



The GMP Gazette™

Hot topics in January 2012 related to Health Canada (HPFBI), U.S. FDA, and USP.

Highlights:

- Revised Guidance Document—Considerations for Inclusion of Women in Clinical Trials and Analysis of Data by Sex
- Interim Notification Pilot Program for Low-Risk Veterinary Health Products
- Guidance for Industry—Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

Health Canada—Health Products and Food Branch Inspectorate (HPFBI)

Hot topics:

- Revised Guidance Document—Considerations for Inclusion of Women in Clinical Trials and Analysis of Data by Sex
- Interim Notification Pilot Program for Low-Risk Veterinary Health Products

[Revised Guidance Document— Considerations for Inclusion of Women in Clinical Trials and Analysis of Data by Sex](#)

- This guidance document updates the 1997 guidance document on the Inclusion of Women in Clinical Trials.
- It addresses the following:
 - Clarifies the scope of the original guidance, including the populations to which it applies
 - Provides further guidance to sponsors on issues not addressed or minimally addressed in the 1997 guidance document. These include: inadvertent pregnancy in the course of a clinical trial and inclusion of pregnant and breastfeeding women in clinical studies/trials
 - Supports and encourages good therapeutic product development practices, including new approaches and methodologies, to identify and analyze potential sex differences across the product life cycle
 - Provides guidance within the current regulatory environment
- Consultation is open for comment until March 9, 2012.
- Posted January 9, 2012.

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Health Canada—Health Products and Food Branch Inspectorate (HPFBI)

[Interim Notification Pilot Program for Low-Risk Veterinary Health Products](#)

- Voluntary program administered by an independent third party, North American Compendiums (NAC).
- Program allows a "notifier" to obtain a notification number from NAC if conditions established by Health Canada are met.
- North American Compendiums started accepting Notification Applications on February 6, 2012 and will start issuing Notification Numbers on March 19, 2012.
- See [Frequently Asked Questions](#).
- Posted January 19, 2012.

Health Canada—Natural Health Products Directorate (NHPD)

- No new topics this month.

U.S. FDA

- Guidance for Industry—Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

[Guidance for Industry—Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling](#)

- Guidance is intended to clarify the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertising for prescription human drugs, including biological drug products, and prescription animal drugs.
- Recommendations in this guidance pertain to product names in traditional print media promotion. For example:
 - Journal ads
 - Detail aids
 - Brochures
 - Audio-visual promotional labeling such as videos shown in a healthcare provider's office
 - Broadcast media promotion such as television and radio advertisements
 - Electronic and computer-based promotional labeling and advertisements, such as Internet promotion, social media, e-mails, CD-ROMs, and DVDs
- Posted January 24, 2012.



USP

- Proposed Standard Offers Best Practices to Help Ensure Supply Chain Integrity, Reduce Risks of Counterfeit or Mishandled Medicines

[Proposed Standard Offers Best Practices to Help Ensure Supply Chain Integrity, Reduce Risks of Counterfeit or Mishandled Medicines](#)

- In an effort to encourage comprehensive public standards across the pharmaceutical industry, the U.S. Pharmacopeial Convention (USP) is proposing a set of recommended best practices that will help ensure that medicines can be traced back to their original manufacturer, are not adulterated or counterfeited, and are transported to their intended destination with their quality intact.
- USP is seeking broad feedback on these recommendations on supply chain integrity.
- See [General Chapter <1083>](#)
- Posted January 6, 2012.

PIC/S

- No new topics this month.