



## The GMP Gazette™

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

### Highlights:

- Health Canada HPFBI: Release of Frequently Asked Questions Related to Health Canada's Guidance Document, *Disinfectant Drugs*
- Health Canada NHPD: Online Solution - Update: Electronic Application Form (e-PLA) Release Schedule
- Health Canada NHPD: Revised Guidance on the Application for International Trade Certificates for Natural Health Products
- US FDA: Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions

### Health Canada - Drug Products (HPFBI)

#### Hot topic:

- Release of Frequently Asked Questions Related to Health Canada's Guidance Document, *Disinfectant Drugs*

Release of Frequently Asked Questions related to Health Canada's Guidance Document, *Disinfectant Drugs*

- [http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/notice\\_faq\\_disinfec\\_avis\\_faq-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/disinfect-desinfect/notice_faq_disinfec_avis_faq-eng.php)
- This Notice contains Frequently Asked Questions (FAQs) related to the information provided in Health Canada's guidance document: *Disinfectant Drugs* (August 29, 2007).
- The FAQs have been developed by the Therapeutic Products Directorate's Disinfectant Unit and take into account the types of questions and responses this unit has responded to since the posting of the guidance document, *Disinfectant Drugs*.
- Posted April 27, 2010.



## Health Canada - Natural Health Products Directorate (NHPD)

### Hot topics:

- NHP Online Solution - Update: Electronic Application Form (e-PLA) Release Schedule
- Revised Guidance on the Application for International Trade Certificates for Natural Health Products
- New NHP Monograph: Glucomannan
- Revised NHP Monograph: Flaxseed and Flaxseed Oil

NHP Online Solution - Update:  
Electronic Application Form  
(e-PLA) Release Schedule

- <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/online-enligne/index-eng.php>
- The latest version of the e-PLA – version 1.4.0 – will be released in May 2010.
- Posted April 1, 2010.

Revised Guidance on the  
Application for International  
Trade Certificates for Natural  
Health Products

- [Revised ITC Guidance](#)
- The revised guidance, above, will be posted on the Natural Health Products Directorate (NHPD) website in the coming weeks.
- BPRA email received April 6, 2010.

New NHP Monograph:  
Glucomannan

- [New Glucomannan Monograph](#)
- NHPD has recently developed a new monograph for Glucomannan. Although it is not yet available on the Natural Health Product Ingredient Database (NHPID), the monograph is available for use (see link above).
- BPRA email received. April 19, 2010.

Revised NHP Monographs:  
Flaxseed and Flaxseed Oil

- [Revised Flaxseed Monograph](#)
- [Revised Flaxseed Oil Monograph](#)
- NHPD has recently revised the monograph for Flaxseed. For greater clarity, the Flaxseed monograph has been separated into two monographs: Flaxseed and Flaxseed oil. Although they are not yet available on the NHPID, these monographs are available for use (see links above).
- BPRA email received April 21, 2010.



## U.S. FDA

### Hot topics:

- Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions –
  - Annex 7: Dissolution Test General Chapter
  - Annex 9: Tablet Friability General Chapter

Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions – Annex 7: Dissolution Test General Chapter

- <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm085366.pdf>
- This annex is one in a series of guidance documents that describe the evaluations and recommendations by the Q4B Expert Working Group (EWG) of selected pharmacopoeial texts to facilitate their recognition by regulatory authorities for use as interchangeable in the ICH regions.
- The ICH Steering Committee, based on the evaluation by the Q4B EWG, recommends that the official pharmacopoeial texts, Ph. Eur. 2.9.3. Dissolution Test for Solid Dosage Forms, JP 6.10 Dissolution Test, and USP <711> Dissolution, can be used as interchangeable in the ICH regions subject to certain conditions.
- Posted April 2, 2010.

Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions – Annex 9: Tablet Friability General Chapter

- <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM176888.pdf>
- This annex is one in a series of guidance documents that describe the evaluations and recommendations by the EWG of selected pharmacopoeial texts to facilitate their recognition by regulatory authorities for use as interchangeable in the ICH regions.
- The ICH Steering Committee, based on the evaluation by the Q4B EWG, recommends that the analytical procedures described in the official pharmacopoeial texts, Ph. Eur. 2.9.7. Friability of Uncoated Tablets, JP General Information 26. Tablet Friability Test, and USP <1216> Tablet Friability, can be used as interchangeable in the ICH regions.
- Posted April 2, 2010.



## USP

### Hot topics:

- USP Pending Monographs
- USP Non-US Monographs
- USP 33-NF28 Reissue

### USP Pending Monographs

- <http://www.usp.org/standards/pending/>
- USP provides Pending Monographs for certain drug products and their drug substances that have been submitted or are intended to be submitted to the U.S. Food and Drug Administration (FDA) for approval to be marketed in the United States, but have not yet received such approval.
- Under this approach, sponsors of Requests for Revision such as manufacturers of generic or over-the-counter (OTC) products and others can work with USP to create a Pending Monograph as authorized text.
- Once FDA approval is granted, USP then works with the sponsor to move that monograph into official USP–NF status, along with an official USP Reference Standard where appropriate.
- Posted March 26, 2010.

### USP Non-US Monographs

- <http://www.usp.org/standards/international/>
- USP provides standards for articles legally marketed outside the United States if intended to treat neglected diseases. The purpose of these monographs is to support testing by first (e.g., manufacturer), second (e.g., payors) and third (e.g., government control laboratories) parties.
- Details of the approach are described in the Non–US Guideline. Manufacturers wishing to signal conformance to these monographs may use the following block letters–S–USP. USP Reference Standards to allow testing in accordance with a Non–US monograph may be available in USP's catalogue at a future date.
- Posted March 26, 2010.

### USP 33-NF28 Reissue

- <http://www.usp.org/USPNF/recall.html>
- The USP 33-NF28 reissue is not available and replacement products have begun to ship.
- Posted April 5, 2010.