

CRPBC Regulatory Update As of November 1, 2010

Below is the regulatory update listings for Canada for the month of October 2010. I have placed a special posting this month in the US section.

Canada

There is not too much to report this month for Health Canada other than the first entry, a new [guidance document on Schedule A and section 3 to the Food and Drugs Act](#). This guidance is a revision of the previous 2003 *Schedule A and section 3 : Guidance Document* and includes information pertaining to the regulatory amendments which came into force on June 1st, 2008. These amendments exempt natural health products and nonprescription drugs from the prohibition on labeling and advertising of preventative claims to the general public for diseases, disorders, or abnormal physical states listed in Schedule A to the *Food and Drugs Act*. This guidance also includes a description of the data that will be required in support of these Schedule A preventative claims. The guidance was published as a draft on July 23, 2008. This is the approved final. Attention to appendix C section 4 is recommended. We are noting a large increase in clinical trials related to NHP in BC.

Natural Health Products

[Guidance Document: Schedule A and Section 3 to the Food and Drugs Act \[2010-10-26\]](#)

[NHP Ingredients Database Issue Form \[2010-11-01\]](#)

[Natural Health Products Ingredients Database Issue Form Guide \[2010-11-01\]](#)

Medical Device

[Fact Sheet: Operation of the reciprocal arrangement between the TGA and HPFB on manufacturers of medical devices \[2010-10-22\]](#)

[Announcement: Australia and Canada - Reciprocal Recognition of Manufacturers' Quality Systems \[2010-10-22\]](#)

[Consultation - Draft Guidance Document - Preparation of the Summary Technical Documentation \(STED\)-based Class III and Class IV Premarket Medical Device Licence Applications \[2010-10-13\]](#)

Drugs and Pharmaceuticals

[Standard Operating Procedures \(SOP\) - Using the Pharmaceutical Labelling Assessment Templates \(PLATs\) to Prepare Labelling Reports on Applications / Submissions for Marketing Authorization \[2010-10-26\]](#)

[Register of Innovative Drugs \[2010-10-22\]](#)

[Therapeutic Products Directorate Statistical Report 2009 Patented Medicines \(Notice of Compliance\) Regulations and Data Protection \(C.08.004.1 of the Food and Drug Regulations\) \[2010-10-15\]](#)

Biologic, Radiopharmaceuticals and Genetics

[Q4B Annex 9\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Tablet Friability General Chapter \[2010-10-26\]](#)

[Frequently Asked Questions: Animal-Sourced Insulin \[2010-10-25\]](#)

[Q4B Annex 10\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Polyacrylamide Gel Electrophoresis General Chapter \[2010-10-26\]](#)

[Q4B Annex 8\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Dissolution Test General Chapter \[2010-10-26\]](#)

[Q4B Annex 7\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Dissolution Test General Chapter \[2010-10-22\]](#)

[Q4B Annex 5\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Disintegration Test General Chapter \[2010-10-22\]](#)

[Q4B Annex 4B\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms General Chapter \[2010-10-18\]](#)

[Q4B Annex 3\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Test for Particulate Contamination: Sub-Visible Particles General Chapter \[2010-10-22\]](#)

[Q4B Annex 4C\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter \[2010-10-20\]](#)

[Q4B Annex 1\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Residue on Ignition/Sulphated Ash General Chapter \[2010-10-13\]](#)

[Q4B Annex 2\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Test for Extractable Volume of Parenteral Preparations General Chapter \[2010-10-13\]](#)

[Q4B Annex 4A\(R1\): Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions on Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter \[2010-10-13\]](#)

United States

A special treat for you this month. By request, here are the most up to date listings for US Clinical Trials Guidance documents in all categories. I really do hope that you find this helpful.

These documents represent the FDA's current thinking on good clinical practice (GCP) and the conduct of clinical trials. Guidance documents included under the umbrella title of FDA Information Sheets represent the agency's current thinking on protection of human subjects in research. The date following the title of each document represents the most recent update for that subject. Many documents were last updated prior to the enactment of good guidance practice requirements. As further updates become necessary, reformatting of some documents may therefore be necessary. While most will still be included under the umbrella of Information Sheets, some may be accessible separately after update. These are presented as they appear on the FDA website.

US FDA Clinical Trials Guidance Documents

General Information Sheet Guidance

- [Institutional Review Boards Frequently Asked Questions - Information Sheet - 01/1998](#)
- [Cooperative Research - Information Sheet -01/1998](#)
- [Non-local IRB Review - Information Sheet -01/1998](#)
- [Continuing Review After Study Approval - Information Sheet -01/1998](#)
- [Sponsor - Investigator - IRB Interrelationship - Information Sheet -01/1998](#)
- [Acceptance of Foreign Clinical Studies - Information Sheet -01/1998](#)
- [Charging for Investigational Products - Information Sheet -01/1998](#)
- [Recruiting Study Subjects - Information Sheet -01/1998](#)
- [Payment to Research Subjects - Information Sheet -01/1998](#)
- [Screening Tests Prior to Study Enrollment - Information Sheet -01/1998](#)
- [A Guide to Informed Consent - Information Sheet -01/1998](#)
- [Use of Investigational Products When Subjects Enter a Second Institution - Information Sheet -01/1998](#)
- [Exception from Informed Consent for Studies Conducted in Emergency Settings: Regulatory Language and Excerpts from Preamble - Information Sheet -01/1998](#)
- ["Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet -01/1998](#)

Drugs and Biologics Information Sheet Guidance

- [Emergency Use of an Investigational Drug or Biologic - Information Sheet](#) - 01/1998
- [Treatment Use of Investigational Drugs - Information Sheet](#) -01/1998
- [Waiver of IRB Requirements for Drug and Biological Product Studies - Information Sheet \(PDF - 35KB\)](#) -01/2006
- [Drug Study Designs - Information Sheet](#) -01/1998
- [Evaluation of Gender Differences in Clinical Investigations - Information Sheet](#) - 01/1998
- [Frequently Asked Questions – Statement of Investigator \(Form FDA 1572\) - Information Sheet \(PDF - 105KB\)](#) -06/2010

Medical Devices Information Sheet Guidance

- [Frequently Asked Questions About Medical Devices - Information Sheet \(PDF - 105KB\)](#) -01/2006
- [Significant Risk and Nonsignificant Risk Medical Device Studies - Information Sheet \(PDF - 121KB\)](#) -01/2006

FDA Operations Information Sheet Guidance

- [FDA Institutional Review Board Inspections - Information Sheet \(PDF - 45KB\)](#) - 01/2006
- [FDA Inspections of Clinical Investigators - Information Sheet \(PDF - 55KB\)](#) - 06/2010
- [Clinical Investigator Administrative Actions - Disqualification \(PDF - 79KB\)](#) - 05/2010

General Guidance Documents

- [Process for Handling Referrals to FDA Under 21 CFR 50.54 - Additional Safeguards for Children in Clinical Investigations](#) -12/2006
- [The Establishment and Operation of Clinical Trial Data Monitoring Committees for Clinical Trial Sponsors](#) -03/2006
- [Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials \(PDF - 75KB\)](#) -10/2008
- [Financial Disclosure by Clinical Investigators](#) -03/2001
- [Financial Relationships and Interests in Research Involving Human Subjects - Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects \(PDF - 163KB\)](#) -
- [Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims \(final\) \(PDF - 295KB\)](#) -
- [Pharmacogenomic Data Submissions \(PDF - 96KB\)](#) -03/2005
- [Collection of Race and Ethnicity Data in Clinical Trials](#) -09/2005
- [Independent Consultants for Biotechnology Clinical Trial Protocols](#) -08/2004
- [Clinical Lactation Studies - Study Design, Data Analysis, and Recommendations for Labeling](#) -02/2005
- [Submitting and Reviewing Complete Responses to Clinical Holds](#) -10/2000

Institutional Review Boards (IRBs) and Informed Consent Guidance Documents

- [Adverse Event Reporting - Improving Human Subject Protection](#) -04/2007
- [Using a Centralized IRB Review Process in Multicenter Clinical Trials](#) -03/2006
- [IRB Review of Stand-Alone HIPAA Authorizations Under FDA Regulations \(PDF - 614KB\)](#) -10/2003
- [Frequently Asked Questions - IRB Registration \(PDF - 48KB\)](#) -07/2009
- [IRB Continuing Review After Clinical Investigation Approval - Draft Guidance \(PDF - 125KB\)](#) -01/2010
- [Exception from Informed Consent Requirements for Emergency Research - Draft Guidance](#) -07/2006

Drugs and Biologics Guidance Documents

- [Available Therapy](#) -07/2004
- [Handling and Retention of Bioavailability and Bioequivalence Testing Samples; Availability \(PDF - 166KB\)](#) -05/2004
- [The Use of Clinical Holds Following Clinical Investigator Misconduct \(PDF - 33KB\)](#) -09/2004
- [Exploratory IND Studies \(PDF - 220KB\)](#) -
- [Food-Effect Bioavailability and Fed Bioequivalence Studies \(PDF - 166KB\)](#) - 12/2002
- [Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs \(PDF - 1875KB\)](#) -07/1993
- [Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment \(PDF - 220KB\)](#) -03/2005
- [IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer \(PDF - 188KB\)](#) -01/2004
- [Investigational New Drug Applications \(INDs\)-Determining Whether Human Research Studies Can Be Conducted Without an IND \(PDF - 210KB\)](#) -
- [Premarketing Risk Assessment \(PDF - 91KB\)](#) -03/2005
- [Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications](#) - 10/2005
- [Development and Use of Risk Minimization Action Plans \(PDF - 84KB\)](#) -03/2005
- [Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions \(PDF - 34KB\)](#) -03/2002
- [Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products - Content and Format](#) -01/2006

Medical Devices Guidance Documents

- [Commercially Distributed Analyte Specific Reagents \(ASRs\): Frequently Asked Questions \(PDF Version\) \(PDF - 139KB\) -09/2006](#)
- [Humanitarian Device Exemption \(HDE\) Regulation: Questions and Answers - 07/2010](#)
- [Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable -04/2006](#)
- [Guidance for Industry and FDA Staff: In Vitro Diagnostic \(IVD\) Device Studies - Frequently Asked Questions \(PDF - 352KB\) -06/2010](#)
- [General Principles of Software Validation -01/2002](#)

Electronic Data Guidance Documents

- [Computerized Systems Used in Clinical Trials \(PDF - 53KB\) -05/2007](#)
- [Electronic Records; Electronic Signatures - Part 11, Scope and Application \(PDF - 215KB\) -08/2003](#)

Manufacturing Requirements for Investigational Products Guidance Documents

- [Current Good Manufacturing Practice for Phase 1 Investigational Drugs \(PDF - 132KB\) -](#)
- [Design Control Guidance For Medical Device Manufacturers -03/1997](#)
- [INDs for Phase 2 and Phase 3 Studies Chemistry, Manufacturing, and Controls Information \(PDF - 193KB\)](#)