



## The GMP Gazette™

*Hot topics in May 2010 related to Health Canada (HPFBI, NHPD), U.S. FDA and USP.*

### Highlights:

- Health Products and Food Branch Inspectorate Policy on Counterfeit Health Products (POL-0048)
- 30-Day Consultation on the Guidance Document to Assist in Distinguishing between Natural Health Products and Ingredients (Replaces Natural Health Product Raw Material Policy)
- NHPD Fourth Quarterly Report for 2009-10 Fiscal Year
- Natural Health Products (Unprocessed Product Licence Applications) Regulations
- International Conference on Harmonisation Quality: Guidance for Industry Q8, Q9, and Q10 Questions and Answers

### Health Canada - Drug Products (HPFBI)

#### Hot topic:

- Health Products and Food Branch Inspectorate Policy on Counterfeit Health Products (POL-0048)

Health Products and Food Branch Inspectorate Policy on Counterfeit Health Products (POL-0048)

- [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/pdf/compli-conform/activit/pol\\_0048\\_counterfeit-contrefacon\\_eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli-conform/activit/pol_0048_counterfeit-contrefacon_eng.pdf)
- This document provides the staff and stakeholders of the Health Products and Food Branch Inspectorate, as well as the public, with guiding principles of Health Canada's Decision-Making Framework for Identifying, Assessing, and Managing Health Risks to address the issue of counterfeit health products.
- These principles will mitigate the health and safety risks posed by counterfeit health products to further promote the safety, quality, and efficacy of all health products in the Canadian supply chain.
- Posted May 14, 2010.

The GMP Gazette™ (Hot topics in May 2010), Page 1 of 5

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## Health Canada - Natural Health Products Directorate (NHPD)

### Hot topics:

- 30-Day Consultation on the Guidance Document to Assist in Distinguishing between Natural Health Products and Ingredients (Replaces Natural Health Product Raw Material Policy)
- NHPD Fourth Quarterly Report for 2009-10 Fiscal Year
- Natural Health Products (Unprocessed Product Licence Applications) Regulations
- Supplementary Quality Assurance Report Form Homeopathic Medicines (HM)
- Quality Assurance Report (QAR) Form
- Updated International Certificate Forms
- Foreign Site Reference Number Authorization Form
- Foreign Site Reference Number Application Form

30-Day Consultation on the Guidance Document to Assist in Distinguishing between Natural Health Products and Ingredients (Replaces Natural Health Product Raw Material Policy)

- [http://www.qualityandcompliance.com/pdfs/NHP\\_and\\_ingredients\\_consultation.pdf](http://www.qualityandcompliance.com/pdfs/NHP_and_ingredients_consultation.pdf)
- The Natural Health Product (NHP) Raw Material Policy was recently removed from the Natural Health Products Directorate (NHPD) website in order for it to be revised. In keeping with the Natural Health Products Directorate's (NHPD) Risk-Based Approach (RBA) to the regulation of NHPs, the NHPD is now proposing to replace the NHP Raw Material Policy with the Guidance Document to Assist in Distinguishing between Natural Health Products and Ingredients.
- NHPD welcomes comments on the draft guidance document. Please submit your comments to [nhpd-dpsn.activ@hc-sc.gc.ca](mailto:nhpd-dpsn.activ@hc-sc.gc.ca) by June 17th, 2010.
- BPRA email received May 18, 2010.

NHPD Fourth Quarterly Report for 2009-10 Fiscal Year

- [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/report-rapport/qar\\_tri\\_4-10-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/report-rapport/qar_tri_4-10-eng.php)
- The Status of Applications Quarterly Report is a publication of Health Canada's NHPD, the federal department responsible for the regulation of natural health products sold in Canada.
- The purpose of this report is to provide the Canadian public with statistical data on the product and site licence applications received and processed by the NHPD.
- Posted May 20, 2010.

The GMP Gazette™ (Hot topics in May 2010), Page 2 of 5

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## Health Canada - Natural Health Products Directorate (NHPD)

### Natural Health Products (Unprocessed Product Licence Applications) Regulations

- <http://www.gazette.gc.ca/rp-pr/p1/2010/2010-05-08/html/reg16-eng.html>
- The proposed Regulations would provide a temporary instrument to permit NHPs, for which a product licence application has been filed with Health Canada but a decision to issue or refuse a licence has not been made, to be sold on the market, with an exemption to the prohibition on sale in the NHPR. The Regulations would make the sale of these products legal.
- The exemption must be provided by Health Canada through a process that is initiated no later than 180 days from the filing of the application, if the Minister has not within that time made a decision to issue or refuse a licence, and is satisfied that the product meets certain safety criteria.
- For those product licence applications filed with Health Canada before the coming-into-force of these Regulations, the 180 days may have already passed, and therefore an exemption number may be issued in less than 180 days. The exemption, granted by the Minister in the form of an exemption number, would stay in effect until the application(s) is withdrawn, is processed and that a decision to issue or refuse a licence is made, or until the proposed Regulations are repealed.
- The proposed Regulations would also assert key safety oversight measures such as adverse reaction reporting, site licensing, and the authority to suspend or stop sales if a safety issue is identified. The proposed Regulations would be repealed 30 months after coming into force.
- Posted May 8, 2010.

### Supplementary Quality Assurance Report Form Homeopathic Medicines (HM)

- [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/forms\\_sqar-sraq-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/forms_sqar-sraq-eng.php)
- New Supplementary Quality Assurance Report Form Homeopathic Medicines (HM).
- Posted May 3, 2010.

### Quality Assurance Report (QAR) Form

- [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/form\\_qar-raq-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/form_qar-raq-eng.php)
- New Quality Assurance Report (QAR) Form.
- Posted May 3, 2010.

The GMP Gazette™ (Hot topics in May 2010), Page 3 of 5

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## Health Canada - Natural Health Products Directorate (NHPD)

Updated International Certificate Forms

- <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/int-certificat/form/index-eng.php>
- Included are: Application Form for Good Manufacturing Certificate of Compliance, International Trade Certificate and Request for Stamping Form.
- Posted May 25, 2010.

Foreign Site Reference Number Authorization Form

- [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/form\\_fsrn-nrse-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/form_fsrn-nrse-eng.php)
- This form is to be completed by a foreign site that has been issued a Foreign Site Registration Number by Health Canada and intends to provide a Canadian importer access to their good manufacturing practice (GMP) information.
- Posted May 25, 2010.

Foreign Site Reference Number Application Form

- [http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/form\\_fsrna-anrse-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/form_fsrna-anrse-eng.php)
- Posted May 25, 2010.

The GMP Gazette™ (Hot topics in May 2010), Page 4 of 5

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## U.S. FDA

Hot topic:

- International Conference on Harmonisation Quality: Guidance for Industry Q8, Q9, and Q10 Questions and Answers

International Conference on Harmonisation Quality: Guidance for Industry Q8, Q9, and Q10 Questions and Answers

- <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM210822.pdf>
- Since the Q8, Q9, and Q10 guidance were made final, experiences implementing the guidances in the ICH regions have given rise to requests for clarification. This question and answer (Q&A) document is intended to clarify key issues. The guidance reflects the current working procedure of the ICH Quality Implementation Working Group (Q-IWG) for implementing the Q8, Q9, and Q10 guidances.
- The benefits of harmonizing technical requirements across the ICH regions can be realized only if the various quality ICH guidances are implemented and interpreted in a consistent way across the three regions. The Q-IWG is tasked to develop Q&As to facilitate implementation of existing quality guidance.
- Posted May 5, 2010.

## USP

Hot topic:

- USP Spring Newsletter

USP Spring Newsletter

- <http://www.usp.org/pdf/EN/aboutUSP/theStandard2010Spring.pdf>

## PIC/S

Hot topic:

- No new topics this month

The GMP Gazette™ (Hot topics in May 2010), Page 5 of 5

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