

NOTICE

Our file number: 10-5500-242

Publication of Updates to Guidance Document: *Patented Medicines (Notice of Compliance) Regulations*

Health Canada is pleased to announce the publication of updates to sections 2, 3.4.1 and 3.5.1 of its guidance document: *Patented Medicines (Notice of Compliance) Regulations*.

This guidance document outlines the roles and responsibilities of first persons, second persons and the Therapeutic Products Directorate under the *Patented Medicines (Notice of Compliance) Regulations*. It has been updated to reflect the Therapeutic Products Directorate's administration of the *Patented Medicines (Notice of Compliance) Regulations* 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 all previous versions, and all other guidance documents that make reference to the *Patented Medicines (Notice of Compliance) Regulations*.

Questions or concerns related to the guidance document: *Patented Medicines (Notice of Compliance) 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

Patented Medicines (Notice of Compliance) Regulations

Published by authority of the
Minister of Health

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Health Products and Food Branch

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p style="text-align: right;"><i>Health Canada</i></p>	<p>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:</p> <ul style="list-style-type: none"> • 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. <p style="text-align: right;"><i>Health Products and Food Branch</i></p>
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Également disponible en français sous le titre : Règlement sur les médicaments brevetés (avis de conformité)

FOREWORD

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

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document **may be** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible discovery 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 document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

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

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1 PURPOSE OF THIS DOCUMENT

1.1 Policy Objectives

In accordance with the Regulatory Impact Analysis Statement (“RIAS”) published in *Canada Gazette*, Part II on October 18, 2006,¹ the pharmaceutical patent policy objective is to “balance the effective patent enforcement over new and innovative drugs with the timely entry of their lower priced generic competitors”. The early working exception of section 55.2(1) of the *Patent Act* allows a subsequent manufacturer to use a patented invention for the purpose of seeking regulatory approval of that product. The provision, therefore, provides an exception from infringement. The *Patented Medicines (Notice of Compliance) Regulations* [S.O.R./93-133 as amended] (“*PM(NOC) Regulations*”) provide the balance, through a patent enforcement mechanism, to ensure that the early working exception is not abused and that copy-cat drugs are not sold before relevant patent expiry. Section 4 of this guidance document also makes reference to the amendments to the *Patented Medicines (Notice of Compliance) Regulations* S.O.R./2008-211, that came into force on June 12, 2008, published in *Canada Gazette* Part II on June 25, 2008 (“the June 2008 amendments”).

Under the *PM(NOC) Regulations*, a subsequent manufacturer (typically a generic manufacturer) seeking to copy a patented innovative drug is required to address the patents listed on the Patent Register against that innovative drug. The subsequent manufacturer may either agree to wait for expiry of the patent before receiving its notice of compliance (NOC) or challenge the patent by making an allegation justifying the issuance of the NOC. The allegation may be accepted by the innovator or upheld through a Federal Court decision.

1.2 Scope and Application

This guidance document is not an exhaustive description or explanation of the *PM(NOC) Regulations*. The purpose of this guidance document is to outline the roles and responsibilities of first persons, second persons and the Office of Patented Medicines and Liaison (OPML) in respect of the *PM(NOC) Regulations*.

This document also provides instructions for the completion of Form IV - Patent List and Form V - Declaration re: Patent List. Consistent with section 6 of the transitional provisions of the amendments to the *PM(NOC) Regulations*², this guidance document is not meant to apply to patents on Form IV - Patent List (patent list) submitted to the OPML prior to June 17, 2006. For transitional issues relating to patent lists submitted prior to June 17, 2006, please refer to section 4 of this guidance document entitled “Transition Issues”.

This document does not constitute part of the *PM(NOC) Regulations*. In the event of any inconsistency or conflict, the *PM(NOC) Regulations* take precedence over this guidance document.

¹ Canada Gazette 2006.II.1510.

² S.O.R./2006-242.

2 DEFINITIONS

ALLEGATION: Pursuant to paragraphs 5(1)(b) and 5(2)(b) of the *PM(NOC) Regulations*, an allegation stating that the statement made by the first person under paragraph 4(4)(d) is false, that the patent has expired, that the patent is not valid, or that no claim will be infringed by the second person making, constructing, using or selling the drug for which a drug submission or supplement is filed.

CLAIM FOR THE DOSAGE FORM: A claim for a delivery system for administering a medicinal ingredient in a drug or a formulation of a drug that includes within its scope that medicinal ingredient or formulation.

CLAIM FOR THE FORMULATION: A claim for a substance that is a mixture of medicinal and non-medicinal ingredients in a drug and that is administered to a patient in a particular dosage form.

CLAIM FOR THE MEDICINAL INGREDIENT: Includes a claim in the patent for the medicinal ingredient, whether chemical or biological in nature, when prepared or produced by the methods or processes of manufacture particularly described and claimed in the patent, or by their obvious chemical equivalents, and also includes a claim for different polymorphs of the medicinal ingredient, but does not include different chemical forms of the medicinal ingredient.

CLAIM FOR THE USE OF THE MEDICINAL INGREDIENT: A claim for the use of the medicinal ingredient for the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms.

COURT: The Federal Court or any other superior court of competent jurisdiction.

DATE OF FILING OF THE SUBMISSION OR SUPPLEMENT: Refers to the date allocated to the submission upon receipt by Health Canada provided that the submission is found to be administratively complete (i.e. once all submission criteria and forms required for processing are completed and submitted to Health Canada). In the event that the submission is found to be administratively incomplete, the date of filing will be the date on which these deficiencies are corrected. Therefore, the date of filing may differ from the date of original receipt should the submission be considered administratively incomplete.

DRUG: Includes any substance or mixture of substances manufactured, sold or represented for use in:

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;
- b) restoring, correcting or modifying organic functions in human beings or animals;

- or
- c) disinfection in premises in which food is manufactured, prepared or kept. (Refer to section 2 of the *Food and Drugs Act*.)

EXPIRE: In relation to a patent, expiry, lapse or termination by operation of law.

FILING DATE OF PATENT: The Canadian filing date of a Canadian patent application.

FIRST PERSON: The person referred to in subsection 4(1) of the *PM(NOC) Regulations*.

IDENTIFICATION NUMBER: A number, preceded by the letters “DIN”, that is assigned to a drug in accordance with subsection C.01.014.2(1) of the *Food and Drug Regulations*.

MINISTER: The Minister of Health.

NEW DRUG SUBMISSION: A new drug submission as that term is used in Division 8 of Part C of the *Food and Drug Regulations*, but excluding a new drug submission that is based solely on the change of name of the manufacturer.

NOTICE OF COMPLIANCE: A notice issued under section C.08.004 of the *Food and Drug Regulations*.

PATENT: A granted Canadian patent (not a patent application).

PATENT REGISTER: The register of patents and other information maintained by the Minister in accordance with subsection 3(2) of the *PM(NOC) Regulations*.

PATENT LIST: A list submitted under subsection 4(1) of the *PM(NOC) Regulations*.

PROOF OF SERVICE: Proof that the Notice of Allegation was served on the first person, consisting of a receipt from the courier or registered mail or an affidavit if served by hand.

SECOND PERSON: The person referred to in subsection 5(1) or (2) of the *PM(NOC) Regulations* who files a submission or supplement referred to in those subsections.

SUBSEQUENT ENTRY BIOLOGIC: This term is as defined in Health Canada’s guidance document entitled *Information and Submission Requirements for Subsequent Entry Biologics (SEBs)*.

SUPPLEMENT TO A NEW DRUG SUBMISSION: A supplement to a new drug submission as that term is used in Division 8 of Part C of the *Food and Drug Regulations*, but excluding a supplement to a new drug submission that is based solely on one or more of the matters mentioned in any of paragraphs C.08.003(2)(b) and (d) to (g) and subparagraphs C.08.003(2)(h)(iv) and (v) of those Regulations.

3 ROLES AND RESPONSIBILITIES

3.1 General

Pursuant to sections 3 and 4 of the *PM(NOC) Regulations*, Health Canada is required to maintain a public register of patents and other information submitted by first persons.

The OPML within the Therapeutic Products Directorate (TPD) administers the *PM(NOC) Regulations* on behalf of Health Canada. All drug submissions seeking an NOC, including those submitted to the Biologic and Genetic Therapies Directorate (BGTD) and Veterinary Drugs Directorate (VDD), are assessed to determine if they fall within the scope of the *PM(NOC) Regulations*. The directorates mentioned above are a part of Health Canada's Health Products and Food Branch (HPFB).

The address for the OPML is:

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

Fax: (613) 946-5610

In accordance with subsection 3(6), the official copy of the Patent Register is available for public inspection during business hours in Room B-100 at the same address as the OPML. An electronic version of the Patent Register is also available online on the following Web site: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/patregbrev/index-fra.php>. The electronic version of the Patent Register will normally be refreshed daily.

Any questions, comments or problems with the Patent Register should be directed to: Patent_Register@hc-sc.gc.ca.

3.2 Responsibilities of First Persons

3.2.1 Patent Eligibility

General

The requirements that must be met before a patent can be listed on the Patent Register are provided by section 4 of the *PM(NOC) Regulations*. Section 4 describes (i) the timing of filing of patent lists; (ii) the information that must be provided on a patent list; (iii) the type of drug submissions for which a patent list may be filed; and (iv) more substantive eligibility requirements relating to the claims of the patent. The following sections provide more detailed guidance regarding these requirements and their interpretation by the OPML. **Note:** As indicated above in section 1, “Purpose of this Document”, the following guidance statements are only applicable to patents on patent lists submitted to the OPML on or after June 17, 2006. For transitional issues relating to patent lists submitted prior to June 17, 2006, please refer to section 4 of this guidance document entitled “Transition Issues”.

Timing Requirements

A first person wishing to file a patent list for a particular drug must meet the timing requirements set out in subsections 4(5) and 4(6) of the *PM(NOC) Regulations*. The timing requirements continue to apply during the reconsideration process set out in Health Canada’s guidance document *Reconsideration of Final Decisions Issued for Human Drug Submissions*.

Patent Lists at Time of Filing a Submission

Pursuant to subsection 4(5) of the *PM(NOC) Regulations*, a first person wishing to submit a patent list must do so **at the time it files** the new drug submission or supplement to a new drug submission to which the patent list relates. Only patent lists that accompany the drug submission will be accepted and patent lists submitted separately will be refused as not meeting the timing requirements.

First persons are requested to complete one form per patent per submission per DIN.

Patent Lists After Time of Filing a Submission

Pursuant to subsection 4(6) of the *PM(NOC) Regulations*, a first person may also submit a patent list in respect of a previously filed drug submission provided that the following conditions are met:

- a) *the Canadian filing date of the patent precedes the drug submission filing date; and,*
- b) *the patent list is submitted to the OPML within **thirty days** of the grant of the patent.* In these circumstances, a first person must, in addition to submitting all of the information required under subsection 4(4) (see section 3.2 for more details), identify the submission number (previously referred to as “control number”) to

which the newly granted patent relates. The submission should be identified by the submission number assigned by the TPD. The date of filing of the submission is the date on which the submission was received by the TPD/BGTD/VDD.

With respect to the filing date of the patent referred to above in a), the proper date is that on which the patent application was filed in Canada. The priority filing date(s) of the patent is/are, therefore, not relevant.

Patent List Information Requirements

In accordance with subsection 4(4) of the *PM(NOC) Regulations*, a first person must identify on each patent list the following information:

- the submission(s) to which the patent list relates. **Note:** this information may not be available to first persons for patent lists filed on the date of filing of a drug submission as the submission number for the particular drug submission has not yet been assigned. In these circumstances, the submission number will be inserted on the patent list by the OPML in accordance with subsection 4(8) of the *PM(NOC) Regulations*;
- the medicinal ingredient, brand name, dosage form, strength, route of administration, and use set out in the submission as it appears on the NOC issued in respect of the submission;
- the patent number, the Canadian filing date of the patent application, the date of grant of the patent, and the expiry date of the patent;
- a statement that the first person is the owner of the patent, has an exclusive licence to the patent, or has obtained the consent of the owner of the patent to its inclusion on the list;
- the address in Canada for service for a notice of allegation under paragraph 5(3)(a). **Note:** it is not acceptable to provide a post office (P.O.) box address as registered mail cannot be delivered to such an address; and
- a certification that the information submitted is accurate and that each patent meets the eligibility requirements of subsections 4(2) and (3) of the *PM(NOC) Regulations*.

As provided for under subsection 4(8) of the *PM(NOC) Regulations*, the OPML is required to insert on all patent lists, the date of filing and submission number of the drug submission in relation to which a patent list was submitted.

First persons are requested to submit this information using the patent list attached in Appendix A to this guidance document. Appendix A also contains information on how to complete a patent list.

Drug Submissions Eligible for Filing a Patent List

Pursuant to subsection 4(1) of the *PM(NOC) Regulations*, a patent list may be filed in relation to a new drug submission or supplement to a new drug submission. Both “new drug submission” and “supplement to a new drug submission” are defined in subsection 3(1) of the *PM(NOC) Regulations*. Pursuant to these definitions and to subsections 4(2) and 4(3), only the following clearly defined submission types provide an opportunity to list a patent:

- a new drug submission, except a new drug submission based solely on the change of name of the manufacturer. (See definition of “new drug submission” in subsection 3(1).);
- a supplement to a new drug submission for a change in formulation;
- a supplement to a new drug submission for a change in dosage form;
- a supplement to a new drug submission for a change in use of the medicinal ingredient.

Product Specificity/Relevance Requirements

In addition to the timing, information and submission requirements outlined in the previous sections, section 4 of the *PM(NOC) Regulations* sets out additional product-specificity factors which are to be considered in determining the eligibility of a patent for listing on the Patent Register. These factors may vary depending on whether or not the patent list is submitted in relation to a new drug submission or to a supplement to a new drug submission.

Patent List in Relation to New Drug Submission

In general, a patent will be eligible where it is relevant to the drug which is the subject of the submission against which the patent is to be listed. More precisely, the factors for determining the eligibility of a patent submitted with a drug submission are:

- (i) the patent must contain:
 - a. a claim for the medicinal ingredient;
 - b. a claim for the formulation that contains the medicinal ingredient;
 - c. a claim for the dosage form; and/or
 - d. a claim for the use of the medicinal ingredient as defined in section 2 of the *PM(NOC) Regulations*; and
- (ii) the “medicinal ingredient”, “formulation”, “dosage form”, or “use of the

medicinal ingredient” has been approved through the issuance of an NOC in respect of the drug submission with which the patent is to be listed; and

- (iii) the patent must have been granted and be in good standing.

The following are examples meant to further clarify factors (i) and (ii):

Claim for the medicinal ingredient

As indicated above, “claim for the medicinal ingredient” is defined in section 2 of the *PM(NOC) Regulations*. As specified in the definition, product-by-process patents and patents claiming biological drugs are eligible for listing on the Patent Register provided that all other requirements set out in the *PM(NOC) Regulations* are met. This definition also clarifies that patents claiming different polymorphs of the medicinal ingredient are eligible for listing. As specified in the RIAS accompanying the *PM(NOC) Regulations*, the term “polymorph” is meant to include different crystalline, amorphous, hydrated and solvated forms of the approved medicinal ingredient. The definition specifically excludes from its scope different chemical forms of the medicinal ingredient such as salts and esters.

Patents claiming a combination of medicinal ingredients are not eligible for listing in respect of a drug that contains only one of the claimed medicinal ingredients. However, a patent claiming, as a compound, a single medicinal ingredient will be eligible for listing with respect to a drug that contains the said medicinal ingredient in combination with other medicinal ingredients, notwithstanding that the medicinal ingredient on the NOC is the combination of medicinal ingredients.

A patent claiming an enantiomer is not eligible to be listed in respect of a medicinal ingredient that is a racemate. In addition, a patent that claims varying ratios of enantiomers is not eligible for listing with respect to a racemate of the medicinal ingredient. Similarly, a patent directed specifically to a racemic mixture or a mixture of two enantiomers in varying ratios will not be eligible for listing in relation to a drug containing only one of the enantiomers.

Claim for the formulation that contains the medicinal ingredient

In the case of formulation patents, the *PM(NOC) Regulations* further specify that the claimed formulation must include, as an element, the medicinal ingredient of the drug. This requirement was added to ensure that a patent directed solely to a formulation with no claim to or inclusion of the approved medicinal ingredient is not eligible for listing on the Patent Register. First persons are encouraged to provide page references to relevant portions of the drug submission, or copies of relevant pages, where applicable.

Furthermore, as indicated above, the formulation claimed in the patent must correspond to the formulation approved in the relevant drug submission. In other words, patent A claiming a formulation that includes excipient X would not be eligible for listing against a drug product that does not contain excipient X. Conversely, if patent A claims a formulation that includes excipients X and Y and the drug against which the patent is requested to be listed includes excipients X, Y, and Z, the OPML will consider such patent as being eligible.

Claim for the dosage form

Similarly for dosage form patents, the claimed dosage form must correspond to the dosage form identified on the NOC and approved in the relevant drug submission. This would include novel dosage forms, for example, patents that claim patches, extended release dosage forms, and implants if said dosage forms are identified on the NOC, but would exclude patents claiming objects such as IV bags and stents. In accordance with the definition of “claim for the dosage form” in section 2 of the *PM(NOC) Regulations*, an eligible dosage form patent must include a claim that includes within its scope the approved medicinal ingredient or formulation. As for formulation patents, this requirement was added to ensure that a patent directed solely to a dosage form with no explicit claim to or mention of the approved medicinal ingredient or formulation is not eligible for listing on the Patent Register. First persons are encouraged to provide page references to relevant portions of the drug submission, or copies of relevant pages, where applicable.

Claim for the use of the medicinal ingredient

Consistent with the other types of eligible claims, subsection 4(2) requires that use patents contain a claim for a use of the medicinal ingredient that has been approved through the issuance of an NOC. The OPML will refer to the indication section of the Product Monograph (PM) of the drug to determine whether or not the patent claims an approved use. However, it is not expected that the language in the patent will be reproduced exactly in the PM. First persons are encouraged to provide page references to relevant portions of the drug submission, or copies of relevant pages, where applicable. As PMs do not exist for veterinary products, generally the labelling information and package insert will be used. Patents claiming the use of a combination of medicinal ingredients will generally not be eligible for listing against a drug containing only one component of the combination. An exception to this approach, however, are patents claiming the use of a medicinal ingredient in combination with one or more other medicinal ingredient(s), where said combination use is found in the indication section of the drug’s approved PM. In addition, in order to be eligible, the patent claims must provide for the sequential administration of the medicinal ingredients, i.e. must not be limited to the use of the combination in a single dosage form.

For example, a patent claiming the sequential use of medicinal ingredient A in

combination with medicinal ingredient B for the treatment of X could be listed against a drug solely containing medicinal ingredient A, if the claimed use of the combination is found in the drug's approved PM.

In general, in light of the above, the OPML will not consider the following types of patents as being eligible for listing on the Patent Register:

- a purely process patent;
- a patent for a medical device;
- a patent for an intermediate used in the manufacture of the medicinal ingredient;
- a patent for a metabolite of the medicinal ingredient;
- a patent for an impurity present in the final drug product;
- a patent for a different chemical form of the medicinal ingredient or uses thereof, including salts, esters and other derivatives of the medicinal ingredient.

Patent List in Relation to a Supplement to a New Drug Submission

As previously mentioned above, a new patent may only be submitted for listing against the following three specific types of supplements to a new drug submission:

- a supplement for a change in formulation (this includes a change in strength);
- a supplement for a change in dosage form;
- a supplement for a change in use of the medicinal ingredient.

In addition to this requirement and in keeping with product-specificity requirements, the patent will only be eligible for listing if it contains a claim for the change that is being sought in the supplement to a new drug submission. Therefore, if the supplement to a new drug submission is for a new formulation, dosage form or use, the patent must contain a claim for the new formulation, dosage form or use for it to be eligible for listing. Subsection 4(3) of the *PM(NOC) Regulations* does not allow the listing of patents containing claims solely for the medicinal ingredient (including polymorphic forms).

3.2.2 Carry-Forward Provision

Subsection 4.1(2) of the *PM(NOC) Regulations* is a “carry-forward” provision. Under subsection 4.1(2), a first person who submits a patent list in relation to a new drug submission referred to in subsection 4(2) may, if the list is added to the register, resubmit the same list in relation to a supplement to the new drug submission, but may not submit a new patent list in relation to a supplement except in accordance with subsection 4(3).

On a plain reading, subsection 4.1(2) appears to relate only to the very narrow situation where a patent list that has been added to the Patent Register in respect of a new drug

submission under subsection 4(2) of the amended *PM(NOC) Regulations* is resubmitted in respect of a supplement.

However, as discussed in the RIAS accompanying the October 5, 2006 amendments, in order for a patent to qualify for protection under the *PM(NOC) Regulations*, it must be relevant to the drug product the first person is approved to sell. The amendments entrench the concept of drug product specificity as the key consideration required of the Minister in applying the listing requirements under the *PM(NOC) Regulations*. In turn, the amended language more precisely reflects the intended link between the subject matter of a patent on a patent list and the content of the underlying submission for the NOC in relation to which it is submitted. The OPML is required to give effect to this intent in applying the “carry-forward” provision under subsection 4.1(2).

Therefore, in the narrow circumstances of subsection 4.1(2), a patent on a patent list that has been added to the Patent Register in respect of a new drug submission under subsection 4(2) will be “carried forward” only in respect of a supplement for the same drug product - in most cases, a product with the same identification number (DIN). If the supplement is for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, patents claiming the formulation, dosage form or use of the medicinal ingredient will not be “carried forward” unless they meet the requirements of drug product specificity.

Similarly, a patent on a patent list that has been added to the Patent Register in respect of a supplement under amended subsection 4(3) will be “carried forward” only in respect of a supplement for the same drug product provided that it also meets the requirements of drug product specificity in light of a change in formulation, a change in dosage form or a change in use of the medicinal ingredient.

When submitting a patent list with a supplement for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient, and the patent is already listed on the Patent Register, the OPML recommends that the first person submit such a

patent list under the “carry forward” provision, unless the patent contains a specific claim for the changed formulation, the changed dosage form or the changed use, for which the supplement was submitted.

Under the transitional provisions, patents on patent lists that have been filed in respect of a new drug submission or supplement prior to June 17, 2006 remain subject to the listing requirements as they were prior to that date (ie. prior to the amendments in force on October 5, 2006).

As such, patents already on the Patent Register that have been resubmitted will be “carried forward” in respect of a supplement for the same drug product, provided that

they are properly listed.

In all cases, the OPML will apply the same timing requirements to patents submitted under the “carry-forward” provision as are applied to patents submitted under section 4 of the *PM(NOC) Regulations*.

3.2.3 Timing of Addition of Patent(s) to the Patent Register

As provided for in subsection 3(7) of the *PM(NOC) Regulations*, no patent on a patent list shall be added to the Patent Register until the drug submission against which the patent list was submitted receives an NOC. In addition to this requirement, the OPML will not add any patent until it has completed a patent audit and is satisfied that the patent meets the eligibility requirements set out in section 4, described above. The OPML will endeavour to complete a patent audit of each patent as quickly as possible. The OPML will prioritize patent audits for patents for which an NOC has already issued.

In the case of newly-issued patents: although the *PM(NOC) Regulations* provide first persons with a 30-day time period for submitting a patent list, it is recommended that patent lists be submitted to the OPML as soon as possible to allow for a patent audit before the end of the 30-day period. While it has been recognized that the Minister does not have a duty to make corrections or suggestions or inform first persons of any deficiencies in the content of patent lists, allowing for a period of time for the patent audit may provide an opportunity for first persons to address any deficiencies before the expiry of the 30-day period.

Furthermore, in light of subsection 5(4) of the *PM(NOC) Regulations* (i.e. freezing of the Patent Register in respect of second person’s submissions) and the fact that the OPML will require some time to conduct an audit of newly-issued patents, it is also suggested that first persons include (i.e. as part of the cover letter) with their patent lists for newly-issued patents, a list of eligible patent claims and a description of how such claims correspond to the drug submission against which the patent list is filed. To further expedite the audit, first persons are encouraged to provide page references to relevant portions of the drug submission, or copies of relevant pages, where applicable.

3.2.4 Accuracy of Patent List Information

Pursuant to subsection 4(7), first persons are required to keep the information on their patent lists up-to-date. The update of information, however, does not provide an opportunity to add a new patent. A first person should notify the OPML in writing of any updates to the information included on the patent lists. Examples of an update include a change to the company name or address, patent lapse, or the dedication of the patent to the public interest. The onus is on the first person to ensure that the information on the patent list and the Patent Register is accurate and current. Please note that information is not automatically updated when an NOC is issued for a company name change or merger.

It is in the best interest of the first person to provide the OPML with any information reflecting changes in the listings on the Patent Register. To ensure notification by a second person, the company name and address for service must be current. First persons wishing to update a patent list should forward to the OPML a letter outlining the requested changes. First persons are requested **not** to provide the OPML with new forms. The OPML will not assume any responsibility for errors arising from the failure of the first person to provide up-to-date information.

3.2.5 Time Limits Subsequent to Service of Notice of Allegation

Where a first person is served with a notice of allegation in respect of a listed patent, that first person may apply to the court for an order of prohibition within forty-five (45) days of the date of service of the notice of allegation. Pursuant to subsection 6(3) of the *PM(NOC) Regulations*, if such an application is made, the Minister must be served with proof thereof within the same 45-day period. To avoid the granting of an NOC to a second person upon expiration of the 45-day period, first persons are requested to provide the OPML with a copy of the application within the 45-day period, notwithstanding service on counsel for the Minister. Should this 45-day period lapse, the first person's rights under section 6 of the *PM(NOC) Regulations* expire.

3.2.6 Service of Documents

Service of any documents referred to in the *PM(NOC) Regulations* may be effected either in person or by registered mail. If personally served, the effective date will be the actual date of service. If served by registered mail, the effective date of service shall be five days after mailing.

3.3 Responsibilities of the Office of Patented Medicines and Liaison (OPML) relating to First Persons

3.3.1 Patent List Audit - Determination of Patent Eligibility

Completeness of Information and Timing Requirements

All patent lists received by the OPML will be audited for completeness against the list of required information set out in subsection 4(4) of the *PM(NOC) Regulations*. The OPML will verify all the dates listed on the patent lists, including dates on any attached schedules, to ensure accuracy and compliance with the *PM(NOC) Regulations*. If the

information requirements are not complete or if the information is inaccurate, the OPML will communicate with the first person and request that the information be changed or provided. It should be noted, however, that the Minister does not have a duty to make corrections or suggestions or inform first persons of any deficiencies in the content of patent lists. As indicated above in section 3.2, in the case of newly-issued patents, it is recommended that patent lists be submitted to the OPML as soon as possible to allow for a determination before the end of the 30-day period. Allowing for a period of time for the patent audit may provide an opportunity for first persons to address any information deficiencies before the expiry of the 30-day period.

3.3.2 Drug Submission Eligibility: Product-Specificity and Relevance Requirements

The *PM(NOC) Regulations* and related jurisprudence establish the factors which are to be considered in determining the eligibility of a patent for listing on the Patent Register. The criteria for patent eligibility are summarized in section 3.2 of this document.

To verify that patent eligibility conditions are met, the OPML will review both the patent and its associated drug submission(s) to determine whether the drug submission in relation to which the patent list is filed is one of the acceptable types of drug submissions, and whether the medicinal ingredient, formulation, dosage form or use described in the patent, corresponds to what is approved in the submission.

As permitted in subsection 3(8) of the *PM(NOC) Regulations*, in conducting its assessment of patent eligibility, the OPML may make a request to the Canadian Intellectual Property Office (CIPO) for a recommendation as to the subject matter of the patent and/or the eligibility of the patent. CIPO will also be consulted to verify that a patent is in good standing.

If the OPML initially determines a patent to be ineligible, the OPML will notify the first person, in writing, that the patent has been found ineligible for inclusion on the Patent Register. The first person will then be provided with an opportunity to submit written representations as to the patent's eligibility for listing on the Patent Register. In general, representations must be forwarded to the OPML within 30 calendar days from the date of the initial decision letter. If representations are provided, they will be taken into consideration by the OPML and a final decision as to patent eligibility will subsequently be communicated to the first person.

3.3.3 Acceptability of Faxed Copies

To facilitate the provision of requested information and documentation, the OPML will accept faxed copies of patent lists and related documents. However, original documents should also be provided as soon as possible. Email documents are not acceptable.

3.3.4 Addition of Patents to Register

As provided for in subsection 3(7) of the *PM(NOC) Regulations*, no patent on a patent list shall be added to the Patent Register until the drug submission against which the patent list was submitted receives an NOC. In addition to this requirement, the OPML will not add any patent until it has completed a patent audit and is satisfied that the patent meets the eligibility requirements set out in section 4 and described above. For patent lists submitted at the time of filing of a drug submission and for newly-issued patents submitted for drug submission under review, the OPML will conduct a preliminary patent audit to ensure that the patents listed meet all eligibility requirements. If a patent is preliminarily found to be eligible, the OPML will confirm this fact in writing indicating that the eligibility determination may be changed at the time of final audit of the patent, i.e. at the time of issuance of the NOC. The OPML will conduct a final check of the eligibility of the patent immediately prior to listing on the Patent Register. This final check is to ensure that no significant changes were made to the drug submission during the review process that would affect the patent list, for example, changes to the dosage form, route of administration or strength of the drug. The final patent check will also ensure that the patent remains in good standing and that there have been no changes to the jurisprudence which would effect listing the patent. This check does not delay the issuance of the NOC. Please note that the first person must notify the OPML of any interim changes to patent status (e.g. patent lapsed due to failure to pay maintenance fees, dedication to the public interest, patent declared invalid by the courts) or the patent list (e.g. company name change, brand name change) while the submission is undergoing review.

The OPML will endeavour to complete a patent audit of each patent as quickly as possible. The OPML will also prioritize patent audits for patents for which an NOC has already issued. In the case of newly-issued patents, although the *PM(NOC) Regulations* provide first persons with a 30-day time period for submitting a patent list, it is recommended that patent lists be submitted to the OPML as soon as possible to allow for

a patent audit before the end of the 30-day period. Allowing for a period of time for the patent audit may provide an opportunity for first persons to address any deficiencies before the expiry of the 30-day period.

Furthermore, in light of subsection 5(4) of the *PM(NOC) Regulations* (i.e. freezing of the Patent Register in respect of second person's submissions) and the fact that the OPML will require some time to conduct an audit of newly issued-patents, it is also suggested that first persons include, with their patent lists for newly-issued patents, a list of eligible patent claims and a description of how such claims correspond to the drug submission against which the patent list is filed. To expedite the process, first persons are encouraged to provide page references to the relevant portions of the drug submission, or copies of the relevant pages.

3.3.5 Drug Identification Number (DIN) Cancellation - Deletion of Patent Lists from the Patent Register

Subsection 3(3) of the *PM(NOC) Regulations* applies to drugs for which the identification number (“DIN”) has been cancelled under the *Food and Drug Regulations*. As provided for in subsection 3(3), patents listed against a drug for which the DIN was cancelled shall be deleted from the Patent Register by the OPML ninety (90) days after the DIN was cancelled. An exception to this rule exists for cancellations effected as a result of a change in manufacturer.

Patent lists deleted as a result of a DIN cancellation will be re-listed on the Patent Register upon re-activation of the DIN, i.e. receipt of a DIN Notification Form by the TPD, BGTD or VDD, as required by section C.01.014.3 of the *Food and Drug Regulations*. A first person who submits such a DIN Notification Form should also notify the OPML.

3.3.6 Public Patent Register

When the NOC is issued, the OPML places a copy of the relevant patent list in the public Patent Register. This Patent Register is open for public inspection at the offices of the OPML during business hours. The OPML also maintains a Web-accessible version of the Patent Register at: www.patentregister.ca. The Web site database is refreshed daily. Templates of both the patent list and the Form V- Declaration re: Patent are also available for downloading from the Web site.

3.4 Responsibilities of Second Persons

3.4.1 Scope and Application of Section 5

When a second person files a submission or a supplement to a submission seeking an NOC for a drug and the submission or supplement directly or indirectly compares the drug with, or makes reference to, another drug that has been marketed in Canada by a first person and in respect of which patents have been listed on the Patent Register, the second person must, in the submission or supplement, comply with section 5 of the *PM(NOC) Regulations* in respect of each listed patent.

Note that section 5 features two triggering provisions. Subsection 5(1) applies to second persons who file “a submission for a notice of compliance.” While this terminology includes abbreviated new drug submissions, it is also meant to include other submissions

approved on the basis of a direct or indirect comparison or reference to an innovative drug. For drugs which have been previously issued an NOC, administrative submissions for a change in manufacturer name and/or product name filed pursuant to Health Canada's policy "Changes in Manufacturer's Name and/or Product Name" do not trigger section 5. Since cross-licensees have not previously met the requirements under section 5, these administrative submissions will trigger the application of section 5. Subsection 5(2) applies to a "supplement to a submission referred to in subsection (1)", whenever a second person files a supplement to a submission for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient.

Subsequent Entry Biologics

The language of section 5 of the *PM(NOC) Regulations* is not exclusive to abbreviated new drug submissions. Rather, it is meant to capture submissions approved on the basis of a direct or indirect comparison with, or reference to, another drug.

As described in Health Canada's guidance document entitled *Information and Submission Requirements for Subsequent Entry Biologics (SEBs)* (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.

New drug submissions submitted in accordance with the SEB Guidance that demonstrate similarity with a biologic drug marketed in Canada, and in respect of which there are patents listed on the Patent Register, are considered to make a comparison or reference within the meaning of section 5. Sponsors of such submissions will be required to fulfill the requirements for second persons under the *PM(NOC) Regulations*.

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 with, or reference to, the Canadian drug as contemplated by section 5 of the *PM(NOC) Regulations*.

For supplemental submissions for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient that rely on a demonstration of similarity to the reference biologic drug in order to justify reduced clinical and non-clinical data, section 5 will apply.

3.4.2 "Form V: Declaration Re: Patent List" Must Be Included In the Submission or Supplement

Under subsections 5(1) and 5(2), a second person must, as part of the submission or

supplement for an NOC, provide the OPML with a “Form V: Declaration Re: Patent List” (Form V) for each patent listed on the Patent Register in respect of the first person’s drug. Refer to Appendix A for instructions on how to complete the Form V.

A submission or supplement requiring a Form V will be considered incomplete without one. It will be placed on “Patent-Form V” hold and will not be transmitted to the relevant reviewing bureau/centre until the requisite documentation has been received by the HPFB. A date of filing will only be assigned when all Form Vs have been received. Note that, in accordance with the current Health Canada’s *Guidance for Industry: Management of Drug Submissions*, the screening and review time frames will not begin until the submission is transmitted to the relevant reviewing bureau/centre.

3.4.3 No Early Filing of “Form V: Declaration Re: Patent List” Prior to Filing a Submission or Supplement

Every required Form V must be a part of a drug submission. There is no provision in the *PM(NOC) Regulations* to permit the filing of a Form V prior to the filing of a drug submission or supplement to a submission.

3.4.4 Freezing the Patent Register: Addressing Additions to the Patent Register On or After the Date of Filing of a Second Person’s Submission or Supplement

An NOC will not be issued to a second person until all patents on the Patent Register in respect of the first person’s drug have been addressed in accordance with section 5 of the *PM(NOC) Regulations*.

Under paragraphs 5(4)(a) and (b) of the *PM(NOC) Regulations*, a second person is not required to address any patent listed on the Patent Register in respect of the first person’s drug on or after the date of filing of the second person’s submission. The Patent Register is, in effect, “frozen” in respect of the first person’s patent list as of the date of filing of the second person’s submission.

The date of filing on which the Patent Register is frozen is specific to a second person’s submission or supplement. Subsequent second persons each benefit from the same freezing mechanism as of the date of filing of their respective submissions or supplements with the HPFB.

As noted in the RIAS, and governed by subsection 5(3) of the *PM(NOC) Regulations*, the corollary to this frozen register concept is that a second person will no longer be permitted to serve a notice of allegation on a first person until the date of filing of its submission or supplement.

Second persons who have questions on addressing patents lists submitted prior to June 17, 2006 and the patents were added to the Patent Register in accordance with the June

2008 amendments, see section 4 of this guidance document entitled “Transition Issues”.

3.4.5 Date of Filing

General

Unless otherwise specified by the *PM(NOC) Regulations*, the date of filing refers to the date on which the HPFB receives a submission or supplement, unless that submission or supplement is considered incomplete or invalid. A submission or supplement will be considered incomplete or invalid if, for example, the second person is required to provide information to the HPFB in order to meet the requirements under either the *PM(NOC) Regulations* or the *Food and Drug Regulations*. In such cases, the date of filing will be the date the HPFB receives either the requisite missing information or a new version of the submission or supplement.

An incomplete or invalid submission or supplement will not trigger the freezing mechanism of the Patent Register. A second person will be required to address all patents that are added to the Patent Register before its submission or supplement is considered complete. (See also Health Canada’s *Guidance for Industry: Management of Drug Submissions*.)

If a second person cancels its submission or supplement and subsequently re-files, or the relevant directorate issues a rejection letter (e.g. a screening rejection letter, a notice of non-compliance-withdrawal or a notice of deficiency-withdrawal), the original date of filing is lost and the new date of filing becomes the date on which the submission or supplement is re-filed and considered complete. The Patent Register is frozen in respect of the first person’s drug as of the most recent filing date.

Deemed Date of Filing Under Canada’s Access to Medicines Regime

In cases where a second person has filed a submission or supplement under Canada’s Access to Medicines Regime (CAMR), also known as *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*³, subsection 5(5) of the *Regulations* provides for a deemed date of filing in order to comply with the data protection provisions under section C.08.004.1 of the *Food and Drug Regulations*.

CAMR 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>. Notwithstanding that a second person may receive authorization to export a given drug under a compulsory license granted by the Commissioner of Patents, the HPFB will not grant an NOC providing Canadian market authorization unless the requirements for data protection under section C.08.004.1 of the

³ R.S.C. 2004, c. 23.

Food and Drug Regulations, and the *PM(NOC) Regulations*, have been met.

Subsection C.08.004.1 of the *Food and Drug Regulations* provides for an eight-year term of data protection for innovative drugs with a six-year no filing period within that eight-year term.⁴ The eight-year period may be extended to eight-and-a-half years through a pediatric extension. As a result, there is a six-year period (within the data protection

term) where a second person, seeking to copy an innovative drug, will not be permitted to file a submission. This introduction of the six-year no filing period requires an exception to allow for the filing of drug submissions within the framework of CAMR.

The addition of subsection 5(5) to the *PM(NOC) Regulations* provides this exception. For the purpose of subsection 5(3), which governs the service of a notice of allegation, and subsection 5(4), which governs the freezing of the Patent Register, there is a deemed date of filing for submissions and supplements filed under CAMR, and referred to in paragraph C.07.003(b) of the *Food and Drug Regulations*. That date of filing is deemed to be six years after the date of issuance of the first person's notice of compliance provided that:

- 1) the drug to which the second person makes a comparison or reference is an innovative drug within the meaning of subsection C.08.004.1(1) of the *Food and Drug Regulations*; and
- 2) the date that the submission or supplement is received by the HPFB is less than six years from the day the first NOC was issued in respect of the innovative drug.

The result is that, under section 5(3) of the *PM(NOC) Regulations*, a second person may not serve a notice of allegation before the deemed filing date of its submission or supplement, which is six years after the date of issuance of the first person's NOC.

In addition, under section 5(4), the Patent Register will be frozen in respect of the first person's patent lists six years after the date of issuance of the first person's NOC. Until that time, a first person may continue to add patents to the Patent Register in accordance with the *PM(NOC) Regulations*.

Deemed Date of Filing for Submissions and Supplements Filed Prior to October 5, 2006

Under the transitional provisions⁵, the *PM(NOC) Regulations* apply to a second person

⁴ For more information, refer to the RIAS accompanying the *Regulations Amending the Food and Drug Regulations (Data Protection)*, C. Gaz. 2006.II.1495.

⁵ S.O.R./2006-242, s. 7.

who has filed either a submission or a supplement, as described in subsections 5(1) and 5(2), respectively, prior to October 5, 2006.

The date of filing for each submission or supplement filed prior to that date is deemed to be October 5, 2006. The Patent Register will be frozen as of October 5, 2006 in respect of the first person's patent lists for each second person's submission or supplement.

Certification of Date of Filing

When a second person's submission or supplement is considered complete, the HPFB will issue to the second person a modified acknowledgment letter (the certification) to certify and confirm the date of filing.

This certification must be included, under paragraph 5(3)(c) of the *PM(NOC) Regulations*, in the material served on the first person when a second person makes an allegation under paragraph 5(1)(b) or 5(2)(b).

3.4.6 Statement of Consent from the Patent Owner

A second person who has obtained the consent of the patent owner to the making, constructing, using or selling of the patented drug in Canada should indicate this consent in Part 3.2 of the Form V. A corresponding statement of consent from the patent owner must be submitted with or following the second person's drug submission.

3.4.7 Statement of Acceptance to Await Patent Expiry

Under paragraphs 5(1)(a) and 5(2)(a) of the *PM(NOC) Regulations*, the second person may, with respect to each patent on the Patent Register in respect of the first person's drug, accept that an NOC will not issue until the patent expires. In such a case, the statement of acceptance should be indicated on Part 3.2 of the Form V.

3.4.8 Making an Allegation

Under paragraphs 5(1)(b) and 5(2)(b) of the *PM(NOC) Regulations*, a second person may address a listed patent by alleging that:

- 1) the statement made under section 4(4)(d) of the *PM(NOC) Regulations* that the first person is the owner of the patent or has an exclusive license to the patent or has obtained the consent of the owner of the patent to its inclusion on the list is false;
- 2) the patent has expired;

- 3) the patent is not valid; or
- 4) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.

The second person must indicate the relevant allegations in the submission or supplement on the requisite Form V filed with the HPFB. In addition, the second person must provide to the first person notice of all relevant allegations.

3.4.9 Notice of Allegation

Contents of Notice of Allegation

Under paragraph 5(3)(b) of the *PM(NOC) Regulations*, a notice of allegation must include:

- a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug in respect of which the submission or supplement has been filed; and
- a detailed statement of the legal and factual basis for the allegation.

Timing of Service

Under paragraph 5(3)(a) of the current *PM(NOC) Regulations*, a second person who makes an allegation under paragraphs 5(1)(b) or 5(2)(b) must serve on the first person a notice of allegation relating to the submission or supplement that forms the basis of the allegation, but may not do so before the filing date of the submission or supplement.

The address for service of the first person is located on the patent list that forms the basis of the second person's allegation.

Note that under subsection 9(1) of the *PM(NOC) Regulations*, service of any document referred to in the *PM(NOC) Regulations* must be effected either in person or by registered mail. Service in person is effected on the date of service. Service by registered mail is deemed to be effected on the addressee five days after mailing.

Certification of Date of Filing of Submission or Supplement

Under paragraph 5(3)(c), the second person must also serve a statement certified by the Minister as to the date of filing of the submission or supplement. As outlined in section 3.4.5.4, this statement will be issued by the HPFB to the second person in a modified acknowledgment letter.

Proof of Service

Paragraph 5(3)(d) requires the second person to serve on the OPML proof of service on the first person of the notice of allegation and proof of service of the certification as to the filing date of the second person's submission or supplement.

3.4.10 Retraction of a Notice of Allegation

Under section 5(6), a second person who has served a notice of allegation on a first person must retract that notice of allegation and serve a notice of retraction on the first person within 90 days after either:

- 1) the date on which the Minister notifies the second person under paragraph C.08.004(3)(b) of the *Food and Drug Regulations* that the submission or supplement does not comply with the requirements of section C.08.002, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1; or
- 2) the date of the cancellation by the second person of the submission or supplement to which the allegation relates.

The types of notices requiring a withdrawal of a notice of allegation include, for example, a screening rejection letter, a notice of non-compliance-withdrawal or a notice of deficiency-withdrawal.

In the event that an allegation is retracted by a second person under subsection 5(6), a first person who, in response to the notice of allegation, has applied for an order prohibiting the Minister from issuing an NOC to the second person, must apply without delay for a discontinuance of the proceedings.

3.4.11 Requirement to Produce Portions of a Submission or Supplement During a Prohibition Proceeding

In response to a second person's allegations, a first person may apply to a court for an order prohibiting the Minister from issuing an NOC until after the expiration of the patent that is the subject of those allegations.

Under paragraph 6(7)(a) of the *PM(NOC) Regulations*, a second person may be ordered by the court to produce any portion of the submission or supplement filed for an NOC that is relevant to the disposition of the issues in the prohibition proceeding. In addition, the court may order the production of any changes, as they are made, to the portion during that proceeding.

Under paragraph 6(7)(b), the OPML may be ordered to verify that any portions of the submission or supplement produced by the second person correspond fully to the

information in the original submission or supplement, usually within 30 days of receipt of the productions. In such cases, the second person should produce the relevant documents directly to the first person. The first person will then direct the documents to the attention

of the OPML through counsel for the OPML. To facilitate the verification process, second persons are encouraged to provide good quality copies that are indexed with respect to their location within the original submission or supplement.

3.5 Responsibilities of the Health Products and Food Branch (HPFB) - Re: Submission by a Second Person

Submissions and supplements are received on behalf of the Minister by the HPFB. Further information is provided regarding submissions or supplements submitted to the TPD and BGTD in Health Canada's *Guidance for Industry: Management of Drug Submissions*.

3.5.1 Scope and Application of Section 5

When a second person files a submission or a supplement to a submission for an NOC for a drug and the submission or supplement directly or indirectly compares the drug with, or makes reference to, another drug that has been marketed in Canada by a first person and

in respect of which a patent list has been submitted, the OPML will ensure that the second person has met the requirements of section 5 of the *PM(NOC) Regulations* with respect to each patent listed on the Patent Register in respect of the first person's drug.

Refer to section 3.4 for further information.

Subsequent Entry Biologics

To determine whether or not there has been a comparison with, or reference to, a drug within the meaning of section 5 of the *PM(NOC) Regulations*, the OPML will look for a demonstration of similarity to the chosen 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. Where there is a demonstration of similarity to a reference biologic drug that is marketed in Canada and in respect of which there are patents on the Patent Register, the submission sponsor will be considered to be a second person who must comply with section 5.

As outlined in the SEB Guidance, if the similarity of an SEB to the reference biologic drug cannot be established, reduced clinical and non-clinical data cannot be justified and the product cannot be considered an SEB. The OPML will consult the relevant review bureau if questions arise as to the nature of a new drug submission for a 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 with, or reference to, the Canadian drug as contemplated by section 5 of the *PM(NOC) Regulations*.

For supplemental submissions for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient that rely on a demonstration of similarity to the reference biologic drug in order to justify reduced clinical and non-clinical data, section 5 will apply. The OPML will consult the relevant review bureau if questions arise as to the nature of a supplemental submission for a biologic drug.

See also section 3.4.

3.5.2 Acceptance of Faxed Copies

To facilitate the provision of requested information and documentation, the OPML will accept facsimile copies of Form V and related documents.

3.5.3 Certification of Date of Filing of the Submission or Supplement

When a second person's submission or supplement is considered complete, the HPFB will issue to the second person a modified acknowledgment letter ("the certification") to certify and confirm the date of filing. The certification will be faxed to the second person. It must be included in the material served on a first person, under paragraph 5(3)(c), in the event that the second person makes an allegation under paragraph 5(1)(b) or 5(2)(b).

3.5.4 Proof of Service of Notice of Allegation

When a second person makes an allegation under paragraph 5(1)(b) or 5(2)(b), it must serve on the first person a notice of allegation and a certification as to the filing date of the second person's submission or supplement. Under paragraph 5(3)(d), the second person is also required to serve on the OPML proof of the service on the first person.

Note that, in compliance with subsection 5(3), proof of service must not be included as part of a second person's submission or supplement, since a notice of allegation must be served on a first person on or after the date of filing of the second person's regulatory submission.

3.5.5 Requirement to Produce Portions of Submissions or Supplements

After receiving a notice of allegation, a first person may apply to a court for an order

prohibiting the Minister from issuing an NOC to the second person until after the expiration of the patent that is the subject of the allegation.

In accordance with paragraph 6(7)(b) of the *PM(NOC) Regulations*, the OPML will, when required by the court, verify that the portions of a second person's submission or supplement produced to a first person correspond to the information in the submission filed by the second person. The OPML requires 30 days to complete this verification.

The OPML is required only to verify whether the portions produced by the second person correspond with the relevant submission or supplement on file at the HPFB. The Minister is not required to produce additional documentation, or make any statements or characterizations regarding the nature of the portions produced by the second person.

Information provided to the court is treated confidentially.

3.5.6 Date of Issuance of a Notice of Compliance (NOC) Absent the Regulations

In accordance with paragraph 8(1)(a) of the *PM(NOC) Regulations*, the HPFB may be asked to certify the date on which an NOC would have been issued to a second person in the absence of these *PM(NOC) Regulations*. This date is the date that the submission or supplement was placed on patent hold and on which the NOC would have otherwise been given to the Director General for signature and transmission to the second person. For submissions or supplements received by the HPFB, this date is recorded in the drug submission tracking system and is indicated by letter to the second person.

It is open to the court to decide that a date other than the certified date is more appropriate. For example, under subparagraph 8(1)(a)(i) of the *PM(NOC) Regulations*, the court may assign a later date if the certified date was determined to be earlier than it otherwise would have been by the operation of *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*.

3.5.7 Monitoring of Judicial Applications / Statutory Stays

The OPML will record and monitor all relevant court applications initiated under the *PM(NOC) Regulations*. For those court applications initiated within the time limits established by the *PM(NOC) Regulations*, the HPFB will not issue an NOC to the second person until the earlier of a decision by the court, or the expiry of the statutory stay period as outlined in paragraph 7(1)(e) of the *PM(NOC) Regulations*. The OPML will monitor court proceedings for any extensions of the statutory stay period and will alter the patent hold period appropriately.

3.5.8 Issuance of a Notice of Compliance (NOC) for Administrative or Subsequent Submissions on Patent Hold

Once a cross-referenced submission on patent hold has met the requirements of the *Food and Drug Regulations*, an NOC is considered to be issuable, subject to compliance with the *PM(NOC) Regulations*. An NOC will not be withheld in circumstances where a second person, whose cross-referenced abbreviated new drug submission is on patent hold, has fulfilled all the requirements under the *PM(NOC) Regulations*, notwithstanding the status of the initial second person's submission.

Note, however, that subsequent submissions, such as supplements to an abbreviated new drug submission or notifiable changes, will remain on patent hold until the NOC is issued for the underlying submission.

3.5.9 Issuance of an Notice of Compliance (NOC) in Compliance with a Court Decision

The OPML will ensure that the issuance of any NOC subsequent to a court decision is in accordance with the terms of the Order and Reasons for Order. To ensure full compliance, the OPML may be required to compare the terms of the Order with the submission or supplement filed by the second person.

4 TRANSITION ISSUES

There have been a number of court decisions that have impacted the application of the *PM(NOC) Regulations* as they read prior to October 5, 2006. The following sections outline some of these issues.

PM(NOC) Regulations in light of AstraZeneca Canada Inc. v. Canada (Minister of Health)

The application of section 5, as it read prior to the amendments coming into force on October 5, 2006, has been addressed by the Supreme Court of Canada in *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49, [2006] 2 S.C.R. 560 ("*AstraZeneca*").

While the *AstraZeneca* decision arose from an unusual factual basis, namely the addition of a patent list for a drug that was no longer marketed, it appears that Mr. Justice Binnie, for the court, clarified the law as to which patents must be addressed by a second person under section 5 of the *PM(NOC) Regulations* as they read prior to the amendments in force on October 5, 2006. Mr. Justice Binnie held at paragraph 39, that a "patent-specific analysis" is necessary and went on to determine that a second person "is only required to address the cluster of patents listed against submissions relevant to the NOC that gave rise to the comparator drug."

To adopt a patent-specific analysis, the OPML established an approach to identify which patents must be addressed by a second person under section 5 of the *PM(NOC) Regulations* in respect of an abbreviated new drug submission. In *Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300, 55 C.P.R. (4th) 271, aff'd 2007 FCA 276, Mr. Justice Hughes held that the OPML's

approach is consistent with the reasoning in the *AstraZeneca* decision and the applicable provisions of the *PM(NOC) Regulations* and the *Food and Drug Regulations*. Now, with the benefit of Justice Hughes's analysis, in *Ferring Inc. v. Canada (Minister of Health)*, 2007 FC 300, 55 C.P.R. (4th) 271, aff'd 2007 FCA 276, the OPML will apply the following approach.

In most cases, the date of filing of the generic drug manufacturer's submission will be used to identify the NOCs that have been issued in respect of the comparator drug. The "comparator drug", for the purpose of the *PM(NOC) Regulations*, is the drug relied upon by the generic drug manufacturer in order to make a comparison for the purpose of demonstrating bioequivalence under paragraph C.08.002.1(1)(b) of the *Food and Drug Regulations*, and is the result of submissions that have received an NOC prior to the date of filing of the generic drug manufacturer's submission. All patents added to the Patent Register in respect of the comparator drug must be addressed under subsections 5(1) and 5(2) of the *PM(NOC) Regulations*.

In cases where an NOC has issued to the first person after the date of filing of the generic drug manufacturer's submission, additional consideration may be required in accordance with Justice Binnie's recognition that a second person must address patents listed in respect of an NOC for a subsequently approved use ("a modified product") if it also seeks approval for that use.

Therefore, the OPML will identify those NOCs issued to the first person for the approval of new uses (for example, a new indication or a new dosage and administration regime). If, upon examination of the generic drug manufacturer's submission, it is evident to the OPML that the submission has been amended in order to seek approval for the new uses, all patents added to the Patent Register in respect of submissions giving rise to those NOCs must be addressed pursuant to subsections 5(1) and 5(2) of the *PM(NOC) Regulations*.

A timing analysis remains appropriate in many of these situations. For example, the OPML will consider whether the generic drug manufacturer's submission was placed on patent hold before the issuance of the notice of compliance to the first person. The timing of the patent hold status, and corresponding inactivity of the generic submission, are in most cases indicative that the second person could not have amended its submission to include new uses approved in the first person's drug submission.

In situations where a notice of compliance issues to the first person before the generic drug manufacturer's submission has been placed on patent hold, or when the generic drug manufacturer has amended its submission while on patent hold, the OPML may seek clarification regarding the first person's drug submission. In such cases, the OPML will seek this clarification from the first person. A period of fifteen days will be provided to respond to a request for clarification, in keeping with the TPD's usual timing requirements for Clarification Requests ("Clarifaxes").

In all cases, the first person will be copied on any decision wherein the OPML determines that, in light of *AstraZeneca*, a generic drug manufacturer is not a second person according to the requirements of section 5 of the *PM(NOC) Regulations*.

Note, however, that a generic drug manufacturer is required to rely on the safety information contained in the first person's product monograph. As set out in paragraph C.08.002.1(1)(d) of the *Food and Drug Regulations*, the conditions of use for the new drug must fall within the conditions of use of the Canadian reference product. Therefore, NOCs issued for the addition of new safety information to the product monograph will not be considered. In the view of the

OPML, the reliance on new safety information is not a reference to a "modified product" for the purpose of demonstrating bioequivalence, as contemplated by Justice Binnie, that would trigger section 5 of the *PM(NOC) Regulations*.

If a first person files a patent list pursuant to subsections 4(4) and 4(5) of the *PM(NOC) Regulations*, the date to be relied on for assessing whether the patent must be addressed is the date the NOC issued for the submission against which it is listed.

The date of filing is the date allocated to the submission upon receipt by Health Canada, provided that the submission is found to be administratively complete according to Health Canada's *Guidance for Industry: Management of Drug Submissions*.

Once all the relevant requirements have been met, the Minister shall issue the NOC to the second person under section C.08.004 of the *Food and Drug Regulations* and in accordance with the *PM(NOC) Regulations*.

In addition, the patent-specific analysis, as outlined by Binnie J., will be applied only in respect of the version of the *PM(NOC) Regulations* as set out in the *AstraZeneca* decision. As a result, the OPML will confine the patent-specific analysis, described above, to cases where a generic drug manufacturer's submission was filed pursuant to the *PM(NOC) Regulations* as they read before the amendments came into force on October 5, 2006.

PM(NOC) Regulations, June 2008 amendments [S.O.R. 2008-211]

The purpose of the June 2008 amendments, as stated in the RIAS, is to reinforce the predictability, stability and competitiveness of Canada's intellectual property regime for pharmaceuticals by reaffirming and clarifying that patents eligible for protection under the *PM(NOC) Regulations* as they were prior to October 5, 2006 ("grandfathered" patents) remain so until expiry.

Shortly after the coming into force of the 2006 amendments, the Supreme Court of Canada rendered a decision under the *PM(NOC) Regulations* as they were prior to that time. This decision cast doubt on some of the reasoning that had been employed by lower courts in interpreting the old listing requirements. In a subsequent judgment, the Federal Court of Appeal cited the Supreme Court's decision in reversing its own previous ruling that a patent containing a claim for the medicine in a drug is listed generally against the drug, rather than against the specific submission for an NOC upon which the patent list is based. In circumstances where the submission in question is an supplement to a new drug submission (SNDS), the Court came to

the view that there must be relevance between the invention claimed in the patent and the change to the drug in respect of which the SNDS was filed.

Maintaining the Patent Register

In accordance with subsection 3.1(1) of the *PM(NOC) Regulations*, the OPML will not delete from the Patent Register a patent on a patent list that was submitted before June 17, 2006, unless one of the following exceptions is present:

- (a) the patent has expired;
- (b) the court has, under subsection 60(1) of the *Patent Act*, declared that the patent is invalid or void;
- (c) the identification number assigned is cancelled under paragraph C.01.014(1)(a) of the *Food and Drug Regulations*; or
- (d) the patent is found, under paragraph 6(5)(a) of the *PM(NOC) Regulations*, not to be eligible of inclusion on the register.

Furthermore, in accordance with subsection 3.1(2) of the *PM(NOC) Regulations*, the OPML will not refuse to add to the Patent Register a patent on a patent list that was submitted before June 17, 2006 solely on the basis that the patent was not relevant to the submission for an NOC to which the patent list relates.

It should be noted that these changes are not intended to interfere with, or circumscribe in any way, the Minister's discretion to refuse to add a patent on other unrelated grounds.

Ineligibility pursuant to Court proceedings

Subsection 6(5.1) of the *PM(NOC) Regulations* prevents the court from dismissing an application in whole or in part solely on the basis that a patent submitted on a patent list before June 17, 2006 (a "grandfathered" patent) is not eligible for inclusion on the Patent Register on the ground that the patent is not relevant to the submission for which it is listed. However, subsection 4(8) of the transitional provisions indicates that subsection 6(5.1) does not apply to summary dismissal motions brought by second persons under subsection 6(5) on or before April 26, 2008.

The OPML will continue to remove ineligible patents from the Patent Register subsequent to court orders in accordance with the other provisions of the *PM(NOC) Regulations*.

Transitional Provisions

Eligibility of listing patents on the Patent Register

In accordance with subsections 4(2) and 4(4) of the transitional provisions accompanying the June 2008 amendments, a 30-day period was provided for first persons to request that the Minister add patents that were deleted or refused to be added to the Patent Register solely on the basis that the patent was not relevant to the submission.

The OPML added those patents to the Patent Register within the time requirements provided in subsections 4(3) and 4(5) of the transitional provisions of the June 2008 amendments.

Addressing Patents listed on the Patent Register

In accordance with subsections 4(6) of the transitional provisions of the June 2008 amendments, a second person is not required to comply with subsection 5(1) of the *PM(NOC) Regulations* for patents added to the Patent Register under subsections 4(3) or 4(5) of the transitional provisions, where that patent was added to the Patent Register on or after the filing date of the submission referred to in subsections 5(1).

Likewise, for supplements to submissions under subsection 5(1) of the *PM(NOC) Regulations*, subsection 4(7) of the transitional provisions provides that a second person is not required to comply with subsection 5(2) of the *PM(NOC) Regulations* in respect of patents added to the Patent Register under subsections 4(3) or 4(5) of the transitional provisions, where that patent was added to the Patent Register on or after the filing date of the submission referred to in subsection 5(2).

5 AUDIT AND COMPLAINT MECHANISMS

5.1 On-Going Maintenance of Patent Register by the Office of Patented Medicines and Liaison (OPML)

The OPML will no longer process complaints for patent lists submitted prior to June 17, 2006, on the grounds that the patents are ineligible to be listed on the Patent Register solely on the basis that the patent is not relevant to the submission for an NOC to which the patent relates. The OPML will, however, continue to process complaints for patents submitted prior to June 17, 2006, as outlined in subsection 3.1(1) of the *PM(NOC) Regulations*, when:

- (a) a patent has expired;
- (b) the court has, under subsection 60(1) of the *Patent Act*, declared that the patent is invalid or void;
- (c) the identification number assigned is cancelled under paragraph C.01.014(1)(a) of the *Food and Drug Regulations*; or

(d) the patent is found, under paragraph 6(5)(a) of the *PM(NOC) Regulations*, not to be eligible for inclusion on the register.

The OPML recognizes its responsibility to maintain the Patent Register. However, due to heavy workloads and limited resources allocated to the administration of the *PM(NOC) Regulations*, it is acceptable for interested parties to notify the OPML of any important information concerning the eligibility of a listed patent. Such information could include patent ineligibility, patent expiry, patent dedication, failure to pay maintenance fees, or court decisions relating to the validity of the patent under the *Patent Act*.

If a patent alleged to be improperly listed is identified, either by the OPML or by the complaint of an interested party, the OPML will undertake a re-audit of the patent to determine the eligibility of the listing. Such an investigation will be conducted on the basis of the factors identified in section 3.2. of this guidance document. If the OPML preliminarily determines that the patent appears to be improperly listed, the first person will be notified and provided with 30 calendar days to make written representations to the OPML as to why the patent should not be removed. To ensure transparency of the process, the letter notifying the first person of the OPML's preliminary determination will also include a copy of the complainant's letter. If the OPML determines that the patent was listed properly, the complainant will be notified and, although the first person will not be requested to provide written representations, the first person will be copied on the correspondence and provided with a copy of the complaint. The OPML will not consider complaints if the letter is marked confidential.

Any written representations received from the first person may be forwarded to CIPO for its recommendations. In the absence of representations, or if, after consideration of the first person's representations, the OPML is of the view that the patent is ineligible, the patent will be removed from the Patent Register in respect of the specific product concerned. One week in advance, the first person will be notified of this removal. On the other hand, if after re-audit of the patent, the OPML concludes that the patent is properly listed, a letter will be sent to the complainant and the first person outlining the OPML's position. If, at any time during the complaint process, the complainant files a Notice of Application to the Federal Court to resolve the matter, the OPML will terminate the complaint process.

There may be instances where the patent at issue is the subject of a subsection 6(5) motion in the context of an on-going prohibition proceeding. If the issue to be dealt with by the Court in the subsection 6(5) motion is the same as that raised in the complaint, the OPML will refrain from making a final determination on the eligibility of the patent and will defer to the Court.

APPENDIX A: How to Complete the Form IV -Patent List

PART 1

PLEASE COMPLETE EITHER SECTION A or B AS APPLICABLE.	
A)	PATENT LIST IS BEING FILED WITH SUBMISSION (please check ONE of the following): i) NDS <input type="checkbox"/> or; ii) SNDS - CHANGE IN FORMULATION <input type="checkbox"/> - CHANGE IN DOSAGE FORM <input type="checkbox"/> - CHANGE IN USE <input type="checkbox"/> iii) CARRY FORWARD, IN ACCORDANCE WITH SECTION 4.1(2) <input type="checkbox"/>
B)	NEWLY ISSUED PATENT* FOR LISTING AGAINST PREVIOUSLY FILED SUBMISSION (please identify ONE of the following): i) NDS SUBMISSION No.: _____ or; ii) SNDS - CHANGE IN FORMULATION, SUBMISSION No.: _____ - CHANGE IN DOSAGE FORM, SUBMISSION No.: _____ - CHANGE IN USE, SUBMISSION No.: _____ iii) CARRY FORWARD, IN ACCORDANCE WITH SECTION 4.1(2) _____
* Newly issued patent must be submitted within 30 days of grant in accordance with subsection 4(6).	

There are only two instances when a patent list may be submitted. Fill out only one of the corresponding sections A) or B) accordingly. **Fill out one form, per patent, per submission.**

- A) A patent can be submitted **at the time of filing** of;
- i) a new drug submission (NDS);
 - ii) a supplement to a new drug submission (SNDS) for a change in formulation, dosage form or use;
 - iii) a patent can also be re-submitted with an SNDS and carried forward in accordance with section 4.1(2).

Note: When submitting a patent with an SNDS for a change in formulation, dosage form or use of the medicinal ingredient, and the patent is already listed on the Patent Register for the same product or DIN, the OPML recommends that the first person submit such a patent under the “carry forward” provision, unless the patent contains a specific claim for the changed formulation, dosage form or use, for which the supplement was submitted.

Indicate which type of submission you are submitting your patent(s) with by checking the appropriate box.

B) A patent can be submitted within 30 days of grant **for listing against a previously filed:**

- i) NDS;
- ii) SNDS for a change in formulation, dosage form or use.

If a newly granted patent is submitted with an NDS or SNDS and found eligible for listing on the Patent Register, it can be carried forward in accordance with section 4.1(2) at the same time.

The *PM(NOC) Regulations* require that all patents submitted for listing must be linked with a submission for an NOC. Therefore, the first person **must** provide the submission number. Enter only one submission number per form.

The newly granted patents must have Canadian filing dates that precede the date of filing of the submission. The patent list **must be submitted within thirty (30) calendar days after the patent was granted.**

PART 2

MEDICINAL INGREDIENT(S):	
BRAND NAME:	
HUMAN: <input type="checkbox"/>	or VETERINARY: <input type="checkbox"/>
DOSAGE FORM:	DIN:
ROUTE(S) OF ADMINISTRATION:	
USE(S) OF THE MEDICINAL INGREDIENT(S):	

Medicinal Ingredient(s): Enter the medicinal ingredient (or combination of ingredients) included in the specific drug product for which an NOC has been issued or is being sought. Where possible refer to the NOC for correct medicinal ingredient. No patent may be listed without this information.

Brand Name: Enter the brand name under which the specific drug is (or will) be marketed. If the name has not yet been determined, it may be left blank and will be entered by the OPML when the NOC is issued. In all other cases, the brand name can be changed at the time the NOC is issued, or any time thereafter, if it does not match the brand name on the NOC. The onus is on the first person to keep patent lists up-to-date and this can be done by sending a letter requesting the change.

Dosage Form: Enter the physical form of the product (e.g. tablet, capsule, solution, powder, aerosol). Note: the dosage form must correspond to that listed on the NOC.

DIN: In the case of the first submission for an NOC for a specific product, the DIN will not be

known by the first person. In this case, this field should be left blank. In all other cases, the DIN for the specific product should be provided. Complete one form per DIN. Alternatively, Part 2 of the form can be replicated and submitted as an attachment.

Human or Veterinary: Indicate human or veterinary.

Route(s) of Administration: Examples include: oral, nasal, subcutaneous as per the NOC.

Strength per unit: Examples include: 10 mg, 100 mcg, 0.5mg/10 ml. Refer to the NOC for the correct strength.

Use(s) of the Medicinal Ingredient: Enter the specific indications or uses for the drug for which approval is being (or has been) sought. The indications listed cannot include any uses/indications for which an NOC has not been issued or is not being sought.

PART 3

PATENT NUMBER	CODE *	CANADIAN FILING DATE OF PATENT APPLICATION (yyyy-mm-dd)	DATE GRANTED (yyyy-mm-dd)	EXPIRATION DATE (yyyy-mm-dd)
<p>* CODE: "A" : APPLICANT IS THE OWNER OF THE PATENT "B" : APPLICANT HAS AN EXCLUSIVE LICENSE "C" : APPLICANT HAS OBTAINED THE CONSENT OF THE OWNER OF THE PATENT FOR THE INCLUSION OF THE PATENT ON THE ABOVE PATENT LIST</p>				

Patent Number: Provide the Canadian patent number in question. No U.S. or international patents will be accepted.

Code: The first person must indicate the status of the patent. That is, indicate whether the first person is the owner of the patent, has an exclusive licence or has obtained consent from the owner of the patent to have it included on the patent list in respect of which it is being submitted.

Filing Date of Patent Application: Indicate the Canadian patent application filing date.

Date Granted: Enter the date on which the patent was granted by the Canadian Intellectual Property Office.

Expiration Date: Enter the date on which the patent term will expire. The term of a patent is 20 years from date of filing for patent applications filed after September 30, 1989. For applications filed prior to September 30, 1989, the expiry date is the longer of 17 years from date of grant of the patent or 20 years from the date of filing, in accordance with sections 44 and 45 of the *Patent Act*.

PART 4 PLEASE UPDATE AS REQUIRED

NAME AND ADDRESS FOR SERVICE IN CANADA:
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Name and Address for Service in Canada: Provide the address to which legal documents can be sent. Do not enter a post office (P.O.) box. Foreign applicants must ensure a service address in Canada is provided.

The onus is on the first person to keep this information up-to-date. To do so, submit a letter requesting a change to your address for service or certification information. Filing of a new patent list is not necessary.

APPENDIX B: How to Complete the Form V: Declaration Re: Patent List

PART 1 COMPLETE ONE FORM PER PATENT PER DIN

SUBMISSION PREVIOUSLY FILED: YES _____ NO _____ IF YES, SUBMISSION No.: _____
AMENDMENT TO PREVIOUSLY FILED FORM: YES _____ NO _____

Submission Previously Filed: Yes _____ No _____

If the Form is not linked to a submission (i.e. it did not come in as part of a submission and does not relate to a previously filed submission), it will not be processed.

If Yes, Submission Number (Section 5(1))

The submission number assigned by the TPD should be entered in this space. If the Form is being submitted as part of a new submission, this field should be left blank. It will, in this instance, be completed by the OPML.

PART 2

SECOND PERSON'S PRODUCT	
MEDICINAL INGREDIENT(S):	
BRAND NAME:	DOSAGE FORM:
ROUTE(S) OF ADMINISTRATION:	
HUMAN: <input type="checkbox"/> OR VETERINARY: <input type="checkbox"/>	STRENGTH PER UNIT:
USE(S) OF MEDICINAL INGREDIENT(S):	

Second Person's Product

Medicinal ingredient(s): Enter the medicinal ingredients included in the specific drug product for which an NOC is being sought.

Brand Name: Enter the brand name under which the specific drug product is or will be marketed.

Dosage Form: Provide the physical form of the product (e.g. tablet, capsule, solution, powder).

Route(s) of Administration: Examples include: oral, nasal, subcutaneous.

Human or Veterinary Use: Indicate human or veterinary.

Strength per unit: Examples include: 10 mg, 100 mg, 0.5 mg/10 ml.

Therapeutic Uses/Indications: Enter the specific indications or uses for the drug product for which approval is being sought in the second person's submission.

PART 3

FIRST PERSON'S REFERENCE PRODUCT: Under subsection 5(1) and 5(2) of the <i>Regulations</i> , address each patent listed in respect of the drug to which you directly or indirectly compare, or make reference.	
MEDICINAL INGREDIENT(S):	
BRAND NAME:	DOSAGE FORM:
DIN:	HUMAN: <input type="checkbox"/> OR VETERINARY: <input type="checkbox"/>
ROUTE(S) OF ADMINISTRATION:	STRENGTH PER UNIT:
USE(S) OF MEDICINAL INGREDIENT(S):	
NAME OF MANUFACTURER:	

Part 3 of the form is used to address patents according to section 5(1) and 5(2) of the *PM(NOC) Regulations*.

First Person's Reference Product: Under subsection 5(1) and 5(2) of the *PM(NOC) Regulations*, address all first person's patent(s) listed on the Patent Register in respect of the drug which you directly or indirectly compare with or make reference to. An adequate description of the reference product must be provided so that the OPML can easily ensure that all applicable patents have been addressed.

Medicinal Ingredient: Enter the medicinal ingredients included in the reference product.

Brand Name: Enter the brand name under which the reference product is marketed.

Dosage Form: Enter the physical form of the product (e.g. tablet, capsule, solution, powder).

DIN: The DIN for the specific product should be provided.

Human or Veterinary Use: Indicate human or veterinary.

Route(s) of Administration: Examples include: oral, nasal, subcutaneous.

Strength per unit: Examples include: 10 mg, 100 mg, .5 mg/10 ml.

Therapeutic Use(s)/Indication(s): Enter the specific indications or uses for the reference product.

Name Of Manufacturer: Enter the name of the manufacturer of the reference product.

PART 3.1

PATENT NUMBER	EXPIRATION DATE (yyyy-mm-dd)

Patent Number: Provide the Canadian patent number being addressed.

Expiration Date: Indicate the expiration date of the patent being addressed.

PART 3.2 CHECK THE FOLLOWING AS APPROPRIATE:

	The Second Person has obtained consent from the patent owner to the making, constructing, using or selling of the drug in Canada.
	The Second Person accepts that the Notice of Compliance will not issue until the patent expires.
The Second Person alleges that:	
	the statement made by the First Person pursuant to paragraph 4(4)(d) is false;
	the patent has expired;
	the patent is not valid;
	no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.
NOTE: IF YOU HAVE CHECKED ANY OF THE ALLEGATIONS ABOVE, YOU ARE REQUIRED TO COMPLY WITH SUBSECTION 5(3) OF THE REGULATIONS.	

In this section, the second person must indicate to the OPML which course of action the second person wishes to take in respect of the patent being addressed. The second person may choose one of the following:

- a) **The second person has obtained consent from the patent owner to the making, constructing, using or selling of the drug in Canada.** A statement of consent from the first person should be found in the submission.
- b) **The second person accepts that the NOC will not be issued until the declared expiration date for the above patent number.** This box should be checked if the second person does not wish to challenge the patent.
- c) **The statement made by the first person pursuant to paragraph 4(4)(d) is false.** This box should be checked if the second person wishes to allege that the first person is neither the owner of the patent nor has an exclusive licence nor has obtained the consent of the owner of the patent to have the patent included on the patent list.
- d) **The patent is not valid.** This box should be checked if the second person wishes to allege that the patent is not valid (i.e. with respect to its novelty, obviousness or utility).

- e) **No claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.** This box should be checked if the second person wishes to allege that the making, constructing, using or selling of the second person's medicine would not infringe the patent being addressed.

PART 4

CERTIFICATION: <i>I certify that the information included in this Declaration is accurate and relevant to the Patented Medicines (Notice of Compliance) Regulations.</i>		
NAME:	TITLE:	
ADDRESS:		
NAME OF MANUFACTURER:		
SIGNATURE:		DATE:
CONTACT:	PHONE #:	FAX#:

Name: Provide the name of an officer with the authority to make such a certification on behalf of the company or entity making the submission.

Title: Enter the title of the officer making the certification.

Address: Include the address at which the officer of the company or entity is located for purposes of the business of the company or entity.

Name of Manufacturer: Enter the name of the company or entity making the submission.

Contact, Phone Number, Fax Number: The name of a person, with phone and fax number, whom we may contact regarding the form. This information will be used to contact the company regarding any problems with the forms. If no contact information is provided, we will contact the company at the address above.

PART 5

FOR OFFICE USE ONLY:	
SUBMISSION No.:	FILING DATE:

NOTES:

Part 5: This section is for office use only.