Investigational Drug Labeling Requirements for Health Canada and US Regulated Studies

Health Canada dictates labels must be written in both English and French languages and include the following (C.05.011):

a) a statement indicating that the drug is an investigational drug to be used only by a qualified investigator;
b) the name, number or identifying mark of the drug;
c) the expiration date of the drug;
d) the recommended storage conditions for the drug;
e) the lot number of the drug;
f) the name and address of the sponsor;
g) the protocol code or identification; and
h) if the drug is a radiopharmaceutical additional regulations apply (C.03.201, C.03.202(1)(b)(vi))

For US Regulated Studies the label must include:

a) Name of the study
b) Name of the study drug (even the placebo is labeled with the study drug code)
c) Participant study number
d) How supplied (for example, the number of tablets per container)
e) Dose per unit (mg per tablet, mg/mL, etc.)
f) Lot number
g) Batch number
h) A federal statement limiting use to experimental studies: "Caution: New Drug - Limited by Federal Law to Investigational Use"