



The GMP Gazette™

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

Highlights:

- Notice - Policy on Importations of Drugs for Human Use Including Natural Health Products (POL-0019)
- Summary of the Results of the Medical Devices Inspection Program from 2004-2009
- Notice - Health Canada 3011: Drug Submission Application Form for Human, Veterinary, Disinfectant Drugs and Clinical Trial Application/Attestation

Health Canada - Drug Products (HPFBI)

Hot topics:

- Notice - Policy on Importations of Drugs for Human Use Including Natural Health Products (POL-0019)
- Summary of the Results of the Medical Devices Inspection Program from 2004-2009
- Notice - Health Canada 3011: Drug Submission Application Form for Human, Veterinary, Disinfectant Drugs and Clinical Trial Application/Attestation

Notice - Policy on Importations of Drugs for Human Use Including Natural Health Products (POL-0019)

- <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/update-miseajour/announce-annonce-eng.php#a1>
- The Policy on Importations of Drugs for Human Use Including Natural Health Products into Canada (POL-0019) published in April 2006 has been replaced by the Import and Export Policy for Health Products under the *Food and Drug Act* and its *Regulations* (POL-0060) and the Import Requirements for Health Products under the *Food and Drug Act* and its *Regulations* (GUI-0084).
- Posted June 1, 2010.

Summary of the Results of the Medical Devices Inspection Program from 2004-2009

- http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/sum_result_md-im_doc_2004-2009-eng.php
- This report describes the results of inspections of medical devices companies conducted by the Health Products and Food Branch Inspectorate between 2004 and 2009, and gives an analysis of the findings.
- Posted June 11, 2010.

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9-6975 Meadowvale Town Centre Circle
Suite 410 Mississauga Ontario
L5N 2V7 Canada

TOLL FREE: 1-877-877-5152

PHONE: 905-363-1182

FAX: 905-542-7981

info@qualityandcompliance.com

www.qualityandcompliance.com

www.validapharm.com

www.nhpcompliance.com



Health Canada - Drug Products (HPFBI)

Notice - Health Canada 3011:
Drug Submission Application Form
for Human, Veterinary,
Disinfectant Drugs and Clinical
Trial Application/Attestation

- http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/hc3011_notice_sc3011_avis-eng.php
- Health Canada is pleased to announce the release of the revised Health Canada 3011: Drug Submission Application Form for Human, Veterinary, Disinfectant Drugs and Clinical Trial Application/Attestation. The revised Health Canada 3011 form and accompanying instructions replace the previous form.
- Effective immediately, sponsors should use this revised form. The form and instruction document are now available on the Health Canada website.
- Posted June 16, 2010.

Health Canada - Natural Health Products Directorate (NHPD)

Hot topic:

- Clarification Regarding Beta-Carotene and Vitamin A Conversion Factors

Clarification Regarding Beta-Carotene and Vitamin A Conversion Factors

- [Beta-Carotene Monograph](#)
- [Vitamin A Monograph](#)
- [Clarification Regarding Beta-Carotene and Vitamin A Conversion Factors](#)
- NHPD has recently revised the monographs for Beta-Carotene and Vitamin A. These monographs will be revised on the Natural Health Products Ingredient Database.
- BPRA email message received June 15, 2010.

U.S. FDA / USP / PIC/S

Hot topics:

- No new topics this month

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