

NOTICE

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Publication of Updates to Guidance Document: Data Protection under C.08.004.1 of the *Food and Drug Regulations*

Health Canada is pleased to announce the publication of updates to sections 2.1 and 3.1 of its guidance document: Data Protection under C.08.004.1 of the *Food and Drug Regulations*.

This guidance outlines the roles and responsibilities of innovative drug manufacturers, subsequent-entry manufacturers and the Therapeutic Products Directorate under the data protection provisions of the *Food and Drug Regulations* which came into force on October 5, 2006. It has been updated to reflect the Therapeutic Product Directorate's administration of the data protection provisions in light of the finalized *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)* published by the Biologics and Genetic Therapies Directorate.

In the course of updating the guidance, the Therapeutic Products Directorate participated in a series of stakeholder consultations regarding subsequent entry biologics, including the *Consultation on the Regulatory Framework for Subsequent Entry Biologics* event held by the Biologics and Genetic Therapies Directorate on June 5-6, 2008. The proposed updates to the guidance document were posted on March 27, 2009 with a 60-day comment period. A summary of the comments is available upon request to the address below.

This guidance document supercedes the previous versions, and all other guidance documents that make reference to data protection.

Questions or concerns related to the guidance document: Data Protection under C.08.004.1 of the *Food and Drug Regulations* should be directed to:

Office of Patented Medicines and Liaison
Therapeutic Products Directorate
Finance Building
101 Tunney's Pasture Driveway
Ottawa, Ontario
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GUIDANCE DOCUMENT

Data Protection under C.08.004.1 of the *Food and Drug Regulations*

Published by authority of the
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Health Products and Food Branch

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Également disponible en français sous le titre : Ligne directrice : La protection des données en vertu de l'article C.08.004.1 du *Règlement sur les aliments et drogues*

FOREWORD

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

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

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

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

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1 INTRODUCTION

1.1 Policy Objectives

In keeping with the North American Free Trade Agreement (NAFTA), articles 1711 (5) and (6), as well as the requirements to protect data under the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) of the World Trade Organization (WTO), Health Canada, through C.08.004.1 of the *Food and Drug Regulations*, will provide for the protection of undisclosed tests or other data necessary to determine the safety and effectiveness of a pharmaceutical product which utilizes new chemical entities. The international agreements require a reasonable period of protection from unfair commercial use of the data.

1.2 Policy Statements

In order to achieve the Policy Objective, Health Canada has amended Part C, Section C.08.004.1 of the *Food and Drug Regulations* to allow the manufacturer of an innovative drug a period of eight years of market exclusivity (extended an additional 6 months when information regarding pediatric use is provided).

1.3 Scope and Application

This guidance document provides information regarding the administration of C.08.004.1 of the *Food and Drug Regulations* which came into force on October 5, 2006. It is applicable only to those drugs that receive a Notice of Compliance (NOC) on or after June 17, 2006 and includes pharmaceutical, biological and radiopharmaceutical drugs that receive NOCs, including relevant products for veterinary use.¹

1.4 Background

In 1995, Health Canada amended the *Food and Drug Regulations* to provide for a regulatory framework for abbreviated new drug submissions. Included in the 1995 amendments was a data protection provision that was triggered upon the examination of any information filed by an innovator manufacturer to obtain approval for its drug, to support the review of a second-entry drug product. Where the Minister relied on the innovator's information, Health Canada would not issue an NOC for the second-entry drug product until five years after the issuance of the NOC to the innovator. In those cases where this would result in a delay in the issuance of the NOC, the Regulatory Impact Analysis statement (RIAS) stated that Health Canada would give the second-entry manufacturer the option of supplying additional information to support its submission without relying on the innovator information. (In most cases, Health Canada does not consult the information in the innovator's drug submission and, therefore, does not rely directly on the innovator's information.) In the view of Health Canada, the provision did not allow for an indirect reliance on the innovator's information. A court challenge to the Minister's

¹ Veterinary biologics do not fall under the *Food and Drug Regulations* and are, therefore, not within the scope of this Guidance.

interpretation of the provision found that the Minister's interpretation was correct. This was upheld in *Bayer Inc. v. Canada (Attorney General)*, 87 C.P.R. (3d) 293 where the court ruled that to trigger the five-year term of data protection required a direct reliance on the innovator's drug submission.

Under the October 5, 2006 data protection provisions, companies introducing a drug containing a new medicinal ingredient not previously approved in a drug by Health Canada and not a variation of a previously approved drug are entitled to an eight-year period of exclusivity. In addition, a second entry manufacturer is prevented from filing a submission for a copy of that innovative drug for the first six years of the eight-year period.

The data protection period may be extended a further six months if, within the first five years of the protection period, the results of pediatric clinical trials, designed and conducted for the purpose of increasing knowledge of the use of the drug in pediatric populations, are also submitted and found acceptable. Extending the term of data protection in this manner is intended to encourage the submission of pediatric research results to provide health benefits to children.

2 INNOVATIVE DRUGS

2.1 Scope of data protection

Innovative drugs, as defined in section C.08.004.1 of the *Food and Drug Regulations*, are entitled to an eight-year term of data protection.

Under the definition of an innovative drug, drugs that contain medicinal ingredients that have been previously approved in Canada, including drugs that have previously received an NOC and/or a Drug Identification Number (DIN), will not be afforded protection under these provisions. An extension of the protection term is not available for drugs that are issued an NOC for a new indication, dosage form or other changes made through a supplement to a new drug submission (S/NDS) with the exception of S/NDSs containing pediatric clinical trial data. See section 4 Pediatric Data Protection - for more information.

“Innovative drug”, by definition, specifically excludes variations of a previously approved medicinal ingredient from the scope of protection. This is to prevent the granting of additional terms of protection where an innovator seeks approval for a minor change to a drug. Examples of minor changes to a drug are salts, esters, solvates, polymorphs or enantiomers. While both solvates and polymorphs are provided as examples, it is recognized that these terms may overlap, such that a solvate may also be considered as a polymorphic form. Other variations not found on the preceding list, such as metabolites or prodrugs, will be assessed on a case-by-case basis. An assessment will be made as to whether or not approval is being sought primarily on the basis of previously submitted clinical data i.e. without the support of new and significant

data. New and significant data is characterized as those clinical trials which provide the evidence to determine the efficacy, properties and conditions of use of the drug (eg. pivotal trials). Drugs containing variants of a medicinal ingredient approved on the basis of comparative studies against prior approved drugs would not be considered innovative. The Office of Patented Medicines and Liaison (OPML) will consult with the relevant review bureau where the significance of the clinical trial(s) is in question.

This is consistent with NAFTA and TRIPS which only require the granting of protection for undisclosed data, the origination of which involved a considerable effort.

Approval for a subsequent entry biologic drug (SEB), as set out in the Health Canada's guidance document entitled *Information and Submission Requirements for Subsequent Entry Biologics (SEBs)* (SEB Guidance), is sought by filing a new drug submission in which the sponsor seeks to reduce the clinical and non-clinical study requirements by demonstrating similarity to a previously approved reference biologic drug. As such, an SEB will not be considered to be an "innovative drug".

2.2 Combination drugs

A combination drug where at least one of the ingredients is an innovative drug for which a data protection term is still in effect, will receive data protection for the innovative drug in the combination until the expiry of the original data protection period of the innovative drug. Combinations of previously approved medicinal ingredients are not eligible for an additional data protection period. The following scenarios of a product-line extension will clarify:

Drug 'A' is an innovative drug that qualifies for an eight-year term of data protection ending January 1, 2017

Drug 'B' is an innovative drug that qualifies for an eight-year term of data protection ending June 1, 2018

Drugs 'C' and 'D' were each previously approved in Canada

Example 1:

A new drug that includes the medicinal ingredients found in Drug 'A' and in Drug 'C' in combination is approved before the expiry of the original term of data protection for Drug 'A'. Data protection for Drug A will also protect the combination until the expiry of the original data protection term for Drug 'A' on January 1, 2017.

Example 2:

A new combination drug containing the medicinal ingredients found in Drugs 'C' and 'D' is approved. However, it will not qualify for data protection.

Example 3:

A new combination drug containing the medicinal ingredient found in Drugs ‘A’ and ‘B’ will qualify for data protection until the expiry of the latest data protection term. In this example, protection would extend to the expiry of the data protection term for Drug ‘B’ on June 1, 2018.

This is intended to prevent the granting of additional terms of protection for new combinations of previously approved medicinal ingredients while still providing protection for combination products containing at least one innovative drug.

2.3 Processes

A manufacturer that believes that its drug qualifies as an innovative drug is requested to communicate such information in one of three ways: (Note that there are no forms or prescribed formats for such communication.)

1. Include such a voluntary statement in the cover letter accompanying the new drug submission and copy the OPML.
2. Submit supporting information in section 1.2.4 – Patent Information in Module 1 of the submission as per the *Guidance for Industry: Preparation of New Drug Submissions in the CTD Format*.
3. Failing step 1 or 2, communicate directly with the OPML by letter drawing attention to the submission.

The OPML will prepare a preliminary assessment, while the submission is under review, to determine if the drug qualifies for data protection. The manufacturer will be notified of the assessment in writing. The result of the assessment will also be entered into the Therapeutic Products Directorate’s (TPD) Drug Submission Tracking System (DSTS) to which the manufacturer has access. Where a dispute arises, a manufacturer will have the opportunity to provide representations in writing within 30 days of the letter on the matter. The OPML will consider the representations before a further assessment is made. Prior to the issuance of the NOC, only a preliminary acceptance can be given as the drug in question must remain the first to be approved with the specific medicinal ingredient. Should there be two manufacturers with products containing the same medicinal ingredient, only the first drug issued an NOC will qualify for the protection.

For combination drugs, where at least one of the drugs is an innovative drug, the manufacturer is requested to include in the submission cover letter a statement that data protection for the innovative drug should also be applicable to the combination. As stated above, information may be placed in section 1.2.4 - Patent Information in Module 1 of the submission.

2.4 Requirement for Marketing in Canada

As per C.08.004.1(5) of the *Food and Drug Regulations*, protection for an innovative drug is only available where the innovative drug has received an NOC and is marketed in Canada. Where the drug is withdrawn by the innovator from the market, no protection will be offered. This is to prevent the situation where the marketed version of a protected innovative drug is withdrawn from the Canadian market by the innovator, but no equivalent generic drug is allowed on the Canadian market until the protection period has expired. The inactivation of a DIN in accordance with C.01.014.6(1)(a) will be accepted as an indication that the drug is no longer being marketed in Canada. The marketing status of the DIN will be confirmed by consulting the Drug Product Database (the DPD). Should questions remain concerning the marketing status of the drug, the manufacturer will be contacted in writing and asked to provide proof of marketing status in Canada within 10 days.

In the case of a DIN newly-issued due to a change in the manufacturer, the data protection will continue to be provided for what remains of the term as long as the new product is marketed by the new manufacturer. The new manufacturer should inform the OPML of the drug's new DIN as soon as possible after the NOC issues for the administrative submission to change the manufacturer's name.

An innovative drug that is re-introduced to the market will receive protection from any subsequent entry submissions for the remainder of the original data protection term.

It is recognized that a drug may not be notified as per C.01.014.3 of the *Food and Drug Regulations* immediately following the issuance of the NOC. Where there is insufficient evidence as to the marketing status of the drug, the innovative manufacturer will be contacted to confirm the status of the drug.

2.5 Register of Innovative Drugs

A Register of Innovative Drugs will be maintained in accordance with Section C.08.004.1(9) of the *Food and Drug Regulations*. This Register is intended to provide a measure of transparency for subsequent manufacturers.

A hard copy of the Register will be available for public viewing during business hours at the following location:

Patent Register Office
Room B-100, Finance Building
101 Tunney's Pasture Driveway
Ottawa, Ontario
K1A 0K9

The Register, updated on a weekly basis, is also posted on the Health Canada Web site at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/regist/reg_innov_dr-eng.php.

Innovative drugs are added to the Register after the issuance of the NOC. Manufacturers should contact the OPML if they have concerns over the listing of a drug.

2.6 Term of Protection

The term of protection will extend for eight years from the issuance of the first NOC for the innovative drug. Where the drug has qualified for the pediatric extension, the term is extended to eight and a half years. See section 4 of this document for information on the six-month pediatric extension.

Within the protection period, a subsequent manufacturer will be prevented from filing its drug submission for the first six years of the eight-year period.

3 SUBMISSIONS COMPARING TO INNOVATIVE DRUGS

3.1 Prevention from filing of a submission on the basis of a direct or indirect comparison with an innovative drug

In accordance with C.08.004.1(3), a subsequent manufacturer seeking an NOC on the basis of a direct or indirect comparison to an innovative drug may file a number of different submissions including an abbreviated new drug submission (ANDS). In that case, the innovative drug is typically the Canadian reference product. However, the provision is also intended to include new drug submissions, including those for subsequent entry biologics, seeking an NOC for a drug on the basis of a comparison to an innovative drug. NDSs which are based on independent clinical trials and where the basis of the submission is not comparative are not captured within the provisions.

Where a manufacturer seeks an NOC on the basis of a direct or indirect comparison with an innovative drug, the manufacturer will not be permitted to file the submission for six years from the date of issuance of the NOC for the innovative drug. The manufacturer will be provided with a preliminary decision by letter informing it of the intent to reject the submission and granting a 30-day period to make representations in response. If, following consideration of the representations, the OPML remains of the view that the submission cannot be filed, then the submission will be returned to the manufacturer at its expense.

As described in the SEB Guidance, approval of an SEB is sought by filing a new drug submission in which the sponsor seeks to reduce the clinical and non-clinical study requirements by demonstrating similarity to a previously approved reference biologic drug. Within the submission, the demonstration of similarity is based on comparative data which may include

analytical testing, biological assays and non-clinical and clinical data. A submission as set out in the SEB Guidance containing a demonstration of similarity to a reference biologic drug will be considered to make a comparison within the meaning of subsection C.08.004.1(3). Such submissions will not be accepted for filing within the six-year period from the date of issuance of the NOC for the reference biologic drug.

An SEB must be subsequent to a biologic drug that is approved in Canada. However, in some cases, a suitable non-Canadian version may be used as a proxy for the Canadian drug in any comparative studies. In such cases, submissions containing demonstrations of similarity with a non-Canadian reference biologic drug are considered to contain a comparison between the SEB and the Canadian drug as contemplated by subsection C.08.004.1(3). These submissions will not be accepted for filing within the six-year period from the date of issuance of the NOC for the Canadian reference biologic drug.

3.2 Prevention from approval

The subsequent manufacturer will not be issued an NOC before the end of the period of eight years after the day on which the first NOC was issued for the innovative drug. The period will be lengthened to eight years and six months where the innovative drug qualifies for the pediatric extension. Once the examination of the submission is complete, the subsequent manufacturer will be notified and an invoice for the review of the submission will be issued. The submission will be placed on “data protection hold” as of that date. If the innovative drug is also listed on the Patent Register, upon expiration of the data protection term the submission will continue on “patent hold” until the requirements of the *Patented Medicines (Notice of Compliance) Regulations (PM(NOC) Regulations)* are met.

3.3 Combination drugs containing one or more innovative drugs

Where a combination consists of an innovative drug and another medicinal ingredient not covered by data protection, a subsequent manufacturer will not be allowed to file or receive an NOC, as the case may be, in respect of the combination until expiry of the original data protection period of the innovative drug. Where two or more innovative drugs are sold in combination, a generic manufacturer will not be allowed to file or receive an NOC, as the case may be, until expiry of the latest data protection term.

3.4 Requirement for marketing of the innovative drug in Canada

As stated in section 2, the protection of an innovative drug is only available where the innovative drug has received an NOC and is marketed in Canada. The marketing status of the innovative drug need only be determined when a subsequent manufacturer seeks to file a submission. Upon receipt of a subsequent manufacturer submission during the protection period, the OPML will confirm the marketing status of the innovative drug. Where there is insufficient evidence of the

marketing status of the drug, the innovative manufacturer may be contacted to confirm the status of the drug. If the OPML determines that the marketing requirement for the innovative drug is not being met, the subsequent manufacturer will be allowed to file its submission. Once a subsequent manufacturer is permitted to file its submission, the submission will proceed and be issued an NOC even if the innovative drug is later marketed and the term of data protection is restored.

3.5 Consent to file a submission

In accordance with C.08.004.1(6) of the *Food and Drug Regulations*, an innovator may consent to the filing of a subsequent manufacturer submission during the protection period. A letter of consent signed by the innovator company must be submitted with the submission of the authorized manufacturer specifically providing authorization to file the submission within the protection period.

3.6 Consent to the issuance of a Notice of Compliance

An innovator may consent to the issuance of the NOC of a subsequent manufacturer submission during the protection period as per C.08.004.1(8) of the *Food and Drug Regulations*. A letter of consent signed by the innovator must be submitted with the submission of the authorized manufacturer or, if provided later, sent directly to the OPML. The innovator may provide consent to both the filing of a submission and the issuance of the NOC in the same letter.

3.7 Exemption under Canada's Access to Medicines Regime

An exemption from the data protection “no file” period has been created to allow a subsequent manufacturer to file a submission under Canada's Access to Medicines Regime under C.08.004.1(7) of the *Food and Drug Regulations*.

Canada's Access to Medicines Regime provides a framework within which eligible countries can import less expensive generic versions of patented drugs and medical devices. For further information, refer to <http://camr-rcam.hc-sc.gc.ca/index-eng.php>. Notwithstanding that a subsequent manufacturer may receive authorization to export a given drug under a compulsory license granted by the Commissioner of Patents, Health Canada will not grant an NOC providing Canadian market authorization unless the requirements for both data protection under section C.08.004.1 of the *Food and Drug Regulations* and the *PM(NOC) Regulations* have been met.

The introduction of the six-year “no-filing” data protection period requires an exception to allow for the filing of drug submissions within the framework of Canada's Access to Medicines Regime. As a result, C.08.004.1(7) provides an exemption where an application is filed pursuant to C.07.003 of the *Food and Drug Regulations*.

For second person submissions filed within the six-year period, for the purposes of the *PM(NOC) Regulations* the date of filing is deemed to be six years after the date of issuance of

the first person's NOC. Please see *Guidance Document: Patented Medicines (Notice of Compliance) Regulations* for details.

4 PEDIATRIC DATA PROTECTION

In addition to the eight-year term of data protection, an additional six-month extension will be applied if an innovator includes, in its new drug submission, or any supplement to that new drug submission filed within the first five years of the eight-year data protection period, results of clinical trials which were designed and conducted with the purpose of increasing knowledge about the use of the drug in pediatric populations and which will lead to a health benefit for children. To qualify, the drug must be an innovative drug and qualify for the eight-year term.

The extension of data protection for submitting the results of pediatric studies is to encourage sponsors to submit trial data pertaining to the use of the drug in pediatric populations. Therefore, it must be clear that the goal of such studies was to increase knowledge about the use of the drug in pediatric populations that will assist health professionals, parents, caregivers and patients in making informed choices about drug therapy. The additional knowledge of the use of these drugs for these populations must be publicly available through additions to the labelling and/or Product Monograph for the drug. Where the clinical studies demonstrate that the drug should not be used in pediatric populations, the addition of contraindications and/or other warning statements in the labelling of the drug may be sufficient to warrant granting of the six-month extension.

This goal of increasing knowledge of the use of the drug in one or more of the pediatric populations should be reflected in the study hypothesis, objectives, design and conduct of the clinical trial. "Clinical trial" is defined in Division 5 of the *Food and Drug Regulations* as "an investigation in respect of the drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug". For the purposes of the six-month extension, the clinical trials must have been conducted in at least one of the three groups set out in the definition of "pediatric populations" in subsection C.08.004.1(1).

Where a manufacturer believes that its submission should qualify for the pediatric extension, it should indicate this on the cover letter accompanying the submission with a copy to the OPML. Failing that, the manufacturer may provide a letter to the OPML drawing attention to the submission in question and the possibility of qualifying for a pediatric extension. As stated in section 2.3 of this guidance, may be placed in section 1.2.4 - Patent Information in Module 1 of the submission.

In accordance with the *Food and Drug Regulations*, the OPML is required to make a

determination before the end of six years after the day on which the first NOC issued that the drug qualifies for the extended period. This decision is independent of the decision to issue an NOC for the submission; rather, the decision requires that the OPML determine that the clinical trials were designed and conducted for the purpose of increasing the knowledge of the use of the drug in pediatric populations and that this increased knowledge would thereby provide a health benefit to children.

Where time permits, the determination will be made concurrently with the review of the submission. However, where time does not permit, the determination will be made ahead of the review of the submission. If the decision is negative, a preliminary decision letter will be sent to the manufacturer and the manufacturer will be given thirty days to make representations. If, after consideration of the representations received, the OPML remains of the position that the submission does not qualify for the protection, the manufacturer will be so informed by letter. If the determination is to extend the data protection period by six months, the Register of Innovative Drugs will reflect the revised date within the six-year period specified in the *Food and Drug Regulations*. Where the pediatric data is submitted by way of an S/NDS and the review of the S/NDS is not complete within the six-year period but a determination is made that the pediatric clinical trial data does qualify for the extension to data protection, the Register of Innovative Drugs will be updated before the completion of the drug submission review. A positive determination as to eligibility for the six-month data protection extension does not preclude the possibility that the S/NDS receives a negative decision (e.g. Notice of Non-compliance).

5 INQUIRIES

The OPML will endeavour to answer general inquiries within 30 days of receipt.

Inquiries regarding a particular listing on the Register of Innovative Drugs should be sent to the OPML at the address below.

The OPML will endeavour to respond to inquiries by providing, whenever possible, information that is in the public domain. Confidential submission information, however, will not be provided.

As discussed in section 2 in this Guidance, a drug is eligible for listing on the Register of Innovative Drugs if it meets the definition of an innovative drug. Protection for the innovative drug applies only where an innovative drug has received an NOC and is marketed in Canada. If the listing is questioned on either of these grounds, the letter of inquiry should provide details. The OPML will confirm to both the originator of the inquiry and the innovative company that the innovative drug's status has been questioned. A copy of the letter of inquiry will be attached to this letter. Therefore, inquiries of this nature cannot be accepted if marked 'confidential'. The OPML will provide the results of the assessment to both parties and will provide 30 days to each

party to make representations. After consideration of any representations received, the OPML will endeavour to make its decision available to both parties within 30 days.

All inquiries should be sent to the OPML at:

Office of Patented Medicines and Liaison
Therapeutic Products Directorate
Health Products and Food Branch
Health Canada
101 Tunney's Pasture Driveway, Address Locator: 0201 A1
Ottawa, Ontario
K1A 0K9

OPML Facsimile: (613) 946-5610
or via email: OPML_BMBL@hc-sc.gc.ca

Sponsors wishing to discuss the suitability of pediatric studies for the pediatric extension to data protection for their innovative drug submission should contact the appropriate review bureau as per the *Guidance for Industry: Management of Drug Submissions*.

APPENDIX 1 - Definitions:

Innovative Drug is a term defined in the regulations as follows:

Pursuant to subsection C.08.004.1 (1) of the *Food and Drug Regulations*, an innovative drug means: “a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, or polymorph”. The term polymorph includes solvates of the drug.

Pediatric Populations is a term defined in the *Food and Drug Regulations* as follows:

Premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age.

Subsequent Manufacturer:

A manufacturer who has filed a submission seeking an notice of compliance on the basis of a direct or indirect comparison between the new drug and an innovative drug.

APPENDIX 2 - Acronyms:

ANDS	Abbreviated New Drug Submission
CAMR	Canada's Access to Medicines Regime
DIN	Drug Identification Number
HPFB	Health Products and Food Branch
NAFTA	North American Free Trade Agreement
NDS	New Drug Submission
OPML	Office of Patented Medicines and Liaison
S/NDS	Supplement to a New Drug Submission
TPD	Therapeutic Products Directorate
TRIPS	Trade Related Aspects of Intellectual Property Rights Agreement
WTO	World Trade Organization