(SOR/DORS)

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1)[a] of the *Food and Drugs Act*, hereby makes the annexed *Natural Health Products Regulations*.

[a] S.C. 1999, c. 33, s. 347

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(SOR/DORS)

NATURAL HEALTH PRODUCTS REGULATIONS

INTERPRETATION

1. (1) The following definitions apply in these Regulations.

"Act" means the *Food and Drugs Act*. (*Loi*)

"adverse reaction" means a noxious and unintended response to a natural health product that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function. (*réaction indésirable*)

"brand name" means a name in English or French, whether or not it includes the name of a manufacturer, corporation, partnership or individual

(*a*) that is used to distinguish the natural health product; and

(*b*) under which a natural health product is sold or advertised. (*marque nominative*)

"case report" means a detailed record of all relevant data associated with the use of a natural health product in a subject. (*fiche d'observation*)

"Compendium" means the *Compendium of Monographs* published by the Department of Health and as amended from time to time. (*Compendium*)

"distributor" means a person who sells a natural health product to another person for the purpose of further sale by that other person. (*distributeur*)

"expiry date" means the earlier of

(*a*) the date, expressed at minimum as a year and month, up to and including which a natural health product maintains its purity and physical characteristics and its medicinal ingredients maintain their quantity per dosage unit and their potency, and

(*b*) the date, expressed at minimum as a year and month, after which the manufacturer recommends that the natural health product should not be used. (*date limite d'utilisation*)

"immediate container" means the container that is in direct contact with a natural health product. (*contenant immédiat*)

"importer" means a person who imports a natural health product into Canada for the purpose of sale. (*importateur*)

"inner label" means the label on or affixed to an immediate container of a natural health product. (*étiquette intérieure*)

"lot number" means any combination of letters, figures, or both, by which a natural health product can be traced in manufacture and identified in distribution. (*numéro de lot*)

"manufacturer" means a person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds a natural health product for the purpose of sale to that patient. (*fabricant*)

"natural health product" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is 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 humans;

(*b*) restoring or correcting organic functions in humans; or

(*c*) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2. (*produit de santé naturel*)

"outer label" means the label on or affixed to the outside of a package of a natural health product. (*étiquette extérieure*)

"principal display panel" has the same meaning as in the *Consumer Packaging and Labelling Regulations*. (*espace principal*)

"probiotic" means a monoculture or mixed-culture of live micro-organisms that benefit the microbiota indigenous to humans. (*probiotique*)

"proper name" means, in respect of an ingredient of a natural health product, one of the following:

(*a*) if the ingredient is a vitamin, the name for that vitamin set out in item 3 of Schedule 1;

(*b*) if the ingredient is a plant or a plant material, an alga, a bacterium, a fungus, a non-human animal material or a probiotic, the Latin nomenclature of its genus and, if any, its specific epithet; and

(*c*) if the ingredient is other than one described in paragraphs (*a*) or (*b*), the chemical name of the ingredient. (*nom propre*)

"recommended conditions of use" means, in respect of a natural health product,

(*a*) its recommended use or purpose;

(*b*) its dosage form;

(*c*) its recommended route of administration;

(*d*) its recommended dose;

(*e*) its recommended duration of use, if any; and

(*f*) its risk information, including any cautions, warnings, contra-indications or known adverse reactions associated with its use. (*conditions d'utilisation recommandées*)

"security package" means a package having a security feature that provides reasonable assurance to consumers that the package has not been opened prior to purchase. (*emballage de sécurité*)

"serious adverse reaction" means a noxious and unintended response to a natural health product that occurs at any dose and that requires in-patient hospitalization or a prolongation of existing hospitalization, that causes congenital malformation, that results in persistent or significant disability atelhe bilion, thiults

"specifications" means a description of a natural health product that contains the information described in subsection 44(2). (*spécifications*)

(2) Subject to subsection (3), the words and expressions used in the provisions of the *Food and Drug Regulations* that are incorporated by reference by these Regulations shall have the meanings assigned to them by these Regulations, but if no meanings are assigned, they shall have any meaning assigned to them by the *Food and Drug Regulations*.

(3) The word "manufacturer" in the provisions of the *Food and Drug Regulations* that are incorporated by reference by these Regulations shall have the meaning assigned to it by the *Food and Drug Regulations*.

APPLICATION

2. (1) These Regulations apply to

(*a*) the sale of natural health products;

(*b*) the manufacture, packaging, labelling and importation for sale of natural health products;

(*c*) the distribution of natural health products; and

(*d*) the storage of natural health products for the purposes of any of the activities referred to in paragraphs (*b*) and (*c*).

(2) For the purposes of these Regulations, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the *Food and Drug Regulations*, is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of those Regulations.

3. Except where otherwise indicated in these Regulations, the provisions of the *Food and Drug Regulations* do not apply to natural health products.

PART 1

PRODUCT LICENCES

Prohibition

4. (1) Subject to subsections (2) and (3), no person shall sell a natural health product unless a product licence is issued in respect of the natural health product.(2) No product licence holder, manufacturer, importer or distributor of a natural health product for which a product licence is issued shall sell the natural health product during any period that the sale of that natural health product is directed to be stopped under section 17.

(3) No person shall sell a natural health product for which a product licence is issued

(*a*) during the period of any suspension of the licence under section 18 or 19; or

(*b*) after cancellation of the licence under paragraph 20(*b*).

Licence Application

5. An application for a product licence shall be submitted to the Minister and shall contain the following information and documents:

(*a*) the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant;

(*b*) if the address submitted under paragraph (*a*) is not a Canadian address, the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant's representative in Canada to whom notices may be sent;

(*c*) for each medicinal ingredient of the natural health product,

(i) its proper name and its common name,

(ii) its quantity per dosage unit,

(iii) its potency, if a representation relating to its potency is to be shown on any label of the natural health product,

(iv) a description of its source material, and

(v) a statement indicating whether it is synthetically manufactured;

(*d*) a qualitative list of the non-medicinal ingredients that are proposed for the natural health product and for each ingredient listed, a statement that indicates the purpose of the ingredient;

(*e*) each brand name under which the natural health product is proposed to be sold;

(*f*) the recommended conditions of use for the natural health product;

(*g*) information that supports the safety and efficacy of the natural health product when it is used in accordance with the recommended conditions of use;

(*h*) the text of each label that is proposed to be used in conjunction with the natural health product;

(*i*) a copy of the specifications to which the natural health product will comply; and

(*j*) one of the following attestations, namely,

(i) if the natural health product is imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3, or

(ii) if the natural health product is not imported, an attestation by the applicant that the natural health product will be manufactured, packaged, labelled, distributed and stored in accordance with requirements set out in Part 3.

Sixty-Day Disposition

6. (1) Subject to subsection (2), the Minister shall dispose of an application submitted under section 5 within 60 days after the day on which it is submitted if, in support of the application, the only information submitted by the applicant under paragraph 5(*g*) is that which is

(*a*) in the case of an application respecting a natural health product that has only one medicinal ingredient, contained in a monograph for that medicinal ingredient in the Compendium; and

(*b*) in the case of an application respecting a natural health product that has more than one medicinal ingredient, contained in a monograph for that combination of medicinal ingredients in the Compendium.

(2) If the Minister requests that additional information or samples be submitted under section 15, the 60-day period referred to in subsection (1) does not include the number of days beginning on the day on which the request is made and ending on the day on which the additional information or samples are received.

(3) For the purposes of this section, the Minister disposes of an application on the earlier of the day on which

(*a*) the licence is issued in accordance with section 7; and

(*b*) the applicant is sent a notice under subsection 9(1).

Issuance and Amendment

7. The Minister shall issue or amend a product licence if

(*a*) the applicant submits an application to the Minister that is in accordance with section 5 or subsection 11(2), as the case may be;

(*b*) the applicant submits to the Minister all additional information or samples requested under section 15;

(*c*) the applicant does not make a false or misleading statement in the application; and

(*d*) the issuance or amendment of the licence, as the case may be, is not likely to result in injury to the health of a purchaser or consumer.

Product Number

8. (1) The Minister shall assign a product number to each natural health product in respect of which a product licence is issued.

(2) In the case of a natural health product that is a drug for which a drug identification number is assigned in accordance with subsection C.01.014.2(1) of the *Food and Drug Regulations*, the product number required under subsection (1) shall be the drug identification number.

Refusal to Issue or Amend

9. (1) If the Minister refuses to issue or amend a product licence, the Minister shall send the applicant a notice that sets out the reason for the refusal.(2) Within 30 days after the day on which the notice is sent, the applicant may make a request that the Minister reconsider the application.

(3) If the applicant makes a request in accordance with subsection (2), the Minister shall

(*a*) give the applicant an opportunity to be heard in respect of the application; and

(*b*) reconsider the application after giving the applicant that opportunity.

10. (1) After reconsidering the application, the Minister shall issue or amend the product licence if the requirements of section 7 are met.

(2) If the Minister again refuses to issue or amend the product licence, the Minister shall send the applicant a final notice that sets out the reason for the refusal.

Amendment

11. (1) If the licensee makes any of the following changes in respect of the natural health product, the licensee shall not sell any lot or batch of the natural health product affected by the change unless the product licence is amended accordingly:

(*a*) a change to its recommended dose;

(*b*) a change to its recommended duration of use;

(*c*) the deletion or modification of risk information shown on any of its labels, including the deletion or modification of a caution, warning, contra-indication or known adverse reaction associated with its use;

(*d*) a change of its recommended use or purpose;

(*e*) a change of the source material of any of its medicinal ingredients;

(*f*) changing any of its medicinal ingredients to or from being synthetically manufactured;

(*g*) a change to the potency of any of its medicinal ingredients;

(*h*) a change affecting its safety or efficacy that does not arise as a result of

(i) a change to the quantity of a medicinal ingredient per dosage unit,

(ii) the addition or substitution of a medicinal ingredient,

(iii) a change to its dosage form, or

(iv) a change to its recommended route of administration; or

(*i*) one or more of the following changes to its specifications, namely,

(i) the removal of a test method set out in the specifications,

(ii) the modification of a test method set out in the specifications in a manner that widens the purity tolerances of the natural health product or the quantity, identity or potency tolerances of any of its medicinal ingredients, or

(iii) the modification of a test method set out in the specifications in a manner that renders it less precise, accurate, specific or sensitive.

(2) An application to amend a product licence shall be submitted to the Minister and shall contain the following information and documents:

(*a*) the product number of the natural health product;

(*b*) a statement identifying each change described in subsection (1) that has been made;

(*c*) information demonstrating that the natural health product is safe and efficacious after the change;

(*d*) the text of each label to be used in conjunction with the natural health product after the change, if the change is any of those described in paragraphs (1)(*a*) to (*h*); and

(*e*) a copy of the revised specifications, if the change is any of those described in paragraph (1)(*g*) or (*i*).

Notification

12. (1) If the licensee makes any of the changes described in subsection (2) in respect of the natural health product, the licensee shall, within 60 days after the day on which the change is made,

(*a*) notify the Minister of the change; and

(*b*) provide the Minister with the text of each label used in conjunction with the natural health product since the change, if the change is any of those described in paragraphs (2)(*d*) to (*f*).

(2) For the purposes of subsection (1), changes in respect of a natural health product are

(*a*) a change to any of the information submitted under paragraph 5(*a*) or (*b*);

(*b*) a change to any of the information provided under section 22;

(*c*) the addition or substitution of a non-medicinal ingredient, the addition or substitution of which does not affect its safety or efficacy;

(*d*) its sale under a brand name other than one submitted under paragraph 5(*e*);

(*e*) a change of the common or proper name of any of its medicinal ingredients; and

(*f*) the addition of risk information to any of its labels, including the addition of a caution, warning, contra-indication or known adverse reaction associated with its use.

Fundamental Change

13. For greater certainty, if the licensee makes any of the following fundamental changes in respect of the natural health product, the licensee may not sell the natural health product affected by the change unless a product licence is issued in accordance with section 7 for the natural health product as changed:

(*a*) a change to the quantity of a medicinal ingredient per dosage unit;

(*b*) the addition or substitution of a medicinal ingredient;

(*c*) a change to its dosage form; or

(*d*) a change to its recommended route of administration.

Licence Contents

14. (1) A product licence shall set out the following information:

(*a*) the name and address of the licensee;

(*b*) the product number of the natural health product;

(*c*) the dosage form that is authorized for the natural health product;

(*d*) the recommended route of administration that is authorized for the natural health product;

(*e*) the recommended dose that is authorized for the natural health product;

(*f*) the recommended duration of use, if any, that is authorized for the natural health product;

(*g*) in respect of each medicinal ingredient of the natural health product

(i) its authorized quantity per dosage unit,

(ii) its authorized potency, if any, and

(iii) its authorized source material;

(*h*) the recommended use or purpose that is authorized for the natural health product; and

(*i*) the date on which the licence was issued.

(2) Within 60 days after the day on which the product licence is issued, the licensee shall notify the Minister of any information set out on the licence that the licensee knows to be incorrect.

Additional Information or Samples

15. If the information and documents submitted in respect of a product licence application under section 5 or an application for amendment under subsection 11(2) are insufficient to enable the Minister to determine whether the product licence should be issued or amended, as the case may be, the Minister may request that the applicant provide such additional information or samples of the natural health product as are necessary to make the determination.

Safety Information

16. If the Minister has reasonable grounds to believe that a natural health product may no longer be safe when used under the recommended conditions of use, the Minister may request that the licensee provide the Minister, within 15 days after the day on which the request is received, with information and documents demonstrating that the natural health product is safe when used under the recommended conditions of use.

Direction to Stop Sale

17. (1) The Minister may direct the licensee, manufacturer, importer and distributor to stop their sale of a natural health product if

(*a*) the licensee does not, within the required period, provide the Minister with the information and documents requested under section 16;

(*b*) the information and documents provided by the licensee in accordance with section 16 do not demonstrate that the natural health product is safe when used under the recommended conditions of use;

(*c*) in the case of a natural health product that is imported, the Minister has reasonable grounds to believe that the natural health product is not manufactured, packaged, labelled, imported, distributed or stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3;

(*d*) in the case of a natural health product that is not imported, the Minister has reasonable grounds to believe that the natural health product is not manufactured, packaged, labelled, distributed or stored in accordance with the requirements set out in Part 3; or

(*e*) the Minister has reasonable grounds to believe that the natural health product is not packaged or labelled in accordance with the requirements set out in Part 5.

(2) The Minister shall lift a direction to stop the sale of a natural health product if the licensee provides the Minister with information and documents demonstrating that

(*a*) in the case of a direction to stop sale arising under either paragraph (1)(*a*) or (*b*), the natural health product is safe when used under the recommended conditions of use;

(*b*) in the case of a direction to stop sale arising under paragraph (1)(*c*), the natural health product is manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3;

(*c*) in the case of a direction to stop sale arising under paragraph (1)(*d*), the natural health product is manufactured, packaged, labelled, distributed and stored in accordance with the requirements set out in Part 3;

(*d*) in the case of a direction to stop sale arising under paragraph (1)(*e*), the natural health product is packaged and labelled in accordance with the requirements of Part 5; or

(*e*) the situation giving rise to the direction to stop the sale of the natural health product did not exist.

Suspension and Cancellation

18. (1) Subject to subsection (2), the Minister may suspend a product licence if the Minister has reasonable grounds to believe that

(*a*) the licensee has contravened these Regulations or any provision of the Act relating to the natural health product; or

(*b*) the licensee has made a false or misleading statement in the application submitted under section 5 or the application for amendment under subsection 11(2).

(2) Subject to section 19, the Minister shall not suspend a product licence unless

(*a*) the Minister has sent the licensee a notice that sets out the reason for the intended suspension; and

(*b*) the licensee has not, within 90 days after the day on which the notice referred to in paragraph (*a*) is received, provided the Minister with information or documents demonstrating that the licence should not be suspended on the grounds that

(i) the situation giving rise to the intended suspension did not exist, or

(ii) the situation giving rise to the intended suspension has been corrected.

19. The Minister shall suspend a product licence before giving the licensee an opportunity to be heard if, as a result of any circumstance, the Minister has reasonable grounds to believe that it is necessary to do so to prevent injury to the health of a purchaser or consumer.

20. If the Minister suspends a product licence under section 18 or 19, the Minister shall send the licensee a notice that sets out the reason for the suspension and the day on which the suspension is effective, and the Minister shall

(*a*) reinstate the licence if, within 90 days after the day on which the suspension is effective, the licensee provides the Minister with information or documents demonstrating that the situation giving rise to the suspension did not exist or that it has been corrected; or

(*b*) cancel the licence if, within 90 days after the day on which the suspension is effective, the licensee has not provided the Minister with the information or documents referred to in paragraph (*a*).

21. If the Minister cancels a licence under paragraph 20(*b*), the Minister shall send the licensee a notice that sets out the reason for the cancellation and the day on which the cancellation is effective.

Site Information

22. (1) Subject to subsection (2), the licensee shall provide the Minister with the following information prior to commencing the sale of the natural health product:

(*a*) in respect of each manufacturer, packager, labeller and importer of the natural health product

(i) the person's name, address and telephone number, and if applicable, the person's facsimile number and electronic mail address, and

(ii) if the person conducts the activity in Canada, the number assigned to the site licence issued in respect of that activity;

(*b*) the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of each distributor of the natural health product;

(*c*) the address of each building in which the natural health product is manufactured, packaged or labelled;

(*d*) the address of each building in which the natural health product is stored for the purposes of importation or distribution; and

(*e*) if the natural health product is imported, evidence demonstrating that the natural health product will be manufactured, packaged, labelled, imported, distributed and stored in accordance with the requirements set out in Part 3 or in accordance with requirements that are equivalent to those set out in Part 3.

(2) If the natural health product is one in respect of which a drug identification number is assigned in accordance with subsection C.01.014.2 (1) of the *Food and Drug Regulations* and at the time the product licence is issued in respect of the natural health product it is already being sold, the licensee shall provide the information referred to in subsection (1) within 30 days after the day on which the product licence is issued.

Records

23. (1) Every licensee who sells a natural health product shall maintain the following records:

(*a*) a list of all ingredients contained in each lot or batch of the natural health product that has been made available for sale; and

(*b*) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale.

(2) The records shall be maintained by the licensee for a period of one year following the expiry date of the natural health product to which that record relates.

Reaction Reporting

24. (1) A licensee shall provide the Minister with

(*a*) a case report for each serious adverse reaction to the natural health product that occurs inside Canada, within 15 days after the day on which the licensee becomes aware of the reaction; and

(*b*) a case report for each serious unexpected adverse reaction to the natural health product that occurs inside or outside Canada, within 15 days after the day on which the licensee becomes aware of the reaction.

(2) A licensee who sells a natural health product shall annually prepare and maintain a summary report that contains a concise and critical analysis of

(*a*) all adverse reactions to the natural health product that have occurred inside Canada; and

(*b*) all reactions for which a case report is required to be provided under subsection (1), that have occurred

(i) during the previous 12 months, and

(ii) at a dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying organic functions in humans.

(3) If after reviewing a case report provided under subsection (1) or after reviewing any other safety data relating to the natural health product, the Minister has reasonable grounds to believe that the natural health product may no longer be safe when used under the recommended conditions of use, the Minister may request that, within 30 days after the day on which the request is received, the licensee

(*a*) provide to the Minister a copy of any summary report prepared under subsection (2); or

(*b*) prepare and provide to the Minister an interim summary report containing a concise and critical analysis of

(i) all adverse reactions to the natural health product that have occurred inside Canada, and

(ii) all reactions for which a case report is required to be provided under subsection (1), that have occurred

(A) since the date of the most recent summary report prepared under subsection (2), and

(B) at a dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying organic functions in humans.

Recall Reporting

25. Every licensee who commences a recall of a natural health product shall provide the Minister with the information referred to in section 62 within three days after the day on which the recall is commenced.

PART 2

SITE LICENCES

Application

26. This Part does not apply to any activity that is conducted in respect of a natural health product solely for the purposes of a clinical trial as defined in section 63.

Prohibition

27. (1) Subject to subsection (2), no person shall manufacture, package, label or import a natural health product for sale unless

(*a*) the person holds a site licence issued in respect of the activity; and

(*b*) the person conducts the activity in accordance with the requirements set out in Part 3.

(2) No person who holds a site licence shall manufacture, package, label or import a natural health product for sale

(*a*) during the period of any suspension of the licence under section 39 or 40; or

(*b*) after cancellation of the licence under paragraph 41(*b*).

Licence Application

28. An application for a site licence shall be submitted to the Minister and shall contain the following information and documents:

(*a*) the name, address and telephone number, and if applicable, the facsimile number and electronic mail address of the applicant;

(*b*) a statement specifying which one or more of the activities of manufacturing, packaging, labelling or importing the applicant is proposing to conduct;

(*c*) if the applicant is proposing to manufacture, package or label a natural health product, the address of each building in which each activity is proposed to be conducted;

(*d*) if the applicant is proposing to import a natural health product, the address of each building in which that natural health product is proposed to be stored;

(*e*) for each activity specified under paragraph (*b*), a statement indicating whether or not the applicant is proposing to conduct the activity in respect of a natural health product in sterile dosage form; and

(*f*) in respect of the buildings, equipment, practices and procedures used to conduct each activity specified under paragraph (*b*), a report from a quality assurance person demonstrating that they comply with the requirements set out in Part 3.

Issuance and Amendment

29. (1) The Minister shall issue or amend a site licence if

(*a*) the applicant submits an application to the Minister that is in accordance with section 28 or subsection 32(2), as the case may be;

(*b*) the applicant provides the Minister with all additional information requested under section 37; and

(*c*) the applicant does not make a false or misleading statement in the application.

(2) If the Minister issues a site licence, the Minister shall assign that licence a site licence number.

Refusal to Issue or Amend

30. (1) If the Minister refuses to issue or amend a site licence, the Minister shall send the applicant a notice that sets out the reason for the refusal.

(2) Within 30 days after the day on which the notice is sent, the applicant may make a request that the Minister reconsider the application.

(3) If the applicant makes a request in accordance with subsection (2), the Minister shall

(*a*) give the applicant an opportunity to be heard in respect of the application; and

(*b*) reconsider the application after giving the applicant that opportunity.

31. (1) After reconsidering the application, the Minister shall issue or amend the site licence if the requirements of subsection 29(1) are met.

(2) If the Minister again refuses to issue or amend the site licence, the Minister shall send the applicant a final notice that sets out the reason for the refusal.

Amendment

32. (1) A licensee shall not conduct any of the following activities unless the site licence is amended accordingly:

(*a*) conduct any activity for a which a site licence is required that the licensee is not already authorized to conduct;

(*b*) if the licensee is authorized to manufacture, package or label a natural health product, conduct that activity in a building that is not one in which the conduct of that activity is authorized;

(*c*) if the licensee is authorized to import a natural health product, store a natural health product in a building that is not one in which the storage is authorized; or

(*d*) if the licensee is authorized to conduct an activity, but not already authorized to conduct it in respect of a natural health product in sterile dosage form, conduct the activity in respect of a natural health product in that form.

(2) An application to amend a site licence shall be submitted to the Minister and shall contain the following information and documents:

(*a*) the licence number;

(*b*) a statement that specifies each activity referred to in subsection (1) that the licensee is proposing to conduct; and

(*c*) a report from a quality assurance person demonstrating that the buildings, equipment, practices and procedures used in respect of each activity conducted by the licensee will remain in compliance with the requirements set out in Part 3.

Notification

33. If the licensee makes any of the following changes, the licensee shall notify the Minister of the change within 60 days after the day on which the change is made:

(*a*) a change to the information submitted under paragraph 28(*a*); and

(*b*) a change that substantially alters any building, equipment, practice or procedure in respect of which a report from a quality assurance person was submitted under paragraph 28(*f*).

Licence Contents

34. A site licence shall set out the following information:

(*a*) the name and address of the licensee;

(*b*) the site licence number;

(*c*) each activity that the licensee is authorized to conduct and a statement indicating whether the activity is authorized to be conducted in respect of a natural health product in sterile dosage form;

(*d*) if the licensee is authorized to manufacture, package or label a natural health product, the address of each building in which the licensee is authorized to conduct that activity; and

(*e*) if the licensee is authorized to import a natural health product, the address of each building in which the licensee is authorized to store that natural health product.

Expiry

35. (1) A site licence expires on the first anniversary of the day on which it was issued unless it is renewed in accordance with section 36.

(2) A site licence that is renewed in accordance with section 36 expires on the day on which the renewal period ends unless the licence is further renewed in accordance with section 36.

Renewal

36. (1) The Minister shall renew a site licence if

(*a*) the licensee submits a request to renew the licence to the Minister no later than 30 days before the day on which the licence expires;

(*b*) the licensee provides the Minister with all additional information requested under section 37; and

(*c*) the renewal of the licence is not likely to result in injury to the health of a purchaser or consumer.

(2) If the Minister renews a site licence, the Minister shall renew it for a period of

(*a*) one year, if on the next anniversary of the day on which the licence was issued, the licensee will have held the licence for a period of less than three years;

(*b*) two years, if on the next anniversary of the day on which the licence was issued, the licensee will have held the licence for a period of at least three years but less than nine years; or

(*c*) three years, if on the next anniversary of the day on which the licence was issued, the licensee will have held the licence for a period of nine years or more.

(3) A site licence renewal becomes effective on the day after the anniversary of the day on which the licence was issued.

Additional Information

37. If the information and documents submitted in respect of an application under section 28, an application for amendment under subsection 32(2) or a request for renewal under section 36 are insufficient to enable the Minister to determine whether the licence should be issued, amended or renewed, as the case may be, the Minister may request that the applicant provide the Minister with such additional information as is necessary to make the determination.

Relinquishment of Authorization

38. (1) A licensee may, by amendment of the site licence, relinquish any part of the authorization given to the licensee under this Part.

(2) An application to amend the site licence for the purposes of subsection (1) shall be submitted to the Minister and shall contain the following information and documents:

(*a*) a document, signed and dated by the licensee, that sets out the site licence number and that specifies each activity or, by address, each building, in respect of which the authorization is requested to be relinquished; and

(*b*) an attestation, signed and dated by a quality assurance person, stating that after the relinquishment, the buildings,

equipment, practices and procedures used in respect of each activity conducted by the licensee will remain in compliance with the requirements set out in Part 3.

(3) The Minister shall amend the site licence as requested by the licensee in paragraph (2)(*a*) if the licensee provides the Minister with an application that is in accordance with subsection (2).

Suspension and Cancellation

39. (1) Subject to subsection (2), the Minister may suspend a site licence if the Minister has reasonable grounds to believe that

(*a*) the licensee has contravened any provision of the Act or these Regulations; or

(*b*) the licensee has made a false or misleading statement in the application submitted under section 28 or the application for amendment under subsection 32(2).

(2) Subject to section 40, the Minister shall not suspend a site licence unless

(*a*) the Minister has sent the licensee a notice that sets out the reason for the intended suspension; and

(*b*) the licensee has not, within 90 days after the day on which the notice referred to in paragraph (*a*) is received, provided the Minister with information or documents demonstrating that the licence should not be suspended on the grounds that

(i) the situation giving rise to the intended suspension did not exist, or

(ii) the situation giving rise to the intended suspension has been corrected.

40. The Minister shall suspend a site licence before giving the licensee an opportunity to be heard if, as a result of any circumstance, the Minister has reasonable grounds to believe that it is necessary to do so to prevent injury to the health of a purchaser or consumer.

41. If the Minister suspends a site licence under section 39 or 40, the Minister shall send the licensee a notice that sets out the reason for suspension and the day on which the suspension is effective, and the Minister shall

(*a*) reinstate the licence if, within 90 days after the day on which the suspension is effective, the licensee provides the Minister with information or documents demonstrating that the situation giving rise to the suspension did not exist or that it has been corrected; or

(*b*) cancel the licence if, within 90 days after the day on which the suspension is effective, the licensee has not provided the Minister with the information or documents referred to in paragraph (*a*).

42. If the Minister cancels a licence under paragraph 41(*b*), the Minister shall send the licensee a notice that sets out the reason for the cancellation and the day on which the cancellation is effective.

PART 3

GOOD MANUFACTURING PRACTICES

Prohibition

43. (1) Subject to subsection (2), no person shall sell a natural health product unless it is manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with this Part.

(2) A person may sell a natural health product that is manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with requirements that are equivalent to those set out in this Part if the natural health product is imported.

Specifications

44. (1) Every natural health product available for sale shall comply with the specifications submitted in respect of that natural health product under paragraph 5(*i*) and with every change to those specifications made by the product licence holder.

(2) The specifications shall contain the following information:

(*a*) detailed information respecting the purity of the natural health product, including statements indicating its purity tolerances;

(*b*) for each medicinal ingredient of the natural health product, detailed information respecting its quantity per dosage unit and

its identity, including statements indicating its quantity and identity tolerances;

(*c*) if a representation relating to the potency of a medicinal ingredient is to be shown on a label of the natural health product, detailed information respecting the potency of the medicinal ingredient, including statements indicating its potency tolerances; and

(*d*) a description of the methods used for testing or examining the natural health product.

(3) The specifications and every change to those specifications shall be approved by a quality assurance person.

Premises

45. (1) Every natural health product shall be manufactured, packaged, labelled and stored in premises that are designed, constructed and maintained in a manner that permits the activity to be conducted under sanitary conditions, and in particular that

(*a*) permits the premises to be kept clean and orderly;

(*b*) permits the effective cleaning of all surfaces in the premises;

(*c*) permits the natural health product to be stored or processed appropriately;

(*d*) prevents the contamination of the natural health product; and

(*e*) prevents the addition of an extraneous substance to the natural health product.

(2) Every natural health product shall be stored under conditions that will maintain the quality and safety of the natural health product.

Equipment

46. Every natural health product shall be manufactured, packaged, labelled and stored using equipment that is designed, constructed, maintained, operated and arranged in a manner that

(*a*) permits the effective cleaning of its surfaces;

(*b*) permits it to function in accordance with its intended use;

(*c*) prevents it from contaminating the natural health product; and

(*d*) prevents it from adding an extraneous substance to the natural health product.

Personnel

47. Every natural health product shall be manufactured, packaged, labelled and stored by personnel who are qualified by education, training or experience to perform their respective tasks.

Sanitation Program

48. Every natural health product shall be manufactured, packaged, labelled and stored in accordance with a sanitation program that sets out

(*a*) procedures for effectively cleaning the premises in which the activity is conducted;

(*b*) procedures for effectively cleaning the equipment used in the activity;

(*c*) procedures for handling any substance used in the activity; and

(*d*) all requirements, in respect of the health, the hygienic behaviour and the clothing of the personnel who are involved in the activity, that are necessary to ensure that the activity is conducted in sanitary conditions.

Operations

49. Every natural health product shall be manufactured, packaged, labelled and stored in accordance with standard operating procedures that are designed to ensure that the activity is conducted in accordance with the requirements of this Part.

50. Every manufacturer, packager, labeller, importer and distributor shall establish and maintain a system of control that permits the rapid and complete recall of every lot or batch of the natural health product that has been made available for sale.

Quality Assurance

51. (1) Every manufacturer, packager, labeller, importer and distributor shall

(*a*) have a quality assurance person who

(i) is responsible for assuring the quality of the natural health product before it is made available for sale, and

(ii) has the training, experience and technical knowledge relating to the activity conducted and the requirements of this Part; and

(*b*) investigate and record every complaint received in respect of the quality of the natural health product and, if necessary, take corrective action.

(2) Every natural health product shall be manufactured, packaged and labelled using only material that, prior to its use in the activity, has been approved for that use by a quality assurance person.

(3) Every natural health product shall be manufactured, packaged, labelled and stored using methods and procedures that, prior to their implementation, have been approved by a quality assurance person.

(4) Every lot or batch of a natural health product shall be approved by a quality assurance person before it is made available for sale.

(5) Every natural health product that is sold and subsequently returned to its manufacturer, packager, labeller, importer or distributor, as the case may be, shall be approved by a quality assurance person before that natural health product may be made available for resale.

Stability

52. Every manufacturer and every importer shall determine the period of time that, after being packaged for sale, the natural health product will continue to comply with its specifications when

(*a*) it is stored under its recommended storage conditions; or

(*b*) if it does not have recommended storage conditions, it is stored at room temperature.

Records

Manufacturers

53. Every manufacturer who sells a natural health product shall maintain the following records at the site at which the natural health product is manufactured:

(*a*) the master production document for the natural health product;

(*b*) a list of all ingredients contained in each lot or batch of the natural health product;

(*c*) records of any testing conducted in respect of a lot or batch of raw material used in the manufacture of the natural health product;

(*d*) records of any testing conducted in respect of a lot or batch of the natural health product;

(*e*) a copy of the specifications for each natural health product that is being manufactured at the site;

(*f*) records demonstrating that each lot or batch of the natural health product was manufactured in accordance with the requirements of this Part;

(*g*) a record of each determination made by the manufacturer in accordance with section 52 and the information that supports that determination;

(*h*) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;

(*i*) a list of all natural health products that are being manufactured at the site; and

(*j*) a copy of the sanitation program in use at the site.

Packagers

54. Every packager who sells a natural health product shall maintain the following records at the site at which the natural health product is packaged:

(*a*) records of any testing conducted in respect of the material used to package the natural health product;

(*b*) records demonstrating that each lot or batch of the natural health product was packaged in accordance with the requirements of this Part;

(*c*) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;

(*d*) a list of all natural health products that are being packaged at the site; and

(*e*) a copy of the sanitation program in use at the site.

Labellers

55. Every labeller who sells a natural health product shall maintain the following records at the site at which the natural health product is labelled:

(*a*) records demonstrating that each lot or batch of the natural health product was labelled in accordance with the requirements of this Part;

(*b*) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;

(*c*) a list of all natural health products that are being labelled at the site; and

(*d*) a copy of the sanitation program in use at the site.

Importers

56. Every importer who sells a natural health product shall maintain the following records:

(*a*) the master production document for the natural health product;

(*b*) a list of all ingredients contained in each lot or batch of the natural health product;

(*c*) records of any testing conducted in respect of a lot or batch of the natural health product;

(*d*) a copy of the specifications for the natural health product;

(*e*) a record of each determination made by the importer in accordance with section 52 and the information that supports that determination;

(*f*) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale; and

(*g*) a copy of the sanitation program in use by the importer.

Distributors

57. Every distributor shall maintain the following records at the site at which the natural health product is stored:

(*a*) records containing sufficient information to enable the recall of every lot or batch of the natural health product that has been made available for sale;

(*b*) a list of all natural health products that are being stored at the site; and

(*c*) a copy of the sanitation program in use at the site.

Record Maintenance

58. Every person required under this Part to maintain a record that relates to a lot or batch of a natural health product shall maintain that record for a period of one year following the expiry date of the natural health product to which that record relates.

Sterile Natural Health Products

59. Every natural health product that is intended to be sterile shall be manufactured and packaged

(*a*) in a separate and enclosed area;

(*b*) under the supervision of a person trained in microbiology; and

(*c*) using a method scientifically proven to ensure its sterility.

Ophthalmic Use

60. (1) Section C.01.064 of the *Food and Drug Regulations* applies in respect of natural health products except that it shall be read without reference to the words "or parenteral".

(2) Section C.01.065 of the *Food and Drug Regulations* applies in respect of natural health products except that it shall be read without reference to

(*a*) the words "or parenteral"; and

(*b*) the words "or to its common name if there is no proper name".

Lot or Batch Samples

61. (1) Subject to subsection (3), if the Minister has reasonable grounds to believe that a lot or batch of a natural health product made available for sale may result in injury to the health of a purchaser or consumer, the Minister may require the manufacturer, importer or distributor to provide a sample of that lot or batch. (2) The sample shall be of sufficient quantity to enable a determination of whether the lot or batch of the natural health product complies with the specifications for that natural health product.

(3) The Minister shall not require a sample of a lot or batch referred to in subsection (1) to be provided if more than one year has elapsed since the expiry date of that natural health product.

Recall Reporting

62. Every manufacturer, importer or distributor who commences a recall of a natural health product shall provide the Minister with the following information in respect of that natural health product within three days after the day on which the recall is commenced:

(*a*) the proper name and the common name of each medicinal ingredient that it contains;

(*b*) each brand name under which it is sold;

(*c*) its product number;

(*d*) the number of each lot or batch recalled;

(*e*) the name and address of each manufacturer, importer and distributor of the natural health product;

(*f*) the reasons for commencing the recall;

(*g*) the quantity manufactured or imported into Canada;

(*h*) the quantity that was distributed in Canada;

(*i*) the quantity remaining in the possession of each manufacturer, importer and distributor of the natural health product; and

(*j*) a description of any other action that the manufacturer, importer or distributor, as the case may be, is taking in respect of the recall.

PART 4

CLINICAL TRIALS INVOLVING HUMAN SUBJECTS

Interpretation

63. The following definitions apply in this Part.

"adverse event" means any adverse occurrence in the health of a clinical trial subject who is administered a natural health product, that may or may not be caused by the administration of the natural health product, and includes an adverse reaction, a serious adverse reaction and a serious unexpected adverse reaction. (*incident thérapeutique*)

"clinical trial" means an investigation in respect of a natural health product that involves human subjects and that is intended to discover or verify its clinical, pharmacological or pharmacodynamic effects, to identify any adverse events that are related to its use, to study its absorption, distribution, metabolism and excretion, or to ascertain its safety or efficacy. (*essai clinique*)

"good clinical practices" means generally accepted clinical practices that are designed to ensure the protection of the rights, safety and well-being of clinical trial subjects and other persons, and the good clinical practices referred to in section 74. (*bonnes pratiques cliniques*)

"import" means to import a natural health product into Canada for the purpose of sale in a clinical trial. (*importer*)

"investigator's brochure" means a document containing the preclinical and clinical information in respect of the natural health product that is described in paragraph 66(*e*). (*brochure du chercheur*)

"protocol" means a document that describes the objectives, design, methodology, statistical considerations and organization of a clinical trial. (*protocole*)

"qualified investigator" means the person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where the clinical trial site is located and who is

(*a*) in the case of a clinical trial respecting a natural health product to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and

(*b*) in any other case, a physician and a member in good standing of a professional medical association. (*chercheur qualifié*)

"research ethics board" means a body that is not affiliated with the sponsor, and

(*a*) the principal mandate of which is to approve the initiation of, and conduct periodic reviews of, biomedical research involving human subjects in order to ensure the protection of their rights, safety and well-being; and

(*b*) that has at least five members, that has a majority of members who are Canadian citizens or permanent residents under the *Immigration Act*, that is composed of both men and women and that includes at least

(i) two members whose primary experience and expertise are in a scientific discipline, who have broad experience in the methods and areas of research to be approved and one of whom is from a medical discipline or, if the clinical trial is in respect of a natural health product to be used for dental purposes only, is from a medical or dental discipline,

(ii) one member knowledgeable in complementary or alternative health care,

(iii) one member knowledgeable in ethics,

(iv) one member knowledgeable in Canadian laws relevant to the research to be approved,

(v) one member whose primary experience and expertise are in a non-scientific discipline, and

(vi) one member who is from the community or is a representative of an organization interested in the areas of research to be approved and who is not affiliated with the sponsor or the site where the clinical trial is to be conducted. (*comité d'éthique de la recherche*)

"sponsor" means an individual, corporate body, institution or organization that conducts a clinical trial. (*promoteur*)

Application

64. (1) Subject to subsection (2), this Part applies to the sale or importation of natural health products to be used for the purposes of clinical trials involving human subjects.

(2) Except for paragraph 65(1)(*a*), subsection 65(2), section 68, paragraphs 74(*a*) to (*i*), subsections 75(1) and 76(1) and (2), paragraphs 76(3)(*a*) to (*d*) and (*f*) to (*h*), subsection 76(4) and sections 77 and 80 to 83, this Part does not apply to the sale or importation of a natural health product for the purposes of a clinical trial authorized under section 68.

Prohibition

65. (1) Despite section 4 and subject to subsection (2), no person shall sell or import a natural health product for the purposes of a clinical trial unless

(*a*) the person is authorized under this Part;

(*b*) the person complies with this Part and section C.01.064 of the *Food and Drug Regulations*; and

(*c*) if the natural health product is to be imported, the person has a representative in Canada who is responsible for the sale of the natural health product.

(2) No person shall sell a natural health product for the purposes of a clinical trial

(*a*) during the period of any suspension of the authorization under section 80 or 81; or

(*b*) after cancellation of the authorization under paragraph 82(*b*).

Application for Authorization

66. An application by a sponsor for authorization to sell or import a natural health product for the purposes of a clinical trial shall be submitted to the Minister and shall contain the following information and documents:

(*a*) a copy of the protocol for the clinical trial;

(*b*) a copy of the statement, as it will be set out in each informed consent form, that states the risks and anticipated benefits arising to the health of clinical trial subjects as a result of their participation in the clinical trial;

(*c*) a clinical trial attestation, signed and dated by the sponsor, containing

(i) the title of the protocol and the clinical trial number,

(ii) the brand name or the code for the natural health product,

(iii) for each medicinal ingredient of the natural health product

(A) the proper name and common name of the ingredient, and

(B) the quantity of the ingredient per dosage unit of the natural health product,

(iv) a qualitative list of the non-medicinal ingredients of the natural health product,

(v) the dosage form of the natural health product,

(vi) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the sponsor,

(vii) if the natural health product is to be imported, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the sponsor's representative in Canada who is responsible for the sale of the natural health product,

(viii) the address of each clinical trial site,

(ix) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the qualified investigator,

(x) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the research ethics board that approved the protocol referred to in paragraph (*a*) and approved an informed consent form containing the statement referred to in paragraph (*b*),

(xi) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of any research ethics board that has previously refused to approve the protocol referred to in paragraph (*a*), its reasons for doing so and the date on which the refusal was given, and

(xii) a statement

(A) that the clinical trial will be conducted in accordance with good clinical practices and these Regulations, and

(B) that all information contained in, or referenced by, the application is complete and accurate and is not false or misleading;

(*d*) an attestation, signed and dated by the research ethics board for each clinical trial site, that it has reviewed and approved the protocol referred to in paragraph (*a*) and an informed consent form containing the statement referred to in paragraph (*b*) and that the board carries out its functions in a manner consistent with good clinical practices;

(*e*) an investigator's brochure that contains the following information, namely,

(i) the physical, chemical and, if any, the pharmaceutical properties of the natural health product,

(ii) the chemistry and manufacturing information of each synthetically manufactured medicinal ingredient of the natural health product,

(iii) the pharmacological properties of the natural health product, including its metabolites in all animal species tested, if any,

(iv) the pharmacokinetics of the natural health product and the natural health product metabolism, including the biological transformation of the natural health product in all animal species tested, if any,

(v) the toxicological effects in any animal species tested under a single dose study, a repeated dose study or a special study in respect of the natural health product, if any,

(vi) the results of carcinogenicity studies in any animal species tested in respect of the natural health product, if any,

(vii) the results of clinical pharmacokinetic studies of the natural health product, if any,

(viii) the information regarding natural health product safety, pharmacodynamics, efficacy and dose responses of the natural health product that were obtained from previous clinical trials in humans, if any,

(ix) the known contra-indications for and the precautions to be taken in respect of the natural health product, and

(x) the recommended treatment in the event of an overdose of the natural health product, if any; and

(*f*) the proposed date for the commencement of the clinical trial at each clinical trial site.

Authorization

67. (1) The Minister shall authorize a sponsor to sell or import a natural health product for the purposes of a clinical trial if

(*a*) the sponsor submits an application to the Minister that is in accordance with section 66;

(*b*) the sponsor provides the Minister with all additional information or samples requested under section 73; and

(*c*) the Minister has reasonable grounds to believe, based on an assessment of the application, an assessment of any samples or information provided under section 73 or a review of any other information that

(i) the use of the natural health product for the purposes of the clinical trial will not endanger the health of a clinical trial subject or other person,

(ii) the clinical trial is not contrary to the best interests of the clinical trial subjects, and

(iii) the objectives of the clinical trial will be achieved.

(2) The Minister shall authorize the sponsor to sell or import a natural health product for the purposes of a clinical trial by sending the sponsor a notice of the authorization.

68. A sponsor is authorized to sell or import a natural health product for the purposes of a clinical trial if the clinical trial is in respect of a recommended use or purpose for which that natural health product is issued a product licence.

Commencement Notice

69. The sponsor shall notify the Minister of the date on which the sale or importation of a natural health product for the purposes of a clinical trial will commence at a clinical trial site at least 15 days before the day on which that sale or importation commences.

Notification

70. If the sale or importation of a natural health product for the purposes of a clinical trial is authorized under this Part, the sponsor may make one or more of the following changes if the sponsor

provides the Minister with notification of the change within 15 days after the day on which the change is made:

(*a*) a change to the information referred to in subparagraph 66(*e*)(ii) that does not affect the quality or safety of the natural health product; and

(*b*) a change to the protocol that does not alter the risk to the health of a clinical trial subject, other than a change for which an amendment is required by section 71.

Amendment

71. (1) Subject to subsection (2), if the sale or importation of a natural health product for the purposes of a clinical trial is authorized under this Part, the sponsor may not make any of the following amendments unless the authorization is amended accordingly:

(*a*) an amendment to the protocol that affects the selection, monitoring or dismissal of a clinical trial subject;

(*b*) an amendment to the protocol that affects the evaluation of the clinical efficacy of the natural health product;

(*c*) an amendment to the protocol that alters the risk to the health of a clinical trial subject;

(*d*) an amendment to the protocol that affects the safety evaluation of the natural health product;

(*e*) an amendment to the protocol that extends the duration of the clinical trial; and

(*f*) an amendment to the information referred to in subparagraph 66(*e*)(ii) that may affect the safety or quality of that natural health product.

(2) If the sponsor is required to immediately make one or more of the amendments referred to in subsection (1) because the clinical trial or the use of the natural health product for the purposes of the clinical trial endangers the health of a clinical trial subject or other person, the sponsor may immediately make the amendment and shall provide the Minister with the information referred to in subsection (3) within 15 days after the day on which the amendment is made.

(3) An application by the sponsor to amend the authorization for the sale or importation of a natural health product under this Part shall be submitted to the Minister and, in addition to a reference to

the application submitted under section 66, shall contain the following information and documents:

(*a*) if as a result of the amendment it is necessary to amend the statement referred to in paragraph 66(*b*),

(i) a copy of the amended statement that indicates the new information, and

(ii) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the research ethics board that approved the amended statement;

(*b*) if the application is in respect of an amendment referred to in any of paragraphs (1)(*a*) to (*e*),

(i) a copy of the amended protocol that indicates the amendment,

(ii) a copy of the protocol submitted under paragraph 66(*a*),

(iii) the rationale for the amendment,

(iv) for each clinical trial site, the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of the research ethics board that approved the amended protocol, and

(v) the name, address and telephone number and, if applicable, the facsimile number and electronic mail address of any research ethics board that has previously refused to approve any amendment to the protocol, its reasons for doing so and the date on which the refusal was given;

(*c*) if the application is in respect of an amendment referred to in paragraph (1)(*e*), a copy of the amended investigator's brochure or an addendum to the investigator's brochure that indicates the new information, including supporting toxicological studies and clinical trial safety data, if any; and

(*d*) if the application is in respect of an amendment referred to in paragraph (1)(*f*), a copy of the amended chemistry and manufacturing information that indicates the amendment, and the rationale for that amendment.

(4) The Minister shall amend the authorization to sell or import a natural health product for the purposes of a clinical trial if

(*a*) the sponsor submits an application for amendment to the Minister that is in accordance with subsection (3);

(*b*) the sponsor provides the Minister with all additional information or samples requested under section 73; and

(*c*) the Minister has reasonable grounds to believe, based on an assessment of the application for amendment, an assessment of any samples or information submitted under section 73 or a review of any other information that

(i) the use of the natural health product for the purposes of the clinical trial will not endanger the health of a clinical trial subject or other person, and

(ii) the clinical trial is not contrary to the best interests of the clinical trial subjects.

(5) The Minister shall amend the authorization to sell or import a natural health product for the purposes of a clinical trial by sending the sponsor a notice of the amendment.

72. If the authorization to sell or import a natural health product for the purposes of the clinical trial is amended in accordance with subsection 71(5), the sponsor shall

(*a*) before commencing to sell or import the natural health product in accordance with the amended authorization

(i) cease to sell or import the natural health product in accordance with the existing authorization, and

(ii) maintain records concerning the information referred to in subparagraph 66(*c*)(ix), if any of that information has changed since it was submitted, and the information referred to in paragraph 66(*f*); and

(*b*) conduct the clinical trial in accordance with the amended authorization.

Additional Information and Samples

73. If the information and documents submitted in respect of an application under section 66 or an application for amendment under subsection 71(3) are insufficient to enable the Minister to determine whether the sale or importation of the natural health product should be authorized or whether the authorization should be amended, as the case may be, the Minister may request that the sponsor provide the Minister with samples of the natural health product or additional

information relevant to the natural health product or the clinical trial that are necessary to make the determination.

Sponsor's Obligations

Good Clinical Practices

74. Every sponsor shall ensure that a clinical trial is conducted in accordance with good clinical practices and, without limiting the generality of the foregoing, shall ensure that

(*a*) the clinical trial is scientifically sound and clearly described in a protocol;

(*b*) the clinical trial is conducted, and the natural health product is used, in accordance with the protocol and this Part;

(*c*) systems and procedures that assure the quality of every aspect of the clinical trial are implemented;

(*d*) for each clinical trial site, the approval of a research ethics board is obtained before the clinical trial begins at the site;

(*e*) at each clinical trial site, there is no more than one qualified investigator;

(*f*) at each clinical trial site, medical care and medical decisions,in respect of the clinical trial, are under the supervision of the qualified investigator;

(*g*) each individual involved in the conduct of the clinical trial is qualified by education, training and experience to perform his or her respective tasks;

(*h*) written informed consent, given in accordance with the applicable laws governing consent, is obtained from every person before that person participates in the clinical trial but only after that person has been informed of

(i) the risks and anticipated benefits to his or her health arising from participation in the clinical trial, and

(ii) all other aspects of the clinical trial that are necessary for that person to make the decision to participate in the clinical trial;

(*i*) the requirements respecting information and records set out in section 76 are met; and

(*j*) the natural health product is manufactured and stored in accordance with the requirements set out in Part 3 except for section 61.

Labelling

75. (1) The sponsor shall ensure that the natural health product bears a label that sets out the following information in both official languages:

(*a*) a statement indicating that the natural health product is an investigational natural health product to be used only by a qualified investigator;

(*b*) the brand name or code of the natural health product;

(*c*) the expiry date of the natural health product;

(*d*) the recommended storage conditions for the natural health product, if any;

(*e*) the lot number of the natural health product;

(*f*) the name and address of the manufacturer;

(*g*) the name and address of the sponsor; and

(*h*) the protocol code or identification.

(2) Sections 86 to 94 do not apply to a natural health product used for the purposes of a clinical trial.

Records

76. (1) The sponsor shall record, handle and store all information in respect of a clinical trial in a way that allows its complete and accurate reporting as well as its interpretation and verification.

(2) The sponsor shall maintain complete and accurate records to establish that the clinical trial is conducted in accordance with good clinical practices and these Regulations.

(3) The sponsor shall maintain complete and accurate records in respect of the use of a natural health product in a clinical trial, including

(*a*) a copy of all versions of the investigator's brochure for the natural health product;

(*b*) records respecting each change made to the investigator's brochure, including the rationale for each change and documentation that supports each change;

(*c*) records respecting all adverse events in respect of the natural health product that have occurred inside or outside Canada, including information that specifies the dosage form and the use and purpose of the natural health product at the time of the adverse event;

(*d*) records respecting the enrolment of clinical trial subjects, including information sufficient to enable all clinical trial subjects to be identified and contacted in the event that the sale of the natural health product may endanger the health of the clinical trial subjects or other persons;

(*e*) records respecting the shipment, receipt, disposition, return and destruction of the natural health product;

(*f*) for each clinical trial site, an undertaking from the qualified investigator that is signed and dated by the qualified investigator prior to the commencement of his or her responsibilities in respect of the clinical trial, that states that

(i) the qualified investigator will conduct the clinical trial in accordance with good clinical practices, and

(ii) the qualified investigator will immediately, on discontinuance of the clinical trial by the sponsor, in its entirety or at a clinical trial site, notify both the clinical trial subjects and the research ethics board of the discontinuance, provide them with the reasons for the discontinuance and advise them in writing of any potential risks to the health of clinical trial subjects or other persons;

(*g*) for each clinical trial site, a copy of the protocol, informed consent form and any amendment to the protocol or informed consent form that have been approved by the research ethics board for that clinical trial site; and

(*h*) for each clinical trial site, an attestation, signed and dated by the research ethics board for that clinical trial site, stating that it has reviewed and approved the protocol and informed consent form and that the board carries out its functions in a manner consistent with good clinical practices.

(4) The sponsor shall maintain all records referred to in this Part for a period of 25 years.

Submission of Information and Samples

77. (1) The Minister shall require a sponsor to provide, within two days after the day on which the request is received, information concerning the natural health product or the clinical trial, or samples of the natural health product, if the Minister has reasonable grounds to believe that

(*a*) the use of the natural health product for the purposes of the clinical trial endangers the health of a clinical trial subject or other person;

(*b*) the clinical trial is contrary to the best interests of a clinical trial subject;

(*c*) a qualified investigator is not respecting the undertaking referred to in paragraph 76(3)(*f*); or

(*d*) information submitted or provided in respect of the natural health product or the clinical trial is false or misleading.

(2) The Minister may require the sponsor to provide, within seven days after the day on which the request is received, any information or records referred to in section 76, or samples of the natural health product, in order to assess the safety of the natural health product or the health of clinical trial subjects or other persons.

Reaction Reporting

78. (1) During the course of a clinical trial, the sponsor shall notify the Minister of any serious adverse reaction and any serious unexpected adverse reaction to the natural health product that has occurred inside Canada as follows:

(*a*) if it is neither fatal nor life threatening, within 15 days after the day on which the sponsor becomes aware of the information; and

(*b*) if it is fatal or life threatening, within seven days after the day on which the sponsor becomes aware of the information.

(2) The sponsor shall, within eight days after the day on which the Minister is notified under paragraph (1)(*b*), provide the Minister with a complete report in respect of that information that includes an assessment of the importance and implication of any findings made.

Discontinuance of a Clinical Trial

79. (1) If the sponsor discontinues a clinical trial in its entirety or at a clinical trial site, the sponsor shall

(*a*) notify the Minister of the discontinuance within 15 days after the day of the discontinuance;

(*b*) provide the Minister with the reason for the discontinuance and its impact on the proposed or ongoing clinical trials in respect of the natural health product conducted in Canada by the sponsor;

(*c*) as soon as possible, notify all qualified investigators of the discontinuance and of the reasons for the discontinuance, and advise them in writing of any potential risks to the health of clinical trial subjects or other persons; and

(*d*) in respect of each discontinued clinical trial site, stop the sale or importation of the natural health product as of the day of the discontinuance and take all reasonable measures to ensure the recovery of all unused quantities of the natural health product that have been sold.(2) If the sponsor discontinues a clinical trial in its entirety or at a clinical trial site, the sponsor may resume selling or importing the natural health product for the purposes of the clinical trial in its entirety or at the clinical trial site if, in respect of each clinical trial site where the sale or importation is to be resumed, the sponsor submits to the Minister the information referred to in subparagraphs 66(*c*)(ix) to (xi) and paragraphs 66(*d*) and (*f*).

Suspension and Cancellation

80. (1) Subject to subsection (2), the Minister may suspend the authorization to sell or import a natural health product for the purposes of a clinical trial, in its entirety or at a clinical trial site, if the Minister has reasonable grounds to believe that

(*a*) the sponsor has contravened these Regulations or any provisions of the Act relating to the natural health product;

(*b*) any information submitted or provided in respect of the natural health product or clinical trial is false or misleading;

(*c*) the sponsor has failed to comply with good clinical practices; or

(*d*) the sponsor has failed to

(i) provide information or samples of the natural health product as required under section 73 or 77, or

(ii) notify the Minister or provide a report under section 78.

(2) Subject to section 81, the Minister shall not suspend the authorization unless

(*a*) the Minister has sent the sponsor a notice that indicates whether the authorization is intended to be suspended in its entirety or at a clinical trial site and the reason for the intended suspension; and

(*b*) the sponsor has not, within 30 days after the day on which the notice referred to in paragraph (*a*) is received, provided the Minister with information or documents demonstrating that the authorization should not be suspended on the grounds that

(i) the situation giving rise to the intended suspension did not exist, or

(ii) the situation giving rise to the intended suspension has been corrected.

81. The Minister shall suspend the authorization to sell or import a natural health product for the purposes of a clinical trial, in its entirety or at a clinical trial site, before giving the sponsor an opportunity to be heard if, as a result of any circumstance, the Minister has reasonable grounds to believe that it is necessary to do so to prevent injury to the health of a clinical trial subject or other person.

82. If the Minister suspends the authorization under section 80 or 81, the Minister shall send the sponsor a notice that sets out the reason for the suspension, the day on which the suspension is effective and indicating whether the authorization is suspended in its entirety or at a clinical trial site, and the Minister shall

(*a*) reinstate the authorization in its entirety or at a clinical trial site, as the case may be, if within 30 days after the day on which the suspension is effective the sponsor provides the Minister with information or documents demonstrating that the situation giving rise to the suspension did not exist or that it has been corrected; or

(*b*) cancel the authorization in its entirety or at a clinical trial site, as the case may be, if within 30 days after the day on which the suspension is effective the sponsor has not provided the

Minister with the information or documents referred to in paragraph (*a*).

83. If the Minister cancels the authorization under paragraph 82(*b*), the Minister shall send the sponsor a notice that sets out the reason for the cancellation, the day on which the cancellation is effective and indicating whether the authorization is cancelled in its entirety or at a clinical trial site.

PART 5

GENERAL

Electronic Signatures

84. Any signature that is required by these Regulations to be shown on a record or document may be an electronic reproduction of the required signature.

Electronic Records

85. Any record that is required to be maintained by these Regulations may be maintained in any electronic format from which a printed copy of the record can be produced.

Labelling and Packaging

General

86. (1) No person shall sell a natural health product unless it is labelled and packaged in accordance with these Regulations.

(2) Despite subsection (1), a person may sell a natural health product that is not labelled and packaged in accordance with these Regulations if the sale is to a manufacturer or distributor.

87. (1) Subject to subsection (2), when required by these Regulations to be shown on a label, the following information respecting a natural health product shall be in both English and French:

(*a*) any of the information referred to in paragraphs (*a*) to (*f*) of the definition "recommended conditions of use" in subsection 1(1);

(*b*) the common name and proper name of each medicinal ingredient and each non-medicinal ingredient that it contains;

(*c*) a description of the source material of a medicinal ingredient; and

(*d*) its storage conditions.

(2) The common name or proper name of a medicinal ingredient or non-medicinal ingredient shall be shown in any other language if the name does not have an English or French equivalent.

88. The statements, information and declarations required by these Regulations to be shown on a label of a natural health product shall be

(*a*) clearly and prominently displayed; and

(*b*) readily discernible to the purchaser or consumer of the natural health product under the customary conditions of purchase and use.

89. If a natural health product has only one label, that label shall show all the statements, information and declarations required by these Regulations to be shown on both the inner and outer labels.

90. Every lot number required by these Regulations to be shown on a label of a natural health product shall be preceded by one of the following designations:

(*a*) "Lot number";

(*b*) "Lot No.";

(*c*) "Lot"; or

(*d*) "(L)".

91. Every product number required by these Regulations to be shown on a label of a natural health product shall

(*a*) in the case of a homeopathic medicine, be preceded by the designation "DIN-HM"; and

(*b*) in any other case, be preceded by the designation "NPN".

92. No reference, direct or indirect, to the Act, the *Food and Drug Regulations* or to these Regulations shall be made on any label of or in any advertisement for a natural health product unless the reference is specifically required by law.

93. (1) Subject to section 3 of the Act and section 94, the inner and outer labels shall show the following information in respect of a natural health product:

(*a*) on the principal display panel,

(i) a brand name,

(ii) its product number,

(iii) its dosage form,

(iv) if it is sterile, the words "sterile" and "stérile", and

(v) the net amount in the immediate container in terms of weight, measure or number; and

(*b*) on any panel,

(i) the name and address of the product licence holder,

(ii) if it is imported, the name and address of the importer,

(iii) the common name of each medicinal ingredient that it contains,

(iv) the proper name of each medicinal ingredient it contains, but only if the proper name is not the chemical name,

(v) a list by proper name, or by common name if the proper name is the chemical name, that sets out the quantity of each medicinal ingredient per dosage unit and, if any, the authorized potency of that medicinal ingredient,

(vi) its recommended use or purpose,

(vii) its recommended route of administration,

(viii) its recommended dose,

(ix) its recommended duration of use, if any,

(x) its risk information including any cautions, warnings, contra-indications or known adverse reactions associated with its use,

(xi) its recommended storage conditions, if any,

(xii) its lot number,

(xiii) its expiry date, and

(xiv) a description of the source material of each medicinal ingredient that it contains.

(2) In addition to the requirements set out in subsection (1), the outer label shall show

(*a*) a qualitative list by common name, preceded by the words "non-medicinal ingredients", of all non-medicinal ingredients of the natural health product; and

(*b*) if the natural health product contains mercury or any of its salts or derivatives as a non-medicinal ingredient, a statement that sets out the quantity of mercury contained in the natural health product.

Small Package Labelling

94. (1) Subject to section 3 of the Act, the natural health product shall be labelled as follows if the immediate container is not large enough to accommodate an inner label that complies with the requirements of section 93:

(*a*) the inner label shall show the following in respect of the natural health product, namely,

(i) a brand name,

(ii) a qualitative list by proper name, or by common name if the proper name is the chemical name, that in descending order of quantity per dosage unit, sets out all medicinal ingredients that it contains,

(iii) its recommended dose,

(iv) its recommended duration of use, if any,

(v) its lot number,

(vi) its expiry date,

(vii) its product number,

(viii) if it is sterile, the words "sterile" and "stérile",

(ix) the net amount in the immediate container in terms of weight, measure or number,

(x) its recommended use or purpose, and

(xi) if it does not have an outer label, a statement that refers the purchaser or consumer to the leaflet that is required in accordance with subsection (2); and

(*b*) the outer label, if any, shall be labelled as required under section 93.

(2) If the natural health product does not have an outer label, the statements, information and declarations required to be shown on the outer label under section 93 shall be shown in a leaflet that is affixed or attached to the immediate container.

Security Packaging

95. (1) Subject to subsection (2), no person shall sell or import a natural health product that is packaged unless the natural health product is contained in a security package.

(2) Subsection (1) does not apply to lozenges.

(3) Subject to subsection (4), a statement or illustration that draws attention to the security feature of the security package referred to in subsection (1) shall be shown

(*a*) on the inner label; and

(*b*) if the security feature is a part of the outer package, on the outer label.

(4) Subsection (3) does not apply if the security feature of a security package is self-evident and is an integral part of the immediate container.

Pressurized Containers

96. Sections A.01.061 to A.01.063 of the *Food and Drug Regulations* apply in respect of natural health products.

Cautionary Statements and Child Resistant Packages

97. Subsections C.01.001(2) to (4) and C.01.028(1), paragraphs C.01.028(2)(*b*) and (*c*), section C.01.029, subsection C.01.031(1), paragraphs C.01.031.2(1)(*a*) and (*c*) to (*g*), subsection C.01.031.2(2), and paragraphs C.01.031.2(3)(*a*) and (*c*) of the *Food and Drug Regulations* apply in respect of natural health products.

Medicinal Ingredient Representations

98. Section C.01.012 of the *Food and Drug Regulations* applies in respect of natural health products.

Inspectors

99. Sections A.01.022 to A.01.026 of the *Food and Drug Regulations* apply in respect of natural health products.

Imported Natural Health Products

100. In addition to these Regulations, sections A.01.040 to A.01.044 of the *Food and Drug Regulations* apply in respect of natural health products.

Export Certificates

101. Section A.01.045 of the *Food and Drug Regulations* and Appendix III to those Regulations apply in respect of natural health products.

Sampling of Articles

102. Sections A.01.050 and A.01.051 of the *Food and Drug Regulations* apply in respect of natural health products.

Tablet Disintegration Times

103. Subsection C.01.015(1) and paragraphs C.01.015(2)(*d*) to (*f*) of the *Food and Drug Regulations* apply in respect of natural health products.

PART 6

AMENDMENTS, TRANSITIONAL PROVISIONS AND COMING INTO FORCE

Amendments

Food and Drug Regulations

104. Section C.01.030 of the *Food and Drug Regulations*[1] is repealed.

105. Division 4 of Part D of the Regulations is repealed.

[1] **C.R.C., c. 870**

106. Sections D.05.001 to D.05.007 of the Regulations are repealed.

107. Section D.05.010 of the Regulations is repealed.

Transitional Provisions

108. (1) Subject to section 110, a person may, without complying with these Regulations, sell a drug to which these Regulations apply that is assigned a drug identification number in accordance with section C.01.014.2(1) of the *Food and Drug Regulations*, until the earlier of

(*a*) the day on which an application for a product licence in respect of the drug is disposed of or withdrawn, and

(*b*) December 31, 2009.

(2) A person who sells a drug under subsection (1) shall conduct that sale in accordance with the requirements of the *Food and Drug Regulations*.

109. An application for a product licence that is made in respect of a drug referred to in subsection 108(1) on or before December 31, 2009 is not required to contain the information referred to in paragraph 5(*g*).

110. A sale or importation of a drug to which these Regulations apply that, before January 1, 2004, is authorized for the purposes of a clinical trial under Division 5 of Part C of the *Food and Drug Regulations* shall continue to be regulated under that Division.

111. Until December 31, 2009, a person may sell a lot or batch of a drug referred to in section 108 that is not labelled or packaged in accordance with the requirements of Part 5 if the lot or batch is packaged in accordance with the requirements of the *Food and Drug Regulations*.

112. If during the period beginning on January 1, 2004 and ending on December 31, 2005, the information referred to in section 22 is not available to the licensee prior to commencing the sale of the natural health product or within 30 days after the day on which the license is issued in respect of the natural health product, as the case may be, the licensee shall provide the information to the Minister immediately after it is available to the licensee.

113. (1) A person who, before January 1, 2004, manufactures, packages, labels or imports for sale a drug to which these Regulations apply may continue to conduct the activity in respect of

that drug without complying with the requirements of Parts 2 and 3, until the earlier of

(*a*) the day on which that person's application for a site licence to conduct that activity in respect of the drug is disposed of or withdrawn, and

(*b*) December 31, 2005.

(2) A person who conducts an activity under subsection (1) shall conduct that activity in accordance with the requirements of the *Food and Drug Regulations*.

114. (1) A person who, before January 1, 2004, distributes a drug to which these Regulations apply may continue to conduct the activity in respect of that drug without complying with the requirements of Part 3 until December 31, 2005.

(2) A person who conducts an activity under subsection (1) shall conduct that activity in accordance with the requirements of Division 2 of Part C of the *Food and Drug Regulations*.

115. A person may sell a lot or batch of a drug referred to in section 108 that is not manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with the requirements of Part 3 if

(*a*) the lot or batch is manufactured, packaged and labelled before January 1, 2006; and

(*b*) any manufacturing, packaging, labelling, importation, distribution or storage of the lot or batch that is not conducted in accordance with the requirements of Part 3 is conducted in accordance with the requirements of Division 2 of Part C of the *Food and Drug Regulations*.

Coming into Force

116. (1) Except for section 6, these Regulations come into force on January 1, 2004.

(2) Section 6 comes into force on July 1, 2004.

SCHEDULE 1
(Subsection 1(1))

INCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1.	A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
2.	An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3.	Any of the following vitamins: biotin folate niacin pantothenic acid riboflavin thiamine vitamin A vitamin B_6 vitamin B_{12} vitamin C vitamin D vitamin E
4.	An amino acid
5.	An essential fatty acid
6.	A synthetic duplicate of a substance described in any of items 2 to 5
7.	A mineral
8.	A probiotic

SCHEDULE 2
(Subsection 1(1))

EXCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1.	A substance set out in Schedule C to the Act
2.	A substance set out in Schedule D to the Act, except for the following: (*a*) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and (*b*) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy
3.	A substance regulated under the *Tobacco Act*
4.	A substance set out in any of Schedules I to V of the *Controlled Drugs and Substances Act*
5.	A substance that is administered by puncturing the dermis
6.	An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic