



December 3, 2009

## NOTICE

Our file number: 09-124788-457

Health Canada is pleased to announce the release of the finalized *Post-Notice of Compliance (NOC) Changes* Guidance Documents.

The purpose of these documents is to provide guidance to sponsors intending to make changes to drugs that have received an NOC pursuant to section C.08.004 of the *Food and Drug Regulations*. These documents are applicable to drugs for both human use (pharmaceuticals, biologics and radiopharmaceuticals) and veterinary use (pharmaceuticals, radiopharmaceuticals and certain biotechnological products). These new guidance documents replace the Changes to Marketed New Drug Products policy (1994), which provided insufficient guidance, to enable both internal staff and industry to appropriately categorize the type of post-NOC change and associated submission requirements.

The Post-NOC Changes guidances were developed as three documents. The Framework provides overarching authorities, general description of the proposed reporting categories, drug submission filing and contact information. Two documents categorize changes using a risk-based approach and provide guidance on associated data requirements for Safety and Efficacy, and Quality changes. The Quality document includes appendices for pharmaceuticals, biologics and radiopharmaceuticals. An additional appendix for changes specific to veterinary drugs is also included.

The final guidance documents reflect comments from two consultations. The first draft of the documents were posted on the Health Canada Web site on March 16, 2007 with a 90 day external stakeholder comment period ending June 15, 2007. A second draft was made available to stakeholders December 5, 2008 to confirm that extensive stakeholder comments were appropriately incorporated from previous consultations. Given the complexity of the documents and high stakeholder interest, the two draft versions of the documents generated substantial input from industry and industry associations representing innovator, generic and veterinary companies for all drug product types. Health Canada considered all stakeholder comments in the finalization of these guidance documents.

The guidance documents were effective as of September 30, 2009 and supersede the following guidance documents and policies:

*New Drug: Sufficient Time policy (1991)*  
*Extension of Expiration Dates policy (1991)*  
*Changes to Marketed New Drug Products policy (1994)*

.../2

*Stability Requirements for Changes to Marketed New Drugs policy (1994)*  
*Guidance for Industry: Changes in Product-Specific Facility Information (revised in 2004)*  
*New Drug: Sufficient Time notice (2005)*  
*Draft Guidance for Industry: Changes in Product Colours or Markings (2005)*

All changes from the effective date of implementation of the Post-NOC Changes guidance documents are expected to be reported as per the procedures detailed within.

Where a Level II change has been submitted to Health Canada for which the review has not commenced, sponsors may request withdrawal of that submission if it is now classified as a Level III change. Sponsors should provide a written request to the appropriate review bureau.

Please note that since the release of these documents via email on September 30, 2009, the following corrections have been made to the Post-NOC Changes Quality document:

- 1) Appendix 1 - corrections in the supporting data requirements for changes #2b and #27d,
- 2) Appendix 6 - addition of "core" weight to the title of the table.

Questions or concerns related to these guidance documents should be directed to:

Bureau of Policy, Science and International Programs  
Therapeutic Products Directorate  
Health Canada  
1600 Scott Street  
Holland Cross, Tower B  
2<sup>nd</sup> Floor, Address Locator 3102C5  
Ottawa, Ontario  
K1A 0K9

Facsimile: (613) 941-1812

E-mail: Policy\_Bureau\_Enquiries@hc-sc.gc.ca