NORTON ROSE FULBRIGHT

Pharma in brief - Canada

Health Canada releases draft guidance documents for consultation related to good manufacturing practices and drug establishment licensing

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Summary

On January 18, 2017, Health Canada released five draft guidance documents for consultation relating to good manufacturing practices and drug establishment licensing:

- GUI-0001: Good manufacturing practices guide for drug products
- GUI-0023: Risk classification guide for drug good manufacturing practices observations
- GUI-0031: Good manufacturing practices for medical gases
- GUI-0080: How to demonstrate foreign building compliance with drug good manufacturing practices
- GUI-0119: Annex 1 to the good manufacturing practices guide – manufacture of sterile drugs

Interested stakeholders can obtain copies of the draft guidance documents by emailing HPIL-Consultation-IPSOP@hc-sc.gc.ca. The consultation period is open until **April 18, 2017.**

Overview of key changes

Many of the changes set out in the draft guidance documents relate to amendments to the *Food and Drug Regulations* that came into force on November 8, 2013, that extended the requirements of Divisions 1A (Establishment Licensing) and Division 2 (Good Manufacturing Practices) to active ingredients used in pharmaceutical drugs for human use. Although the amendments came into force on November 8, 2013, implementation occurred over a three-year period with full implementation by November 8, 2016.

The key changes to the guidance documents are set out below.

GUI-0001: Good manufacturing practices guide for drug products

This guidance document is applicable to all fabricators, packagers/labelers, testers, importers, distributors and wholesalers who work with drugs. Highlights of this draft guidance document include:

- Content to address issues such as data integrity and new regulations pertaining to active pharmaceutical ingredients (API);

- Additional responsibility for importers of products from non-MRA (Mutual Recognition Agreement) countries, including requirements to conduct audits of foreign buildings and increased retesting of imported products;
- Removal of guidance related to sterile products and replacement with guidance published by the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

GUI-0023: Risk classification guide for drug good manufacturing practices observations

This guidance document is applicable to all fabricators, packagers/labelers, testers, importers, distributors and wholesalers who work with drugs. Highlights of this draft guidance document include:

- An expanded scope to include on-site inspections of domestic and foreign buildings relates to finished dosage form and API sites;
- Information on Health Canada's assessment of good manufacturing practices evidence to ensure information submitted by importers meets foreign building compliance requirements within Division 2 of the *Food and Drug Regulations*;
- New sample observations to reflect requirements being introduced by the draft guidance documents GUI-0001 (Good manufacturing practices guide for drug products) and GUI-0119 (Annex 1 to the good manufacturing practices guide – manufacture of sterile drug products).

GUI-0031: Good manufacturing practices for medical gases

This guidance document is applicable to all fabricators, packagers/labelers, testers, importers, distributors, wholesalers and home care providers who work with medical gases. Highlights of this draft guidance document include:

- A revised definition for wholesaler based on amendments to the *Food and Drug Regulations* relating to APIs;
- Updates on quality risk management and quality management through a product's lifecycle;
- An expanded rationale related to senior management responsibilities, deviations and non-conformances, accuracy and reliability of data and records, and records expectations.

GUI-0080: How to demonstrate foreign building compliance with drug good manufacturing practices

This guidance document is applicable to all Canadian importers who work with drugs. Highlights of this draft guidance document include:

- Incorporation of information related to foreign buildings that fabricate, package, label or test non-sterile APIs;
- Incorporation of the "new evidence required by date" to replace the expiry date on a drug establishment license;
- Revised evidence requirements for foreign building that fabricate, package, label or test finished dosage forms or APIs.

GUI-0119: Annex 1 to the good manufacturing practices guide – manufacture of sterile drugs

This guidance document is applicable to applicable to all fabricators, packagers/labelers, testers, importers, and distributors who work with sterile drugs.

Health Canada is seeking feedback on whether to adopt the international good manufacturing practice guidance published by the Pharmaceutical Inspection Cooperation Scheme (PIC/S) as set out in this draft guidance document.

Link to Health Canada's Notice to Stakeholders

Notice to Stakeholders – Release of Guidance Documents for Consultation: various good manufacturing practices and drug establishment licensing guidance documents

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For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

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