



The GMP Gazette™

Hot topics in February 2010 related to Health Canada (HPFBI, NHPD) and the U.S. FDA.

Highlights:

- Health Canada HPFBI – Mandatory and Voluntary Problem Reporting for Medical Devices
- Health Canada NHPD – Statement Regarding NAPRA Resolution on Unlicensed NHPs
- US FDA – Guidance for Industry Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes

Health Canada - Drug Products (HPFBI)

Hot topic:

- Mandatory and Voluntary Problem Reporting for Medical Devices

Mandatory and Voluntary Problem Reporting for Medical Devices

- http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/mavprfmd-rioevraim-eng.pdf
- Revisions were made to this document to reflect changes to the Health Products and Food Branch organizational structure. There were no other changes made to the content of the document.
- Posted February 2, 2010.



Health Canada - Natural Health Products Directorate (NHPD)

Hot topics:

- Health Canada Departmental Statement Regarding NAPRA Resolution on Unlicensed NHPs
- New Natural Health Product Monograph- Conjugated Linoleic Acid (CLA)

Health Canada Departmental Statement Regarding NAPRA Resolution on Unlicensed NHPs

- <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/napra-stmt-anorp-avis-eng.php>
- Health Canada is aware of the National Association of Pharmacy Regulatory Authorities (NAPRA) Position Statement on the sale of Non-Approved Marketed Health Products indicating that pharmacists should not sell a marketed health product without a Drug Identification Number (DIN), Natural Product Number (NPN) or Drug Identification Number for Homeopathic Medicine (DIN-HM). The position statement does not affect Health Canada's Compliance Policy for NHPs. The current policy will continue to be applied and actions will be taken where appropriate, based on the risk that a product represents.
- Health Canada's compliance and enforcement efforts target primarily products that present an unacceptable risk to the health of Canadians. As such, the vast majority of natural health products have not been the target of compliance and enforcement actions.
- Some products which had been labelled with Drug Identification Numbers (DINs) will now require Natural Health Product Numbers (NPN) as of January 1, 2010. In most circumstances, manufacturers will still be able to sell NHPs with non-compliant labelling (still bearing the "DIN") for a period of 6 to 12 months. Provided that no significant risks have been identified, enforcement discretion will be applied so as not to cause a disruption to the market by allowing depletion of product still bearing a DIN.
- Canadians can identify NHPs that have been authorized for sale by Health Canada by looking for the NPN, DIN-HM or DIN on the product label. Since 2004, Health Canada has issued over 18,000 product licences which represent approximately 23,000 NHPs. Although there are 23,000 licensed NHP products, an average retail location may carry less. (An average retail outlet carries up to 6,000 products.)
- Posted February 1, 2010.



Health Canada - Natural Health Products Directorate (NHPD)

New Natural Health Product
Monograph- Conjugated Linoleic
Acid (CLA)

- [http://www.qualityandcompliance.com/pdfs/Conjugated linoleic acid 2010-01-27.pdf](http://www.qualityandcompliance.com/pdfs/Conjugated%20linoleic%20acid%202010-01-27.pdf)
- NHPD has recently developed a new monograph for Conjugated Linoleic Acid (CLA). Although it is not yet available on the Natural Health Product Ingredient Database (NHPID), the monograph is available for use.
- BPRA email message received February 3, 2010.

U.S. FDA

Hot topic:

- [Guidance for Industry Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes](#)

Guidance for Industry
Submission of Documentation in
Applications for Parametric
Release of Human and
Veterinary Drug Products
Terminally Sterilized by Moist
Heat Processes

- <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072180.pdf>
- This guidance provides recommendations to applicants on information to include in support of parametric release for sterile products terminally sterilized by moist heat when submitting a new drug application (NDA), abbreviated new drug application (ANDA), new animal drug application (NADA), abbreviated new animal drug application (ANADA), biologics license application (BLA), or supplement or other post-marketing report.
- Posted February 25, 2010.

USP

Hot topic:

- No new topics this month

PIC/S

Hot topic:

- No new topics this month