Page 4 Section 1.1 3rd paragraph

In order to concretise further these rules, Article 9(8) of Directive 2001/20/EC establishes that:

Comment [A1]: This is not an English word

Page 15 Section 2.7.1. last sentence

certification of the CMP compliance of the manufacturing of any active biological substance.

Comment [A2]: CMP should read GMP

Page 24 Section 3.3.2. last bullet

- Minor changes in the labelling of the investigational product

Comment [A3]: need example of what is considered "minor", further clarification definitely needed

Page 31 Section 4.3 Clinical Trial Summary Report

The clinical trial summary report is part of the end of trials notification. However, the clinical trial summary report can be submitted subsequently to the end of trials notification. With regard to the modalities of the submission of the clinical trial summary report, its format and content and its accessibility for the public, reference is made to the applicable guidelines and in particular Commission Communications 2009/C28/01 and 2008/C168/02.[48]

Comment [A4]: no longer states within 1 year of the end of the trial.
Is this omission intentional?

M:\
2009_06_11-publiccor