



HIGHLIGHTS RELATED TO HEALTH CANADA (HPFBI, NHPD):

- Health Canada HPFBI – Changes to 2011 Drug Establishment Licence Renewal Process
- Health Canada HPFBI – **Available Now!** Draft Guidance Document - Labelling of Pharmaceutical Drugs for Human Use
- Health Canada NHPD – **Available Now!** Draft Natural Health Product Abbreviated Labelling Standard for Caffeinated Energy Drinks

HEALTH CANADA - DRUG PRODUCTS (HPFBI):

Hot topics:

- Changes to the 2011 Drug Establishment Licence Renewal Process
- **Available Now!** Draft Guidance Document - Labelling of Pharmaceutical Drugs for Human Use

Changes to the 2011 Drug Establishment Licence Renewal Process

- <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/ren-doc/index-eng.php>
- All required renewal documentation, including acceptable foreign site evidence of GMP compliance for importers, was due to Health Canada by **August 1st, 2010**.

Draft Guidance Document - Labelling of Pharmaceutical Drugs for Human Use

- http://www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/draft_ebauche_label_guide-eng.php
- **Available Now!** This document provides guidance to sponsors to facilitate compliance with labelling requirements.
- This document is applicable to pharmaceutical drug products for human use. It is not applicable to disinfectants, drugs for veterinary use, drugs regulated solely as natural health products subject to the provisions of the *Natural Health Products Regulations*, and radiopharmaceuticals and biological drugs as listed in schedules C and D of the *Food and Drugs Act*.
- The previous guideline, Labelling of Drugs for Human Use, revised in 1991, is no longer available or in use.
- Consultation is open for comment until October 5, 2010.

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HEALTH CANADA - NATURAL HEALTH PRODUCTS DIRECTORATE (NHPD):

Hot topic:

- **Available Now!** Draft Natural Health Product Abbreviated Labelling Standard for Caffeinated Energy Drinks

Draft Natural Health Product Abbreviated Labelling Standard for Caffeinated Energy Drinks

- <http://www.qualityandcompliance.com/pdfs/CAFFEINATED ENERGY DRINKS AbLS 2010-06-28.pdf>
- **Available Now!** The NHPD has developed the above draft labelling standard for caffeinated energy drink products.

U.S. FDA:

No new topics this month

USP:

No new topics this month

PIC/S:

No new topics this month

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