REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1447 — GOOD MANUFACTURING PRACTICES)

AMENDMENTS

1. The definition "quality control department" in section C.02.002 of the *Food and Drug Regulations*[a] is repealed.

2. Section C.02.003 of the French version of the Regulations is replaced by the following:

C.02.003. Il est interdit au distributeur visé à l'alinéa C.01A.003*b*) et à l'importateur de vendre une drogue qui n'a pas été manufacturée, emballée-étiquetée, analysée et entreposée conformément aux exigences du présent titre.

3. The portion of section C.02.004 of the Regulations before paragraph (*a*) is replaced by the following:

C.02.004. The premises in which a lot or batch of a drug is fabricated, packaged/labelled or stored shall be designed, constructed and maintained in a manner that

4. Section C.02.013 of the Regulations is replaced by the following:

C.02.013. (1) Every fabricator, packager/labeller, wholesaler, distributor referred to in paragraph C.01A.003(*b*) and importer 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, the quality control department referred to in subsection (1) 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.

5. (1) Subsections C.02.014(1) and (2) of the Regulations are replaced by the following:

C.02.014. (1) Except in the case of a wholesaler, no lot or batch of a drug shall be made available for sale unless the sale of that lot or batch is approved by the person in charge of the quality control department.

(2) A drug that is returned to the fabricator, packager/labeller, wholesaler, distributor referred to in paragraph C.01A.003(*b*) or importer thereof shall not be made available for further sale unless the sale of that drug is approved by the person in charge of the quality control department.

(2) Subsection C.02.014(4) of the Regulations is replaced by the following:

(4) No lot or batch of a drug shall be reprocessed or reworked without the approval of the person in charge of the quality control department.

6. Subsection C.02.015(2) of the Regulations is replaced by the following:

(2) The person in charge of the quality control department shall cause to be investigated every complaint or other information respecting the quality of a drug or its deficiencies or hazards that is received and cause corrective action to be taken if necessary.

7. Subsections C.02.023(1) and (2) of the Regulations are replaced by the following:

C.02.023. On receipt of a complaint or other information respecting the quality of a drug or its deficiencies or hazards every fabricator, packager/labeller, wholesaler, distributor referred to in paragraph C.01A.003(*b*) or importer of the drug, as the case may be, shall make a record of the complaint or other information and its investigation and retain the record for a period of at least one year after the expiration date of the lot or batch of that drug, unless their establishment licence specifies otherwise.

8. Subsection C.02.025(2) of the Regulations is replaced by the following:

(2) The fabricator shall retain a sample of each lot or batch of medicinal ingredient used in the fabrication of a drug for a period of at least two years after the medicinal ingredients were last used in the fabrication of the drug, unless the fabricator's establishment licence specifies otherwise.

9. Section C.02.026 of the Regulations is replaced by the following:

C.02.026. The samples referred to in section C.02.025 shall be

(*a*) retained in a package that is identical to that in which the drug or medicinal ingredient is stored, or that is equivalent with respect to stability;

(*b*) appropriately identified; and

(*c*) of sufficient quantity to determine whether the drug or medicinal ingredient complies with the specifications for that drug or medicinal ingredient.

10. Section C.02.030 of the Regulations is replaced by the following:

C.02.030. The provisions of paragraph C.02.020(1)(*d*) and sections C.02.025, C.02.027 and C.02.028 do not apply to medical gases.

COMING INTO FORCE

11. These Regulations come into force on the day on which they are registered.