



The GMP Gazette™

Hot topics in March 2010 related to Health Canada (HPFBI, NHPD).

Note: There are no hot topics related to the U.S. FDA, PIC/S or USP in this edition of The GMP Gazette™.

Highlights:

- HPFBI: Good Manufacturing Practices (GMP) – Establishment Licence (EL) Information Sessions
- NHPD: Regulatory Review Action Plan – Phase I
- NHPD: Labelling Requirements Checklist

Health Canada - Drug Products (HPFBI)

Hot topics:

- Release of Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)
- Good Manufacturing Practices (GMP) – Establishment Licence (EL) Information Sessions

Release of Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)

- http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applc-demande/guides/seb-pbu/notice-avis_seb-pbu_2010-eng.php
- The objective of this document is to provide guidance to sponsors to enable them to satisfy the information and regulatory requirements under the *Food and Drugs Act* and *Regulations* for the authorization of subsequent entry biologics (SEBs) in Canada.
- Two draft versions of this guidance document have been shared for consultation purposes on February 27, 2008, and March 27, 2009. Consultation reports are available upon request. As no transition period is required, the guidance will be effective on the date of publication.
- Posted March 5, 2010.



Health Canada - Drug Products (HPFBI)

Good Manufacturing Practices (GMP) – Establishment Licence (EL) Information Sessions

- <http://www.hc-sc.gc.ca/dhp-mps/consultation/compli-conform/2010gmp-bpf-rs-tp-index-eng.php>
- We are pleased to inform you that Health Canada has finalized the guidance document entitled "Good Manufacturing Practices (GMP) Guidelines - 2009 Edition (GUI-0001)", which is available on Health Canada's Compliance and Enforcement website under "What's New". Implementation of the guidelines came into effect on November 8, 2009.
- In order to inform stakeholders of changes, new requirements, and to answer their questions, Health Canada will be delivering information sessions in the following six (6) Canadian cities: Halifax, Montreal, Toronto, Winnipeg, Calgary, and Vancouver. The sessions are planned for the end of April and throughout May. Each session will be a day-and-a-half long (1.5 days), with the exception of Halifax, which will be one (1) day. Two sessions will be offered in Toronto and in Montreal, and depending on interest, a bilingual or a French session will be held in Montreal.
- Posted March 28, 2010.

Health Canada - Natural Health Products Directorate (NHPD)

Hot topics:

- Labelling Requirements Checklist
- Regulatory Review Action Plan – Phase I
- New Single Ingredient Monograph – Conjugated Linoleic Acid
- New Single Ingredient Monograph – Cod Liver Oil
- Finished Product Specification Template

Labelling Requirements Checklist

- <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/label-list-etiquet-eng.php>
- Applicants are responsible for ensuring that the label complies with the Labelling and Packaging requirements set out in Part 5 of the *Natural Health Products Regulations* (NHPR), specifically Sections 93, 94, 95, and 97, if applicable. As per section 86(1) no person shall sell a Natural Health Product (NHP) unless it is packaged and labelled in accordance with these *Regulations*.
- The following checklist is a resource tool to be used for label generation by applicants intending to submit a Product Licence Application (PLA) for an NHP.
- Posted March 17, 2010.

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Health Canada - Natural Health Products Directorate (NHPD)

The Natural Health Products Directorate's Regulatory Review Action Plan – Phase I

- <http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/act-plan-act-phase1-eng.php>
- This document describes the four themes of the framework and also provides an outline of the first phase (Fall 2009 - Fall 2010) of the Action Plan. The NHPD will report on issues considered under the scope of this Action Plan in multiple phases determined by priority. If not in Phase I, the NHPD hopes to explore each policy issue compiled in later phases of this Action Plan.
- Posted March 9, 2010.

New Single Ingredient Monograph – Conjugated Linoleic Acid

- http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/mono_cla-alc-eng.php
- This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.
- Posted March 9, 2010.

New Single Ingredient Monograph – Cod Liver Oil

- http://www.qualityandcompliance.com/pdfs/Cod_liver_oil_2010-02-24.pdf
- This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.
- Posted March 8, 2010.

Finished Product Specification Template

- Overview: http://www.qualityandcompliance.com/pdfs/Finished_Product_Specification_Template.pdf
- Template: http://www.qualityandcompliance.com/pdfs/FPS_ENG.pdf
- User Guide: http://www.qualityandcompliance.com/pdfs/FPS_User_Guide_EN.pdf
- As part of the Natural Health Products Directorate's process improvement initiatives, a Finished Product Specifications (FPS) form has been developed to help applicants comply with the quality requirements set out in Section 44 of the *Natural Health Products Regulations*. The NHPD released a copy of the FPS form for use in a pilot with the new Abbreviated Labelling Standards in Fall 2009. Due to the success of the FPS form in this pilot, the NHPD is now releasing an updated version for all non-compendial applications.
- Email received from BPRA March 24, 2010.



U.S. FDA

Hot topic:

- No new topics this month.

USP

Hot topic:

- No new topics this month.

PIC/S

Hot topic:

- No new topics this month.