/antibiotics, antivirals, antifungals, antiparasitics)

BGIVD also houses the Labelling Division (LD), which reviews labelling information that is distributed with a drug, such as:

- brand name assessments
- product monographs for subsequent entry products
- inner and outer package labels and package inserts
- patient and consumer information on product monographs
    - explains what the medication is for, how to use it and the potential side effect

The Administrative Submissions Unit (ASU) in the Labelling Division conducts the administrative screening of submissions and applications filed for changes to the manufacturer or brand name.

Email:

- bgivd_enquiries@hc-sc.gc.ca (all enquiries except to the ASU and LD)
- pdd.bgivd.asu-dmp.bgmiv.usa@hc-sc.gc.ca (ASU enquiries)
- pdd.bgivd.ld-dmp.bgmiv.de@hc-sc.gc.ca (LD enquiries)

The Bureau of Medical Sciences (BMS) has medical evaluators assigned to 1 of 2 medical sciences divisions (set up like the review bureaus in PDD). Among their responsibilities, the evaluators:

- review first-in-class submissions
- review submissions relying on third-party data, especially when the Canadian medical practice context is required
- determine priority review submission status
- assess requests for advance consideration of a notice of compliance with conditions
- conduct medical necessity determinations for the PDD
- conduct health risk assessments

BMS also provides a medical consultation service to the other review bureaus when requested. As such, medical evaluators attend pre-submission meetings across the review bureaus.

The Risk Management Division (RMD), which resides within BMS, coordinates health risk assessments, medical necessity determinations and drug shortages files. It also liaises with the Regulatory Operations and Enforcement Branch (ROEB).

Email:

- bmsenquiriesenquetesbsm@hc-sc.gc.ca (general enquiries)
- bmsrisk-bsmrisque@hc-sc.gc.ca (BMS-RMD Risk Management Division)

The Bureau of Cardiology, Allergy and Neurological Sciences (BCANS) has 3 divisions:

- Division for Cardio-Renal Drugs
- Division of Allergy and Respiratory Drugs
- Division for Central Nervous System Drugs

Among its responsibilities, BCANS oversees the clinical, pre-clinical and labelling review of submissions used in or for:

- stroke
- obesity
- dialysis
- neurology
- psychiatry
- vasodilators
- hypertension
- diuretic drugs
- anesthesiology
- antiplatelet drugs
- pain management
- plasma expanders
- myocardial ischemia
- antithrombotic drugs

- substance-related disorders
- immunosuppressant drugs for allergies, asthma, coughs and colds

Email: bcansenquiries@hc-sc.gc.ca

Bureau of Pharmaceutical Sciences (BPS) oversees the chemistry and manufacturing review as well as the scientific review of clinical comparative bioavailability studies. These studies include, for example, bioequivalence studies for all submission types of all therapeutic classes of pharmaceutical products. BPS also assesses pharmaceutical product information and labelling of generic product submissions.

Email: bpsenquiries@hc-sc.gc.ca

The Office of Clinical Trials (OCT) manages and evaluates information related to clinical trial applications for drug products used in phase 1, 2 or 3 clinical trials. Among its responsibilities, OCT receives and reviews clinical trial applications, including serious unexpected adverse drug reactions related to clinical trials. It also provides guidance to stakeholders.

Submission Management Division, Office of Clinical Trials
Pharmaceutical Drugs Directorate
Health Canada
5th Fl, Holland Cross, Tower B
1600 Scott St
Address Locator: 3105A
Ottawa ON K1A 0K9

Email:

- oct.enquiries-requetes.bec@hc-sc.gc.ca (general enquiries)
- oct.pre.cta-dec.bec@hc-sc.gc.ca (pre-CTA meeting requests)

The Regulatory Project Management Division (RPMD) resides in the Office of Planning, Performance and Review Services where regulatory project managers are assigned to each bureau.

The regulatory project managers are the key regulatory contacts for submissions and applications. They:

- communicate progress internally and externally
- coordinate review streams as well as pre-submission meetings
- ensure that policies, guidelines, processes and practices are applied consistently across the division

They also:

- ensure that sponsors of submissions and applications have met the minimum requirements
- monitor adherence to review performance standards

Email: rpmd-dgpr@hc-sc.gc.ca

Medical Devices Directorate (MDD)

MDD reviews scientific information to assess the safety, effectiveness and quality of medical devices. MDD also:

- assesses the potential benefits and risks of a medical device
- reviews applications for investigational testing authorizations for medical devices to ensure that studies are well designed and participants will not be exposed to undue risk

The Bureau of Licensing Services within MDD:

- authorizes the sale of lower-risk Class II medical devices
- provides project management services and logistical support for medical device licence applications
- responds to enquiries from stakeholders on the classification of their medical device

Medical Devices Directorate
Health Products and Food Branch
Health Canada
11 Holland Ave, Tower A, 2nd Fl
Address Locator: 3002A
Ottawa ON K1A 0K9

Telephone: 613-957-4786
Fax: 613-957-6345

Email: meddevices-instrumentsmed@hc-sc.gc.ca

Business Facilitation and Modernization Directorate (BFMD)

BFMD supports the Health Products and Food Branch. It provides direction, coordination, support on information technology and information management. It also ensures that governance mechanisms are in place to allow the branch to deliver effectively on legislated functions.

The Business Informatics and Information Science Division within BFMD:

- manages the issuance of dossier IDs for eCTD and non-eCTD pharmaceutical, biological, master file and clinical trial submissions
- receives and evaluation samples in eCTD format
- manages the Electronic Submission Gateway (ESG)

Email: ereview@hc-sc.gc.ca

Natural and Non-prescription Health Products Directorate (NNHPD)

NNHPD oversees the regulation of non-prescription drugs, biocides, disinfectant drugs and natural health products. Among its responsibilities, the Non-Prescription Drug Evaluation Division within NNHPD manages the scientific review of pre-market applications and all issues related to non-prescription drugs, including DIN applications for products subject to Category IV monographs and labelling standards, as well as biocides and disinfectant products. (Responsibility for reviewing Division 8 generic drugs, such as ANDSs and SANDSs, lies with BPS.)

Regulatory Project Management Unit
Natural and Non-prescription Health Products Directorate
Health Canada
7th Fl, 2 Constellation Dr
Address Locator: 2607A
Ottawa ON K1A 0K9
Email: nnhpd-dpsnso@hc-sc.gc.ca

Marketed Health Products Directorate (MHPD)

MHPD monitors and assesses the safety of authorized health products in Canada and takes regulatory action when safety issues are identified. MHPD uses a risk-based approach to make regulatory decisions, which are communicated in an open and transparent manner to help people in Canada make informed decisions. The directorate:

- monitors and collects adverse reaction and medication incident data for drugs and medical devices
- reviews and analyzes marketed health product safety data
- conducts risk-benefit assessments of marketed health products
- communicates risks about a product to health professionals and the public

Regulatory Project Management Office
Bureau of Strategic Engagement and Integrated Management Services
Health Canada
200 Eglantine Dr
Address Locator: 1912A
Ottawa ON K1A 0K9

Email:

- bbrs.rpm-gpr.bbra@hc-sc.gc.ca (biologics and radiopharmaceuticals)
- mpb.rpm-gpr.bppc@hc-sc.gc.ca (pharmaceuticals)

The Office of Submissions and Intellectual Property (OSIP) within MHPD processes submissions and applications, including invoicing of fees. It also:

- maintains databases such as the Drug Submission Tracking System, the Drug Products Database and the Notice of Compliance Database
- administers the Fees in Respect of Drugs and Medical Devices Regulations
- assigns drug identification numbers (DINs)
- applies regulatory requirements for DINs

The Office of Patented Medicines and Liaison within OSIP administers the:

- Patented Medicines (Notice of Compliance) Regulations
- data protection provisions under section C.08.004.1 of the Food and Drug Regulations
- Certificates of Supplementary Protection under the Patent Act

Office of Submissions and Intellectual Property
8th Fl, Room 811A, Jeanne Mance Building
200 Eglantine Driveway
Address Locator 1908A
Ottawa ON K1A 0K9

Telephone: 613-941-7281
Fax: 613-941-0825
Teletypewriter: 1-800-465-7735 (Service Canada)

Email: osip-bppi@hc-sc.gc.ca

Cost recovery (human drug submissions)
Fax: 613-941-0285
Email: cost.recovery@hc-sc.gc.ca

Drug Identification Number Unit
Email: din@hc-sc.gc.ca

Master File Administration Unit
Email: dmf.enquiries-fmm@hc-sc.gc.ca

How to file submissions and applications
Email: ereview@hc-sc.gc.ca

Office of Patented Medicines and Liaison
Email: opml-bmbl@hc-sc.gc.ca