His Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to section 30 (see footnote a) of the Food and Drugs Act (see footnote b), makes the annexed Regulations Amending the Food and Drug Regulations (1475 — Good Manufacturing Practices).

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1475 — GOOD MANUFACTURING PRACTICES)

AMENDMENTS

1. The definition “expiration date” in subsection C.01.001(1) of the Food and Drug Regulations (see footnote 1) is replaced by the following:

“expiration date” means

- (a) in the case of a drug in dosage form, the earlier of the following dates, expressed at minimum as a year and month:
  - (i) the date up to and including which the drug maintains its labelled potency, purity and physical characteristics, and
  - (ii) the date after which the manufacturer recommends that the drug not be used; and
- (b) in the case of an active ingredient, whichever of the following dates is applicable, expressed at minimum as a year and month:
  - (i) the retest date, or
  - (ii) the date after which the manufacturer recommends that the active ingredient not be used. (date limite d'utilisation)

2. (1) The definition “wholesale” in subsection C.01A.001(1) of the Regulations is repealed.

(2) Subsection C.01A.001(1) of the Regulations is amended by adding the following in alphabetical order:

“active ingredient” means a drug that, when used as a raw material in the fabrication of a drug in dosage form, provides its intended effect. (ingrédient actif)
"active pharmaceutical ingredient" means an active ingredient that is used in the fabrication of a pharmaceutical. (ingrédient actif pharmaceutique)

“bulk process intermediate” means an active ingredient that is used in the fabrication of either a drug of biological origin that is listed in Schedule C to the Act or a drug that is listed in Schedule D to the Act. (produit intermédiaire en vrac)

“wholesaler” means a person who is not a distributor described in section C.01A.003 and who sells any of the following drugs other than at retail sale:

- (a) a drug in dosage form that is listed in Schedule C or D to the Act or in Schedule F to these Regulations, or a controlled drug as defined in subsection G.01.001(1);
- (b) an active ingredient; or
- (c) a narcotic as defined in the Narcotic Control Regulations. (grossiste)

(3) Subsection C.01A.001(2) of the Regulations is replaced by the following:

(2) In this Division and in Division 2, “drug” does not include a dilute drug premix, a medicated feed as defined in subsection 2(1) of the Feeds Regulations, 1983, an active ingredient that is for veterinary use or a drug that is used only for the purposes of an experimental study in accordance with a certificate issued under section C.08.015.

3. Section C.01A.003 of the Regulations is replaced by the following:

C.01A.003. This Division and Divisions 2 to 4 apply to the following distributors:

- (a) a distributor of an active ingredient or a drug in dosage form that is listed in Schedule C to the Act; and
- (b) a distributor of a drug for which the distributor holds the drug identification number.

4. Subsection C.01A.004(1) of the Regulations is replaced by the following:

C.01A.004. (1) Subject to subsection (2), no person shall, except in accordance with an establishment licence,

- (a) fabricate, package/label or import a drug;
- (b) perform the tests, including examinations, required under Division 2;
- (c) distribute a drug as set out in section C.01A.003 that is not an active pharmaceutical ingredient; or
- (d) wholesale a drug that is not an active pharmaceutical ingredient.

5. (1) Paragraphs C.01A.005(f) and (g) of the Regulations are replaced by the following:

- (f) whether the applicant proposes to carry out a licensed activity in respect of an active ingredient;
• (g) the address of each building in Canada in which the applicant proposes to fabricate, package/label, test as required under Division 2 or store drugs, specifying for each building the activities and the categories of drugs and, for each category, the dosage form classes, if any, and whether any drug will be in a sterile form;

(2) Subparagraph C.01A.005(m)(i) of the Regulations is replaced by the following:

• (i) the name and address of each fabricator, packager/labeller and tester of the drug and the address of each building in which the drug is fabricated, packaged/labelled or tested, specifying for each building the activities and the categories of drugs and, for each category, the dosage form classes, if any, and whether any drug will be in a sterile form;

(3) Paragraph C.01A.005(n) of the Regulations is replaced by the following:

• (n) in the case of any other importer, the name and address of each fabricator, packager/labeller and tester of the drugs proposed to be imported and the address of each building in which the drugs will be fabricated, packaged/labelled and tested, specifying for each building the activities and the categories of drugs and, for each category, the dosage form classes, if any, and whether any drug will be in a sterile form;

6. (1) Item 4 of Table I to section C.01A.008 of the Regulations is replaced by the following:

<table>
<thead>
<tr>
<th>Item</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>Distribute as set out in paragraph C.01A.003(a) a drug that is not an active pharmaceutical ingredient</td>
</tr>
</tbody>
</table>

(2) Item 7 of Table I to section C.01A.008 of the Regulations is replaced by the following:

<table>
<thead>
<tr>
<th>Item</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.</td>
<td>Wholesale a drug that is not an active pharmaceutical ingredient</td>
</tr>
</tbody>
</table>

(3) Table II to section C.01A.008 of the Regulations is amended by adding the following after item 1:

<table>
<thead>
<tr>
<th>Item</th>
<th>Categories of drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Active ingredients</td>
</tr>
</tbody>
</table>

7. The Regulations are amended by adding the following after section C.02.003:

C.02.003.1 No person shall sell a drug that they have fabricated, packaged/labelled, tested or stored unless they have fabricated, packaged/labelled, tested or stored it in accordance with the requirements of this Division.
**C.02.003.2** (1) No person shall import an active ingredient into Canada for the purpose of sale unless they have in Canada a person who is responsible for its sale.

(2) No person who imports an active ingredient into Canada shall sell any lot or batch of it unless the following appear on its label:

- (a) the name and civic address of the person who imports it; and
- (b) the name and address of the principal place of business in Canada of the person who is responsible for its sale.

*Use in Fabrication*

**C.02.003.3** No person shall use an active ingredient in the fabrication of a drug unless it is fabricated, packaged/labelled, tested and stored in accordance with the requirements of this Division.

**8. Subsections C.02.012(2) to (4) of the Regulations are replaced by the following:**

(2) Every fabricator and packager/labeller and, subject to subsections (3) and (4), every distributor referred to in paragraph C.01A.003(b) and importer of a drug shall maintain a system to ensure that any lot or batch of the drug fabricated and packaged/labelled on premises other than their own is fabricated and packaged/labelled in accordance with the requirements of this Division.

(3) Subsection (2) does not apply to a distributor if the drug is fabricated, packaged/labelled and tested in Canada by a person who holds an establishment licence that authorizes those activities in respect of that drug.

(4) Subsection (2) does not apply to a distributor or importer if the drug is fabricated or packaged/labelled in an MRA country at a recognized building and both of the following requirements are met:

- (a) the address of the building is set out in their establishment licence; and
- (b) they retain a copy of the batch certificate for each lot or batch of the drug that they receive.

**9. Sections C.02.013 and C.02.014 of the Regulations are replaced by the following:**

**C.02.013.** (1) Every fabricator, packager/labeller, wholesaler, distributor referred to in section C.01A.003 and importer of a drug shall have on their premises in Canada a quality control department that is supervised by personnel described in section C.02.006.

(2) Except in the case of a wholesaler or a distributor referred to in paragraph C.01A.003(a), the quality control department shall be a distinct organizational unit that functions and reports to management independently of any other functional unit, including the manufacturing, processing, packaging or sales unit.

**C.02.014.** (1) Except in the case of a wholesaler or a distributor referred to in paragraph C.01A.003(a), no lot or batch of a drug shall be made available for further use in fabrication or for sale unless the person in charge of the quality control department approves the sale or the further use.
(2) A drug that is returned to its fabricator, packager/labeller, wholesaler, distributor referred to in section C.01A.003 or importer shall not be made available for further use in fabrication or for further sale unless the person in charge of the quality control department approves the further sale or further use.

(3) No lot or batch of a raw material or packaging/labelling material shall be used in the fabrication or packaging/labelling of a drug unless the person in charge of the quality control department approves the use.

(4) No lot or batch of a drug shall be reprocessed unless the person in charge of the quality control department approves the reprocessing.

10. Subsections C.02.018(1) and (2) of the Regulations are replaced by the following:

C.02.018. (1) Each lot or batch of a drug shall, before it is made available for further use in fabrication or for sale, be tested against the specifications for that drug.

(2) No lot or batch of a drug shall be made available for further use in fabrication or for sale unless it complies with the specifications for that drug.

11. Sections C.02.019 to C.02.023 of the Regulations are replaced by the following:

C.02.019. (1) A packager/labeller of a drug, a distributor referred to in paragraph C.01A.003(b) and an importer of a drug other than an active ingredient shall perform the finished product testing on a sample of the drug that is taken either

- (a) after receipt of each lot or batch of the drug on their premises in Canada; or
- (b) before receipt of each lot or batch of the drug on their premises in Canada if the following conditions are met:
  - (i) the packager/labeller, distributor or importer
    - (A) has evidence satisfactory to the Director to demonstrate that drugs sold to them by the vendor of that lot or batch are consistently manufactured in accordance with and consistently comply with the specifications for those drugs, and
    - (B) undertakes periodic complete confirmatory testing, with a frequency satisfactory to the Director, and
  - (ii) the drug has not been transported or stored under conditions that may affect its compliance with the specifications for that drug.

(2) If the packager/labeller, distributor or importer receives a lot or batch of a drug on their premises in Canada the useful life of which is more than 30 days, the lot or batch shall be tested for identity and the packager/labeller shall confirm the identity after the lot or batch is packaged/labelled.

(3) Subsections (1) and (2) do not apply to a distributor if the drug is fabricated, packaged/labelled and tested in Canada by a person who holds an establishment licence that authorizes that activity.
(4) Subsections (1) and (2) do not apply to a distributor or importer if the drug is fabricated, packaged/labelled and tested in an MRA country at a recognized building and both of the following requirements are met:

- (a) the address of the building is set out in their establishment licence; and
- (b) they retain a copy of the batch certificate for each lot or batch of the drug that they receive.

**Records**

C.02.020. (1) Every fabricator, packager/labeller, distributor referred to in paragraph C.01A.003(b) and importer shall maintain all of the following records on their premises in Canada for each drug that they fabricate, package/label, distribute or import:

- (a) except in the case of an importer of an active pharmaceutical ingredient, master production documents for the drug;
- (b) evidence that each lot or batch of the drug has been fabricated, packaged/labelled, tested and stored in accordance with the procedures described in the master production documents;
- (c) evidence that the conditions under which the drug was fabricated, packaged/labelled, tested and stored are in compliance with the requirements of this Division;
- (d) evidence that establishes the period during which the drug in the container in which it is sold or made available for further use in fabrication will meet the specifications for that drug; and
- (e) evidence that the finished product testing referred to in section C.02.018 was carried out and the results of that testing.

(2) Every distributor referred to in paragraph C.01A.003(b) and importer shall make available to the Director, on request, the results of testing performed on raw materials and packaging/labelling materials for each lot or batch of a drug that it distributes or imports.

(3) Every fabricator shall maintain on their premises written specifications for all raw materials and adequate evidence of the testing of those raw materials referred to in section C.02.009 and of the test results.

(4) Every person who packages a drug shall maintain on their premises written specifications for all packaging materials and adequate evidence of the examination or testing of those materials referred to in section C.02.016 and of any test results.

(5) Every fabricator, packager/labeller and tester shall maintain on their premises in Canada detailed plans and specifications of each building in Canada where they fabricate, package/label or test drugs and a description of the design and construction of those buildings.

(6) Every fabricator, packager/labeller and tester shall maintain on their premises in Canada personnel records in respect of each person who is employed to supervise the fabrication, packaging/labelling and testing of drugs, including the person’s title, responsibilities, qualifications, experience and training.
C.02.021. (1) All records and evidence of the fabrication, packaging/labelling, finished product testing referred to in section C.02.018 and storage of a drug in dosage form that are required to be maintained under this Division shall be retained for one year after the expiration date of the drug unless the person’s establishment licence specifies some other period.

(2) Subject to subsection (4), all records and evidence of the fabrication, packaging/labelling, finished product testing referred to in section C.02.018 and storage of an active ingredient that are required to be maintained under this Division shall be retained in respect of each lot or batch of the active ingredient for the following period unless the person holds an establishment licence that specifies some other period:

- (a) in the case of an active ingredient that has a retest date, three years after the lot or batch has been completely distributed; or
- (b) in any other case, one year after the expiration date of the lot or batch.

(3) Subject to subsection (4), all records and evidence of the raw material testing referred to in section C.02.009 and of the testing of packaging/labelling materials that are required to be maintained under this Division shall be retained for five years after the raw materials and packaging/labelling materials were last used in the fabrication or packaging/labelling of a drug unless the person’s establishment licence specifies some other period.

(4) If a fabricator is required to maintain records and evidence in respect of the same active ingredient under subsections (2) and (3), they shall maintain them for the longest period that is applicable.

C.02.022. (1) Every wholesaler, distributor referred to in section C.01A.003 and importer of a drug in dosage form shall retain records of sale of each lot or batch of the drug, which enable them to recall the lot or batch from the market, for one year after the expiration date of that lot or batch unless their establishment licence specifies some other period.

(2) Every distributor of an active ingredient referred to in paragraph C.01A.003(a) and every wholesaler and importer of an active ingredient shall retain records of sale of each lot or batch of the active ingredient, which enable them to recall the lot or batch from the market, for the following period unless the person holds an establishment licence that specifies some other period:

- (a) in the case of an active ingredient that has a retest date, three years after the lot or batch has been completely distributed; or
- (b) in any other case, one year after the expiration date of the lot or batch.

C.02.023. (1) On receipt of a complaint or any information respecting the quality of a drug or its deficiencies or hazards, every fabricator, packager/labeller, wholesaler, distributor referred to in section C.01A.003 and importer of the drug shall make a record of the complaint or information that contains the following:

- (a) the results of any investigation carried out under subsection C.02.015(2) and, if applicable, the corrective action taken; or
- (b) the name and business address of the person in charge of the quality control department to whom the complaint or information was forwarded under subsection C.02.015(2.1) and the date on which it was forwarded.
(2) Records referred to in subsection (1) shall be retained for the following period unless the person holds an establishment licence that specifies some other period:

- (a) in the case of a drug in dosage form, one year after the expiration date of the lot or batch of the drug; and
- (b) in the case of an active ingredient,
  - (i) if the active ingredient has a retest date, three years after the lot or batch has been completely distributed, or
  - (ii) in any other case, one year after the expiration date of the lot or batch of the active ingredient.

12. The Regulations are amended by adding the following after section C.02.024:

C.02.024.1 Every distributor of an active ingredient referred to in paragraph C.01A.003(a) and every fabricator, packager/labeller, wholesaler and importer of an active ingredient shall add all of the following information to the documentation that accompanies the active ingredient, immediately after any like information that has been added by another person:

- (a) their establishment licence number, or if there is none, their name, address, telephone number, fax number and email address;
- (b) an indication whether they have fabricated, packaged/labelled, wholesaled, distributed or imported the active ingredient and the date on which that activity was carried out;
- (c) the expiration date; and
- (d) the lot number.

13. Section C.02.025 of the Regulations is replaced by the following:

C.02.025. (1) Every distributor referred to in paragraph C.01A.003(b) and importer of a drug in dosage form shall retain in Canada a sample of each lot or batch of the packaged/labelled drug for one year after the expiration date of the drug unless their establishment licence specifies some other period.

(2) Subject to subsection (4), the fabricator of a drug in dosage form shall retain a sample of each lot or batch of raw materials used in the fabrication for two years after the materials were last used in the fabrication unless their establishment licence specifies some other period.

(3) Subject to subsection (4), the fabricator of an active ingredient shall retain a sample of each lot or batch of it for the following period unless their establishment licence specifies some other period:

- (a) in the case of an active ingredient that has a retest date, three years after the lot or batch has been completely distributed; or
- (b) in any other case, one year after the expiration date of the lot or batch.

(4) If a fabricator is required to maintain samples in respect of the same active ingredient under subsections (2) and (3), they shall maintain them for the longest period that is applicable.

14. Sections C.02.027 and C.02.028 of the Regulations are replaced by the following:
C.02.027. (1) Every distributor referred to in paragraph C.01A.003(b) and importer of a drug in dosage form shall establish the period during which each drug in the package in which it is sold will comply with the specifications for that drug.

(2) Every fabricator and importer of an active ingredient shall establish the period during which each drug in the package in which it is sold will comply with the specifications for that drug.

C.02.028. (1) Every distributor referred to in paragraph C.01A.003(b) and importer of a drug in dosage form shall monitor, by means of a continuing program, the stability of the drug in the package in which it is sold.

(2) Every fabricator and importer of an active ingredient shall monitor, by means of a continuing program, the stability of the drug in the package in which it is sold.

15. The definition “drug” in section C.03.001 of the Regulations is replaced by the following:

“drug” means a drug that is listed in Schedule C to the Act that is in dosage form or a drug that is an active ingredient of biological origin that can be used in the preparation of a drug listed in that Schedule; (drogue)

16. The definition “drug” in section C.04.001 of the Regulations is replaced by the following:

“drug” means a drug that is listed in Schedule D to the Act that is in dosage form or a drug that is an active ingredient that can be used in the preparation of a drug listed in that Schedule; (drogue)

TRANSITIONAL PROVISIONS

17. (1) Every person who, on the day on which these Regulations come into force, fabricates, packages/labels, tests or imports an active pharmaceutical ingredient may continue to do so without an establishment licence if they submit an application for a licence under section C.01A.005 of the Food and Drug Regulations within three months after that day.

(2) Subsection (1) applies until the determination of the licence application under section C.01A.008 or C.01A.010 of the Food and Drug Regulations.

18. The Food and Drug Regulations, as they read immediately before the coming into force of these Regulations, continue to apply in respect of whole blood and blood components for a period of one year after the day on which these Regulations come into force.

COMING INTO FORCE

19. These Regulations come into force six months after the day on which they are published in the Canada Gazette, Part II.