Health Canada Santé Canada

GUIDANCE DOCUMENT

Reconsideration of Decisions Issued for Human Drug Submissions

Published by authority of the
Minister of Health

Adopted Date	2005/11/30
Revised Date	2014/07/08
Administrative Change Date	2014/07/08
Effective Date	2015/04/01

Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by: • Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Également disponible en français sous le titre : Ligne directrice : Révision des décisions sur les présentations de drogues pour usage humain

FOREWORD

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

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

To enable the Department to adequately assess the safety, efficacy or quality of a therapeutic product, Health Canada may request information or define conditions in addition to those described in this guidance. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

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

Document Change Log			
Version	Guidance Document : Reconsideration of Decisions Issued for Human Drug Submissions	**Replaces**	Guidance for Industry: Reconsideration of Final Decisions Issued for Human Drug Submissions
Date	2015/01/01	**Date**	2006/03/01 and 2006/12/11

Change	**Nature of and/or Reason for Change**
Submission and Intellectual Property Division (SIPD) to Office of Submissions and Intellectual Property (OSIP)	Name change of the office.
Regulatory Affairs Directorate to Office of Regulatory Affairs	Name change of the office.
Roles and responsibilities in managing/administering the Reconsideration Process	Requested by Industry.
Removal of option for sponsors to identify potential panel members in Request for Reconsideration	Nominations will be sought in Invitation Letter if External Panel is deemed appropriate.
Change in the Process Map and Performance Targets	To reflect changes made within the Guidance Document.
Changed “final decisions” to “Eligible Decisions”	To properly reflect the reconsideration process. *This change also affects the *Guidance for Industry: Management of Drug Submissions.*
Removal of Summary Basis of Reconsideration Decision (SBRD)	Not the best vehicle for communicating policy changes/revisions and have been infrequently prepared. Health Canada is committed to providing regulatory information under its Openness and

	Transparency Framework and will continue to do so using the most appropriate process.
Removal of Scientific Advisory Committees as a mechanism to review the Request for Reconsideration	Due to infrequency of their meetings.
Re-organizing the Guidance Document	Better flow

TABLE OF CONTENTS

ABBREVIATIONS

BGTD:	Biologics and Genetic Therapies Directorate
DG:	Director General ***or*** his/her delegate
FDALO:	Food and Drugs Act Liaison Office
IAS:	Issue Analysis Summary
NOD/W:	Notice of Deficiency - Withdrawal
NON/W:	Notice of Non-compliance - Withdrawal
Office:	Office of Science (TPD) ***or*** Office of Business Integration and Risk Management (BGTD)
RPMD:	Regulatory Project Management Division (TPD)
RR:	Request for Reconsideration
OSIP:	Office of Submissions and Intellectual Property
ORA:	Office of Regulatory Affairs (BGTD)
TPD:	Therapeutic Products Directorate

1.0 OVERVIEW

When Health Canada issues certain negative decisions related to a human drug submission, the drug sponsor may formally request the Directorate to reconsider its decision. This document provides guidance regarding the formal reconsideration process, including how and when sponsors may request reconsideration, how and when the Directorate will respond, and the process provided to reach a resolution.

2.0 GUIDING PRINCIPLES

Certain guiding principles are inherent in the reconsideration process.

First, the reconsideration is a dispute resolution process designed to ensure that decisions about a specific human drug submission were made correctly and are in keeping with existing scientific and regulatory standards. In this context, it is important to note that:

- The Director General or delegate (DG[1]) of the relevant Health Canada Directorate that reviewed the submission retains the final regulatory authority to render decisions on Requests for Reconsideration. This process provides the DG with further analysis of the issues under reconsideration on which he or she can base the reconsidered decision. The DG also has final authority regarding whether to proceed with reconsideration and whether outside expertise will be required.
- The reconsideration process will not proceed if at any point the sponsor files a Notice of Application to the Federal Court to challenge the decision that is the subject of the reconsideration.
- To avoid a duplication of effort, sponsors are discouraged from refiling a submission while undergoing a reconsideration process for the same submission.

Second, the process is designed to be impartial and to provide additional scrutiny for the decision making process by assigning scientific and regulatory experts to the review who were not involved in the original decision. These individuals may come from inside Health Canada and/or from outside as discussed in Section 5.2.

The reconsideration process re-examines the decision made on information that was included in the original submission. Data which was not available to the review bureau/centre at the time of the original decision will not be considered as part of the reconsideration.

All timelines indicated in this document are in calendar days. For clarity, should any deadline for submitting documents fall on a weekend or a statutory holiday, the deadline will be extended to the next business day.

1 For the purposes of this Guidance, all references to the Director General (DG) includes his or her delegate.

Finally, this reconsideration Guidance applies only to eligible decisions about human drug submissions as noted in Table 1, made by the Therapeutic Products Directorate (TPD) or the Biologics and Genetic Therapies Directorate (BGTD) of Health Canada.

3.0 DECISIONS ELIGIBLE FOR RECONSIDERATION

The sponsor must file a Letter of Intent within 30 days of the original decision. If the sponsor does not file a reconsideration request within this time frame, the Minister's decision will become final on the thirty-first day after the date of the original decision, for the reasons given in the original decision.

Table 1 lists the decisions regarding human drug submissions that are eligible to be reconsidered as per this Guidance ("Eligible Decision"). When a sponsor believes that an error has been made in an Eligible Decision, the sponsor may request reconsideration. Examples of issues that could lead to a reconsideration request include:

- interpretation of submitted scientific data;
- disagreement regarding applied methodology;
- relative weights given to data and its impact on the risk/benefit assessment;
- issues which do not follow Health Canada Guidance Documents where the sponsor has provided science-based rationale for an alternate approach;
- application of Guidance or internal processes.

The decision to grant or refuse a Request for Reconsideration of a decision listed in Table 1 will be communicated by the Food and Drugs Act Liaison Office (FDALO) as discussed in Section 5.2.1.

Table 1: Eligible Decisions for Reconsideration
– Rejection of a Priority Review Request under the Priority Review Policy; – Rejection of a Request for Advance Consideration under the Notice of Compliance with Conditions Policy; – Screening Rejection Letter (SRL) (including New Drug Letter); – Notice of Deficiency - Withdrawal Letter (NOD/W); – Notice of Non-compliance - Withdrawal Letter (NON/W); – Not Satisfactory Notice (NSN); – Notice of Insufficient Information Withdrawal – Notice of Refusal

Reconsideration requests are meant to deal with specific submissions and not complaints about perceived systemic issues.

The following are not eligible for reconsideration:

- decisions based on submissions containing documented falsified information;
- allegations of bias;
- complaints regarding service delivery.

4.0 WHAT ARE THE POSSIBLE OUTCOMES OF A REQUEST FOR RECONSIDERATION?

If a sponsor requests a reconsideration of an eligible decision listed in Table 1, the outcome of the reconsideration process can be to amend the original decision or to uphold it. Amended decisions are returned to the review bureau/centre for implementation, and if appropriate, the review process is re-instated. If the original decision is upheld through the reconsideration process, a reconsideration decision letter is issued and becomes the Minister's final decision. No further action is taken by the Directorate.

In cases where the original negative decision contained a number of major objections, and the sponsor chooses to address only some of them through the reconsideration process, the submission will remain rejected based on the outstanding major objections. As such, if the reconsideration process results in an amendment of some of the major objections, but others remain rejected, the file will not go back into review. The sponsor may re-file making the necessary changes to the submission to address the issues that remain rejected.

The reconsideration process is intended to reduce the need for ongoing conflict resolution through improved communications, understanding and sharing of perspectives between drug sponsors and the Department. It is the final step in the review process and is designed to deal with disagreements in a specific submission. However, while opinions may continue to differ about particular decisions, the reconsideration process will facilitate shared understanding about the scientific and regulatory aspects in the review process to clarify expectations for future submissions.

5.0 THE RECONSIDERATION PROCESS

5.1 Overview of Reconsideration Process

This section of the Guidance provides a brief overview of the process in chronological order.

1. Within 30 days of receipt of an Eligible Decision, the sponsor requests a reconsideration by filing a Letter of Intent[2].

2. FDALO communicates whether the decision is eligible for reconsideration in an Eligibility Letter.

2 A Letter of Intent will not be accepted after 30 days from the date of the original decision as the decision becomes final on the thirty-first day.

3. If eligible, the sponsor submits a full Request for Reconsideration package including relevant background information and rationale within 45 days of the Eligibility Letter.

4. FDALO and the Office of Science (TPD) or the Office of Business Integration and Risk Management (BGTD)[3] assesses whether the Request for Reconsideration includes new data. Reconsideration will only proceed if no new data is included.

5. FDALO and the Office of Science (TPD) or the Office of Business Integration and Risk Management (BGTD) make a recommendation to the DG on the reconsideration process. The two options include convening a Reconsideration Panel of external experts if outside expertise or perspective is required or conducting an Internal Review, assigning staff not previously involved in the review. FDALO sends the sponsor an Invitation Letter confirming the process.

6. In the case of a Reconsideration Panel, the sponsor and review bureau/centre each send a list of nominees for the Panel. FDALO and the Office select one Panel member from each list, as well as make a recommendation for a Chair, aiming to balance the overall expertise required. The DG approves the Panel membership. The sponsor and review bureau/centre also submit proposed questions which are taken into consideration by FDALO and the Office in preparing the questions that will be posed to the Panel. FDALO convenes the meeting, with the DG and the Office present, to give the sponsor and the review bureau/centre an opportunity to put their perspective forward. The Panel makes written recommendations to the DG on each question that was the subject of reconsideration.

7. In the case of an Internal Review, Health Canada staff who had not been involved in the review of the submission are assigned to the reconsideration process. Staff can be drawn from the Office or elsewhere within Health Canada based on the expertise required. The sponsor is given the option to make either (1) a written submission or (2) a written submission and an oral presentation. The presentation is made to the Internal Review staff, the DG and the Office. Internal Review staff will make a written recommendation to the DG.

8. The Office is responsible for preparing an Issue Analysis Summary (IAS) for approval by the DG upon receiving a written report from the Reconsideration Panel or upon completion of the Internal Review process.

9. In cases where a Reconsideration Panel is convened, the entire process should be completed within approximately 140 days of the receipt of the Request for Reconsideration. Where an Internal Review is conducted, the process should take approximately 70 days.

3 Throughout the rest of this Guidance document, "the Office" will be used to refer to the Office of Science (TPD) or the Office of Business Integration and Risk Management (BGTD).

5.2 Detailed Outline of Reconsideration Process

This section of the Guidance provides a detailed description of the reconsideration process. Additional supporting materials can be found in the Appendices which include a diagram of the process in Appendix A; performance targets, in calendar days, for each step in Appendix B; and a template for completing the Request for Reconsideration in Appendix C.

5.2.1 Letter of Intent

Within 30 days of the date of the eligible decision, the sponsor must submit a Letter of Intent which explicitly states their intention to commence the formal reconsideration process.

FDALO will determine whether the decision is eligible for reconsideration, including whether it is among those listed in Table 1 and whether the Letter of Intent was submitted within 30 calendar days of the original decision.

Within 5 days of receiving the Letter of Intent, FDALO will send the sponsor an Eligibility Letter to confirm whether the Request for Reconsideration has been approved or refused with supporting rationale.

5.2.2 Request for Reconsideration

Within 45 days of the date of the Eligibility Letter, the sponsor must submit a formal Request for Reconsideration.

The Request for Reconsideration should be filed using the same format as the original submission and according to the template set out in Appendix C. It should contain the following information:

- a copy of the decision letter for which the Reconsideration is requested;
- statements, in numbered paragraphs, with the sponsor's definition of the issue(s) of dispute, cross-referenced with points in the original decision;
- for each issue identified, rationale for the objection, in numbered paragraphs.

The information should be a brief, high-level summary of the issue(s) in dispute, and should not introduce new issues. If the Request for Reconsideration is not complete, FDALO will contact the sponsor to request the necessary information.

The package must not include data which was not in the submission at the time of the original decision. FDALO and the Office, in consultation with the review bureau/centre, will assess whether it contains new data. Where new data is found, the sponsor will be given the option of withdrawing the request or proceeding without the inclusion of the new data. In the case of withdrawal, the sponsor can choose to re-file a new submission.

FDALO may grant an extension of the time allowed to file the Request for Reconsideration after a positive Letter of Eligibility is issued. Extension requests should be made in writing, and should include a rationale for the request. The rationale will be evaluated and decisions will be made by FDALO on a case-by-case basis.

5.2.3 Decision Regarding Process Path

FDALO and the Office will review the Request for Reconsideration package and will recommend a process to the DG for approval. Within 20 days of receiving the Request for Reconsideration, FDALO will send the sponsor an Invitation Letter indicating the process selected.

Efforts to ensure fairness, impartiality and responsible stewardship of resources will be made when selecting a reconsideration process. The process could involve an Internal Review or Reconsideration Panel, or a combination of the two based on the issues. Factors that could lead to selecting a Reconsideration Panel include:

- internal expertise, not previously involved, is not available for the reconsideration;
- Health Canada determines an external perspective is required.

The decision of a Reconsideration Panel or an Internal Review is not related to the perceived importance of the issues involved. Instead, the choice is related to the *type* of issues under consideration and the availability of expertise within Health Canada. The sponsor may notify FDALO of any objections to the process selected. FDALO will review the concerns and rationale provided.

5.2.4 Review by the Reconsideration Panel

If a Reconsideration Panel is selected, the sponsor and the review bureau/centre will be required to provide nominee(s) within 7 days of the date of the Invitation Letter. It is preferable for each party to nominate more than one member to make allowances for the nominee's availability and interest in participating in the process. Nominees can be rank ordered according to preference. FDALO and the Office will select from each list taking into consideration the rank order, each member's experience, expertise, and/or analytical skills relevant to issues under reconsideration.

FDALO and the Office will recommend the overall membership of the Reconsideration Panel to the DG for final approval as follows[4]:

- one member selected from nominations by the sponsor;
- one member selected from nominations by the relevant Bureau/Centre Director; and

4 A panel will usually consist of three members, but this may increase depending on the issues under reconsideration.

- a Chair recommended by FDALO in consultation with the Office.

5.2.4.1 Eligibility of Panelists

Any person who conducted the review of the submission, or reviewed information related to the submission on behalf of the Directorate or sponsor is *not* eligible to be a member of the Reconsideration Panel. Public statements made by potential panel members about a product, similar products or work for other sponsors, will be reviewed in context of the conflict of interest requirements. To ensure that the nominees can comply with conflict of interest requirements, the sponsor and review bureau/centre must *not* contact the nominees, and must *not* provide them with any material for review. The nominees must not have publicly expressed their views regarding the product or issues in question and must *not* have been involved with the sponsor for the product. The nominees must complete a conflict of interest declaration.

5.2.4.2 Selection of Panelists

FDALO is responsible for coordinating the Reconsideration Panel and managing the process.

FDALO will contact all nominees to determine whether they are interested and available to participate on the Panel. Nominees will be asked to provide current *curriculum vitae* and must satisfy all conflict of interest and security clearance requirements. FDALO will complete the screening process and make recommendations to the DG, who will make the final determination on the Panel membership. Concerns about how conflict of interest guidelines were applied to a nominee should be directed to FDALO, and each situation will be assessed on its individual merits. Upon request, FDALO will endeavor to explain the basis for its screening process. Panel members are contracted by Health Canada and are not volunteers.

5.2.4.3 Submission for the Reconsideration Panel

Within 14 days of the date of the Invitation Letter where a Reconsideration Panel has been selected, sponsors and the review bureau/centre are required to submit proposed questions for the Panel to deliberate.

The questions should solicit advice from the Panel on the issue(s) highlighted in the Request for Reconsideration. They should be formulated in such a way as to draw upon the scientific expertise of the panelists so that they can provide the DG with a response to a scientific issue, and should not be leading in nature (i.e. worded so as to suggest the desired answer). General questions that do not touch on the scientific or regulatory merits of the submission, such as “should a specific product be approved”, will not be accepted.

FDALO, in consultation with the Office, will take into consideration questions provided by the sponsor and review bureau/centre to formulate questions for the Panel. In so doing,

FDALO will attempt to build consensus between the sponsor and the review bureau/centre, but will make the final determination on which questions will be put to the Panel. The final questions will be shared with both parties who may provide minor revisions, if necessary. In addition, FDALO, in consultation with the Office, will ensure the questions and background material provided by the sponsor and review bureau/centre are sent to the Reconsideration Panel with enough time for review and consideration. FDALO will communicate the timeframes and deadlines to the sponsors and review bureau/centre.

A draft copy of presentations to be made during the reconsideration meeting will be required from the sponsor and the review bureau/centre one week prior to the meeting. FDALO will facilitate the exchange of presentations between the review bureau/centre and the sponsor. Based on this exchange, the parties can modify their respective presentations and send a copy of the final presentations two days before the meeting to allow for full disclosure of each party's perspective prior to the Reconsideration meeting.

5.2.4.4 The Reconsideration Panel Meeting

The Reconsideration meeting will be held within 60 days from the date the Panel members have been selected and their availability confirmed. This date is considered firm and both the sponsor and Health Canada representatives are expected to make themselves available.

The sponsor will provide a list in advance of their representatives (up to 6 individuals) expected to participate in the Reconsideration meeting indicating their titles and roles (e.g. 'presenter') as well as whether they will participate via teleconference or in person.

FDALO will open the meeting with brief remarks about the process and hand it over to the Panel Chair to moderate. The sponsor and review bureau/centre will be invited to make formal presentations to the Panel, the DG, and the Office who will also be present. The sponsor and review bureau/centre will both be present during both presentations. The purpose of this meeting is to provide both parties the opportunity to share their perspectives. Each presentation should consist of a brief overview of the salient points of the issue(s) under dispute. The Panel members, DG and Office may ask questions following each party's presentation. If the sponsor or review bureau/centre has clarifying questions for each other, these will be permitted at the discretion of the Panel Chair. (See Appendix D for answers to common questions about the meetings.)

The sponsor will be given the option of presenting first or second. FDALO will create the agenda and allow approximately 45 minutes each for the sponsor and review bureau/centre to complete all of their presentations.

Following the presentations and questions, the DG, sponsor and review bureau/centre will leave the Reconsideration Panel to deliberate on the issues under reconsideration. Office staff will remain with Panel members to provide them with clarification on relevant Regulations and Guidance.

The Chair of the Reconsideration Panel will submit a report to FDALO with recommendations for each question posed. The report is analyzed by the Office who can ask the Panel for clarification on their recommendations. The Office is responsible for preparing an Issue Analysis Summary with recommendations for the DG's approval.

5.2.5 Internal Review and Recommendation by the Office

When an Internal Review is deemed appropriate, the sponsor is given the choice of making a written submission alone, or making a written submission and participating in a meeting or teleconference. Should the sponsor select a meeting or teleconference, it will be chaired by FDALO.

The Office staff or other Health Canada staff not previously involved in the review bureau/centre decision will conduct the Internal Review. If a meeting or teleconference is convened, it is intended to be non-confrontational and will allow the sponsor and review bureau/centre an opportunity to present their position on the issues under reconsideration to Internal Review staff, and the DG, who will also be present. Each party's presentation will be followed by questions from Internal Review staff and/or the DG. If the sponsor or review bureau/centre have clarifying questions for each other, these will be permitted at the discretion of the Chair (See Appendix D for answers to common questions about the meetings.)

There is no requirement for the sponsor or review bureau/centre to propose questions for the Internal Review. The process will address the issues communicated in the original decision for which the sponsor filed a Request for Reconsideration.

Following the Internal Review meeting, the Office may consult with areas of expertise within Health Canada as needed. These steps will be captured and explained in the Issue Analysis Summary prepared by the Office with recommendations for the DG's approval.

Where a reconsideration request requires an external Reconsideration Panel and an Internal Review, FDALO will attempt to schedule both meetings on the same day, where possible.

5.2.6 Decision by the Director General

Following the Internal Review process and/or Reconsideration Panel report, the Office will prepare an Issue Analysis Summary (IAS) that includes a summary of the process, information considered in the analysis, as well as recommendations and details regarding follow-up actions required. This report will be submitted within 14 days of the meeting, for an Internal Review, or receipt of the Panel Report in case of a Reconsideration Panel.

For each issue under dispute, the Office can recommend one of three actions to the DG who will issue a Decision Letter to:

1. Uphold his/her original position which becomes the final decision.
2. Refer back to the review bureau/centre to amend his/her original position and ask that an amended version of the original Decision Letter be issued.
3. Refer the submission back to the review bureau/centre for re-evaluation of the issues under dispute and request that a new Decision Letter be prepared reflecting the outcome of the reconsideration process.

5.2.7 Follow-up Action

Once the DG's decision is issued, FDALO will forward all documents generated through the Reconsideration process to RPMD (TPD)/ORA (BGTD) and the review bureau/centre. It is the responsibility of RPMD/ORA and the review bureau/centre to ensure appropriate follow-up actions are taken.

Specific follow-up actions will depend on the nature of the Reconsideration decision.

If the Reconsideration process results in an amendment of one or more issues, then an amended Decision Letter will be prepared for the DG's signature. If the decision was to refer the submission back to the review bureau/centre for re-evaluation, RPMD/ORA and the review bureau/centre are responsible for ensuring that the appropriate process is followed and the appropriate information is considered in any re-evaluation.

RPMD/ORA will ensure a new target date for completing the review is set and communicated to the sponsor within 14 calendar days of the Reconsideration decision. The new target will be set on a case-by-case basis, depending on such factors as the number of issues involved, the remaining data to be reviewed, the complexity of the issues, etc.

RPMD/ORA and the review bureau/centre will have regard for the Reconsideration decision which may inform future decisions as appropriate. RPMD/ORA and the review bureau/centre will also share recommendations in the Reconsideration decision concerning dispute prevention or early resolution within their respective Directorates. FDALO will also follow-up on systemic issues as these become apparent.

6.0 ROLES AND RESPONSIBILITIES

This section of the Guidance document outlines the roles and responsibilities of each party involved in the Reconsideration process.

Party	Responsibilities with Request for Reconsideration Process
DG (or delegate) Therapeutic Products Directorate (TPD) **DG (or delegate) Biologics and Genetic Therapies Directorate (BGTD)**	• Decides on the process for the disposition of the Request for Reconsideration; • Approves the membership of the Reconsideration Panel; • Attends the Reconsideration Panel and/or Internal Review meeting; • Makes the Reconsideration decision.
The Food and Drugs Act Liaison Office (FDALO)	• Responds to inquiries regarding the Reconsideration process, in consultation with other Health Canada representatives; • Reviews sponsor's Letter of Intent and responds within 5 days with an Eligibility Letter; • Responds to extension requests related to the Reconsideration process; • Coordinates and manages the Internal Review or Reconsideration Panel meeting. **In consultation with the Office of Science (TPD)/Office of Business Integration and Risk Management (BGTD):** • Carries out preliminary review of the issues presented in the Request for Reconsideration to recommend how each issue should be addressed (i.e. Internal Review or Reconsideration Panel); • Recommends membership of Reconsideration Panel to the DG; • Liaises with the sponsor, review bureaux/centres and panel members; • Convenes the Reconsideration meeting; • Consults with other areas of expertise as needed; • Reviews draft questions to synthesize final questions to be posed to the Reconsideration Panel; • Forwards all documents generated during the Reconsideration process to the Regulatory Project Management Division (TPD) or the Office of Regulatory Affairs (BGTD) for action.
Drug Submission Sponsor	• Files a Letter of Intent within 30 days of the date of a negative review bureau/centre decision; • Files a Request for Reconsideration package within 45 calendar days

Party	Responsibilities with Request for Reconsideration Process
	of receiving a positive Eligibility Letter; • Ensures no new data is included in the Request for Reconsideration; • Cross-references the information filed in the original submission (and/or the response to a Screening Deficiency Notice, Notice of Deficiency, or Notice of Non-compliance); • Provides nomination(s) for one member of a Reconsideration Panel, if applicable; • Submits proposed questions and related background information within the required timeframes to Food and Drugs Act Liaison Office (FDALO) to be posed to the Reconsideration Panel; • Makes a presentation to the DG, the Office of Science / Office of Business Integration and Risk Management (referred to as "the Office"), and the Reconsideration Panel.
Office of Science, Therapeutic Products Directorate (TPD) **Office of Business Integration and Risk Management (BGTD)**	• Recommends to the DG an Internal Review, External Panel or combination of both based on the issues; • Prepares an Issue Analysis Summary (IAS) with recommendations for the DG; • Reviews issues presented in the Request for Reconsideration, in the case of an internal review; • Reviews Reconsideration Panel report to ensure that all issues have been clearly addressed, if the request goes to a Reconsideration Panel.
Office of Submissions and Intellectual Property (OSIP)	• Receives Letters of Intent, Requests for Reconsideration and other related information; • Forwards the Letter of Intent and the Request for Reconsideration to FDALO with a copy to the Office, the Regulatory Project Management Division (TPD) or the Office of Regulatory Affairs (BGTD), and the relevant review bureau/centre.
Reconsideration Panel	• Listens impartially to each party's perspective; • Provides written responses to the questions posed.
Regulatory Project Management Division (TPD) **Office of Regulatory Affairs (BGTD)**	• Ensures follow-up actions are taken on each submission after the Reconsideration decision has been made; • Ensures Reconsideration decisions and recommendations for dispute prevention and early resolution are incorporated into the process for future submissions; • Communicates with the sponsor on follow-up actions of the Reconsideration decision, including time-frames.
Review Bureaux (TPD)	• Assists FDALO in reviewing the Request for Reconsideration to

Party	Responsibilities with Request for Reconsideration Process
or Review Centres (BGTD)	ensure it does not contain new data; • Provides nomination(s) for one member of a Reconsideration Panel (if required); • Submits proposed questions and related background within the appropriate timeframes for the Reconsideration Panel (if required); • Ensures a presentation is prepared for the Reconsideration process (if required); • Identifies bureau/centre representatives to present and participate in the Reconsideration meeting; • Communicates with the sponsor within 14 days of the Reconsideration decision the new target date for the submission review (if applicable). • Ensures Reconsideration decisions, and recommendations for dispute prevention and early resolution are incorporated into the process for future submissions.

7.0 INFORMATION FORMATS AND ADDRESS

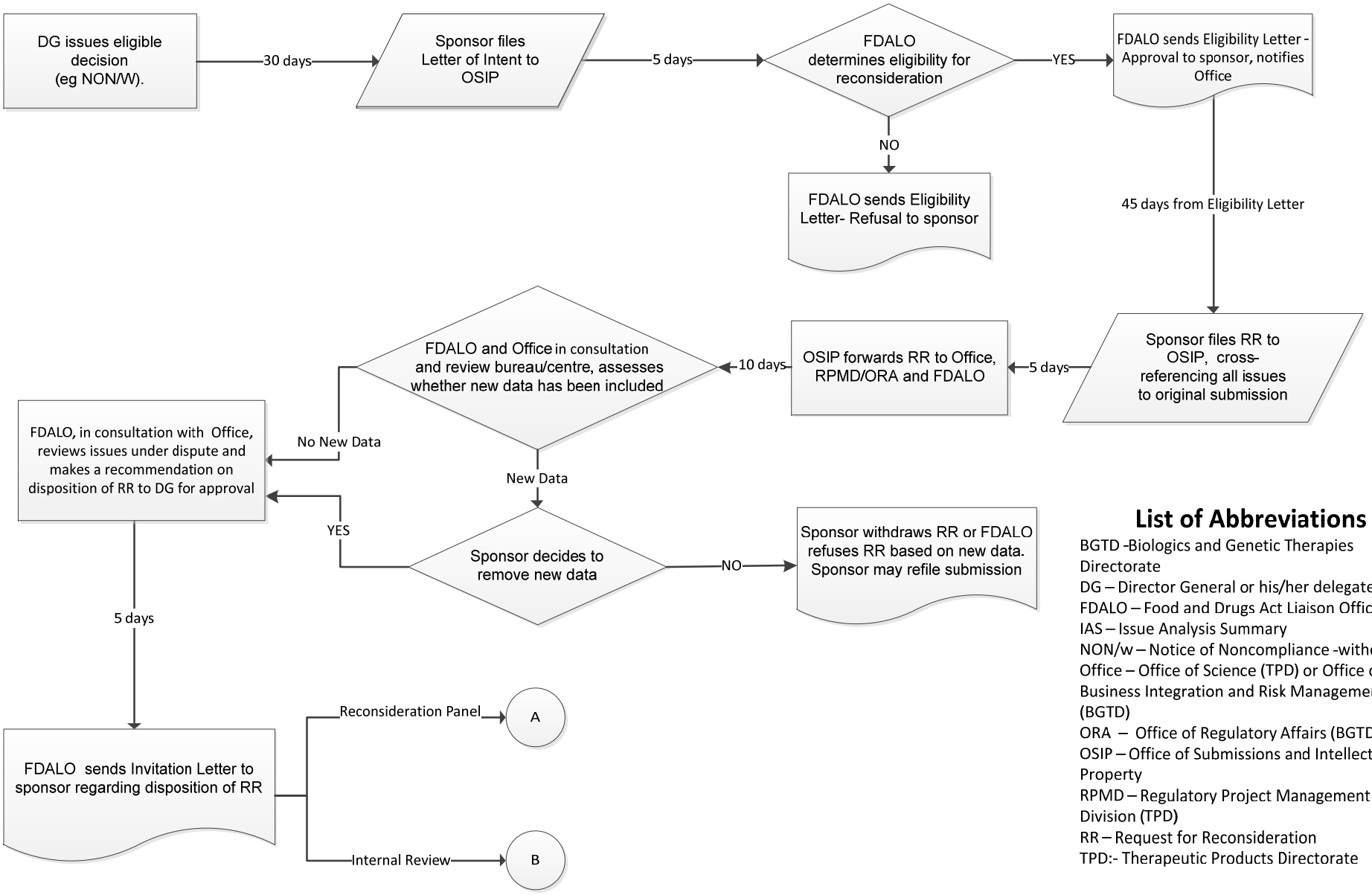
The Letter of Intent, Request for Reconsideration and other information (such as presentations for the meeting, proposed Reconsideration Panel questions, and background material) should be sent electronically via the Common Electronic Submission Gateway (CESG) or via mail with attention to FDALO at:

Attention: Food and Drugs Act Liaison Office (FDALO)
Office of Submissions and Intellectual Property (OSIP)
Therapeutic Products Directorate
Health Canada
Finance Building, Address Locator # 0201A1
101 Tunney's Pasture Driveway
OTTAWA, Ontario
K1A 0K9

Where the original submission was made using the Electronic Common Technical Document (eCTD) format, all Reconsideration documents should be submitted using this format. Sponsors should refer to the latest version of *Guidance Document: Preparation of Drug Regulatory Activities in the Electronic Common Technical Document (eCTD) Format* and the *Guidance Document: Creation of the Canadian Module 1 Backbone*, for preparing submissions in eCTD format.

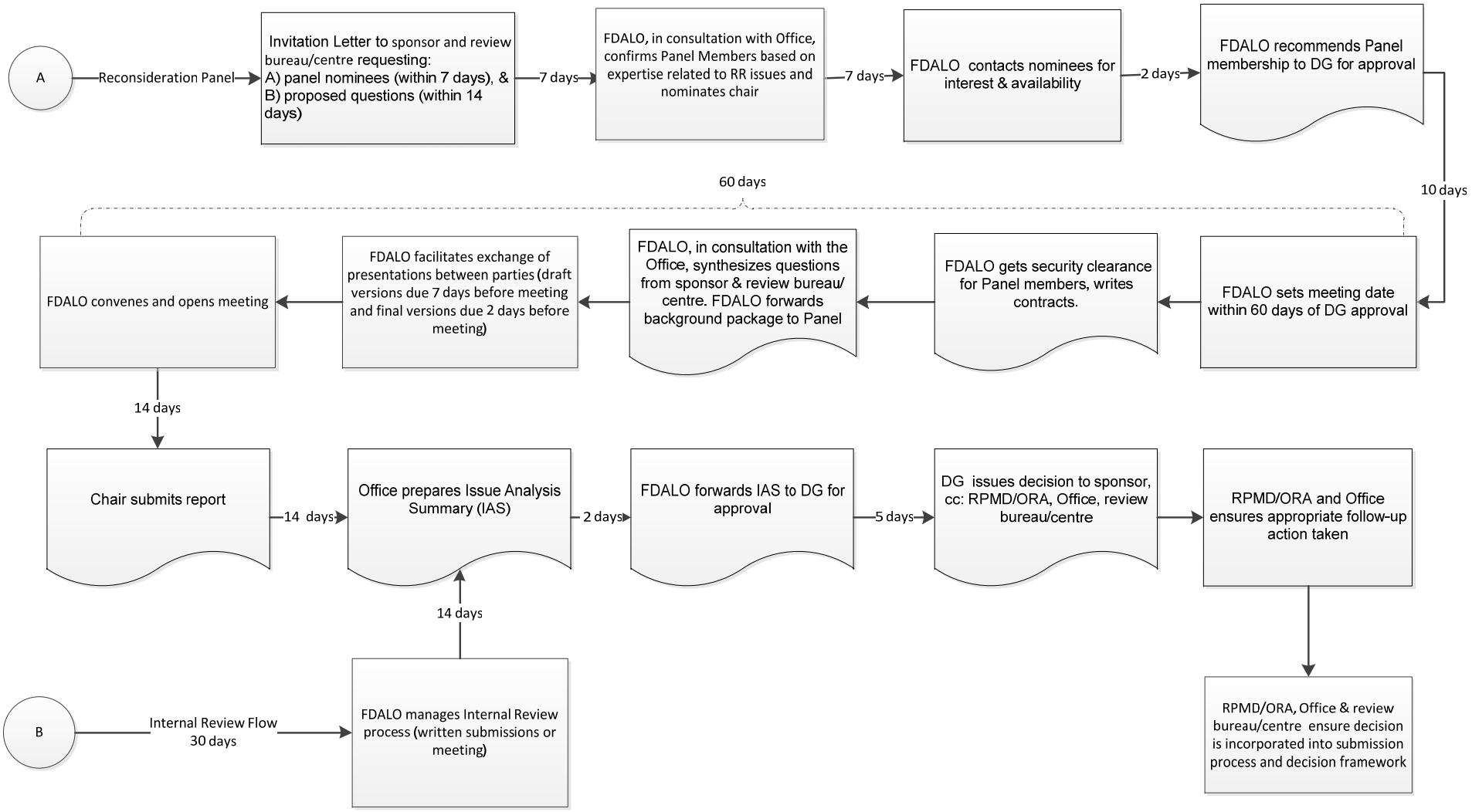
Where the original submission was not made in the eCTD format, Reconsideration documents should be sent electronically in Portable Document Format (PDF). The information should be organized in folders and should be named according to: *"Appendix D: Common Technical Document (CTD) Format"* of the *Guidance Document: Preparation of Drug Regulatory Activities in the Common Technical Document (CTD) Format*.

APPENDIX A: RECONSIDERATION PROCESS MAP



List of Abbreviations

BGTD -Biologics and Genetic Therapies Directorate
DG – Director General or his/her delegate
FDALO – Food and Drugs Act Liaison Office
IAS – Issue Analysis Summary
NON/w – Notice of Noncompliance -withdrawal
Office – Office of Science (TPD) or Office of Business Integration and Risk Management (BGTD)
ORA – Office of Regulatory Affairs (BGTD)
OSIP – Office of Submissions and Intellectual Property
RPMD – Regulatory Project Management Division (TPD)
RR – Request for Reconsideration
TPD:- Therapeutic Products Directorate


A
Reconsideration Panel
Invitation Letter to sponsor and review bureau/centre requesting:
A) panel nominees (within 7 days), &
B) proposed questions (within 14 days)
7 days
FDALO, in consultation with Office, confirms Panel Members based on expertise related to RR issues and nominates chair
7 days
FDALO contacts nominees for interest & availability
2 days
FDALO recommends Panel membership to DG for approval
10 days
60 days
FDALO sets meeting date within 60 days of DG approval
FDALO gets security clearance for Panel members, writes contracts.
FDALO, in consultation with the Office, synthesizes questions from sponsor & review bureau/ centre. FDALO forwards background package to Panel
FDALO facilitates exchange of presentations between parties (draft versions due 7 days before meeting and final versions due 2 days before meeting)
FDALO convenes and opens meeting
14 days
Chair submits report
14 days
Office prepares Issue Analysis Summary (IAS)
2 days
FDALO forwards IAS to DG for approval
5 days
DG issues decision to sponsor, cc: RPMD/ORA, Office, review bureau/centre
RPMD/ORA and Office ensures appropriate follow-up action taken
RPMD/ORA, Office & review bureau/centre ensure decision is incorporated into submission process and decision framework
14 days
FDALO manages Internal Review process (written submissions or meeting)
B
Internal Review Flow
30 days

APPENDIX B: PERFORMANCE TARGETS

This table highlights key steps in the Reconsideration process and is provided for a quick-reference. Full details are contained in the appropriate sections of this Guidance.

Section	Step in Reconsideration Process	Output of Step	Performance Targets/Deadlines[5] (calendar days)
BOTH RECONSIDERATION PANEL & INTERNAL REVIEW PROCESSES			
5.2.1	Sponsor files Letter of Intent.	Letter of Intent filed to OSIP who forwards it to FDALO.	30 (from decision issued by the DG)
5.2.1	FDALO issues Eligibility Letter.	Eligibility Letter issued with rationale. If Reconsideration allowed, Letter of Intent forwarded to Office.	5 (from date of receipt of Letter of Intent)
5.2.2	Sponsor files Request for Reconsideration	Request for Reconsideration filed to OSIP	45 (from the date of the Eligibility Letter)
5.2.2	OSIP processes the Request for Reconsideration	Request for Reconsideration forwarded to Office.	5 (from date of receipt of Request for Reconsideration in OSIP)
5.2.2 5.2.3	FDALO (in consultation with the review bureau/centre) assesses the Request for Reconsideration for new data.	If information is complete with no new data; recommendation made to DG on disposition of the Reconsideration. If the information contains new data, the sponsor is given the option of removing the new data or of withdrawing request.	10 (from date of receiving Request for Reconsideration from OSIP)

[5] For clarity, should any deadline for submitting documents fall on a weekend or a statutory holiday throughout the Reconsideration process, the deadline will be extended to the next business day.

Section	Step in Reconsideration Process	Output of Step	Performance Targets/Deadlines[5] (calendar days)
5.2.3	FDALO sends Invitation Letter to sponsor with decision on the Reconsideration process (Reconsideration Panel and/or Internal Review).	FDALO issues Invitation Letter to sponsor.	5 (from DG decision on Reconsideration process)
RECONSIDERATION PANEL PROCESS			
5.2.4	Sponsor and review bureau/centre submit nominees.	Nominees received.	7 (from date of Invitation Letter)
5.2.4	FDALO, in consultation with the Office, reviews conflict of interest and eligibility of nominees.	Potential panel members identified.	7 (from receiving nominees from sponsor and review bureau/centre)
5.2.4.2	FDALO contacts nominees for interest and availability.	Members are confirmed.	7 (after consulting with the Office)
5.2.4.2	FDALO receives DG approval on Panel membership.	Membership list approved.	2 (from when “draft” membership is completed)
5.2.4.3	Sponsor and review bureau/centre submit proposed questions and background material for Reconsideration.	Questions are submitted to FDALO.	14 (from date of Invitation Letter)
5.2.4.4	FDALO contacts Panel members to determine a meeting date.	Meeting date is set.	10 (from the date of DG approval)
5.2.4.4	FDALO convenes Reconsideration meeting.	Meeting is held with presentations to panel members and DG.	60 (from the date of membership approval)
5.2.4.4	Chair submits report.	Report submitted to the Office.	14 (from the meeting)
5.2.5	Office reviews Panel’s report	Office prepares Issue Analysis Summary and forwards it to FDALO.	14 (from date the report was submitted)

INTERNAL REVIEW PROCESS			
5.2.5	FDALO convenes appropriate Internal Review process and ensures that new staff who have not been involved in original decision is selected in reviewing the information, if applicable.	Internal Review meeting held via written submission or presentations to DG.	30 (from date of Invitation Letter)
5.2.5	Office analyses issue(s) and prepares Issue Analysis Summary (IAS).	IAS forwarded to FDALO.	14 (from the meeting)
BOTH RECONSIDERATION PANEL & INTERNAL REVIEW PROCESSES			
5.2.6	FDALO reviews IAS received from Office.	FDALO forwards IAS to DG.	2 (from the date the IAS is received)
5.2.6	DG makes a decision on the Reconsideration.	Decision letter and IAS are sent to the sponsor.	5 (from receiving the IAS from FDALO)
5.2.7	Follow-up Action.	Review bureau/centre will contact sponsor to communicate new target dates.	14 (from date of Reconsideration Decision by DG)

Note: Every effort will be made to meet this target; however, unforeseen delays can occur as a result of conflict of interest and security clearance requirements, and the need to accommodate schedules of external experts. It is expected that issues referred for Internal Review will be fully addressed within approximately 70 days of the receipt of the Request for Reconsideration from the sponsor. Similarly, for issues referred for review by External Panel, the Reconsideration Process should be completed within approximately 140 days of the receipt of the Request for Reconsideration. Sponsors should make every effort to respect specified timelines or risk having their Request for Reconsideration cancelled by the Directorate.

APPENDIX C: REQUEST FOR RECONSIDERATION TEMPLATE

Health Canada Santé Canada

Request for Reconsideration

SECTION A – ADMINISTRATIVE SECTION	
Brand (Proprietary) Name, or Licence Application/Amendment Subject	
Manufacturer/Sponsor Name	
Contact Person for this Request for Reconsideration	Name: Telephone: Facsimile: E-mail::
Proper, Comment or Non-proprietary Name of Medicinal (Active) Ingredient(s)	
Dosage Form(s)/Strength(s)	
Route(s) of Administration	

SECTION B – SUBMISSION TRACKING IDENTIFIERS			
Submission Type (check one)	□ NDS □ ANDS □ CTA □ APPLICATION for Authorization - □Application for Authorization - Amendment	□ S/NDS □ S/ANDS □ CTA-A	□ NC □ DINA
Control Number			
CR File Number			
Decision for which Request for Reconsideration is filed (check one) ***(attach copy of decision letter)***	□ Screening Rejection Letter (including New Drug Letter) □ Notice of Deficiency – Withdrawal Letter □ Notice of Non-compliance – Withdrawal Letter □ Not Satisfactory Notice □ Notice of Insufficient Information –Withdrawal Letter□ Notice of Refusal □ Rejection of Accelerated Licence Amendment Submission		
Date of issuance of decision for which Request for Reconsideration is filed			

SECTION C – DEFINITION OF ISSUE(S) AND GROUNDS OF DISPUTE

This section should be a brief, high-level summary of the issue(s) in dispute, and should not introduce new issues.

In this section the sponsor should include statements, in numbered paragraphs, with the definition of the issue(s) of contention, linking closely with the points of the original decision (attached). For each issue identified, the grounds of the dispute should be provided in numbered paragraphs. The grounds should be cross-referenced to the information filed in the original submission (and/or the response to a Screening Deficiency Notice, Notice of Deficiency, or Notice of Non-compliance). Issues not contested will remain outstanding at the end of the Reconsideration process and will have to be addressed in a refile.

APPENDIX D: FREQUENTLY ASKED QUESTIONS ABOUT THE RECONSIDERATION MEETING

Is the meeting run in the format of a debate?
No, the meeting is an opportunity to be heard and is intended to provide the sponsor and the review bureau/centre with an opportunity to ensure that the Reconsideration Panel members or Internal Review staff, the DG, and Office staff (if they are not part of the Internal Review) are aware of the salient points of the submission that support their position.

Will the sponsor and the review bureau/centre pose questions to one another?
Following each party's presentation, questions can be posed by the Reconsideration Panel members or Internal Review staff, the DG, and Office staff (if they are not part of the Internal Review). At the Chair's discretion, the sponsor and review bureau/centre may ask clarifying questions of each other. The questions must seek to better understand the other's position, and not to debate the merits of each position.

Will the Sponsor be present during the Bureau/Centre's presentation and will the review bureau/centre be present during the Sponsor's presentation?
Yes, each party will hear the other's presentation.

Which party presents first, the sponsor or the review bureau/centre?
The sponsor may choose their preference regarding order of presentations.

Is there a maximum number of slides that can be presented?
There is no maximum number of slides. However, each party will be given a total of 45 minutes to complete all of its presentations. Questions will follow each 45 minute presentation.