**Suggested Example Label Wording**

An example label should be sent to the MHRA with the CTA application. It should include all text, measurements and the sample provided be the actual size used.

Where a placebo is used, it must be labelled and packaged identically to the MP to maintain the blind.

**Medicinal Product used with a marketing authorisation** (Licensed product):

May be labelled in accordance with the requirements for a dispensed medicine only. This needs to be justified in the CTA application/cover letter. Instances where the MP is being taken home by participants should still follow the guidelines in Annexe 13 of the GMP regulations to identify as an Investigational Medicinal Product.

Example:

**Project Name/Acronym and (EudraCT number) [RESEARCH PROJECT LOGO]**

Chief Investigator: xxxxx

MP name, formulation, strength, quantity, expiry/use by date for reconstituted MP

Instructions (as specified by the prescriber)

Participant Number: Date of Supply:

Name and address of hospital/primary care supplier

**Keep out of reach of children**

Additional cautions (as recommended by the BNF**)**

**Medicinal Product without a marketing authorisation** (Unlicensed product):

Must be labelled in accordance with Annexe 13 of the GMP regulations for Investigational Medicinal Products

Example:

For Clinical Trials Use Only **[RESEARCH PROJECT LOGO]**

**Project Name/Acronym and (EudraCT number)**

For use in project name/acronym

Instructions for use as stated in participant information sheet

Chief Investigator: xxxxx

MP name, formulation, strength, quantity, expiry/use by date for reconstituted MP, stability/re-test date

Batch No.: Storage Instructions:

Participant Number: Date of Supply:

Sponsor contact name and address:

**Keep out of reach of children**

Additional cautions (as recommended by the BNF**)**