Safeguarding public health



Ms J Gambell
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21/06/2010

Dear Ms J Gambell

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference:

20363/0273/001-0004

Eudract Number:

2009-012717-22

Product:

rituximab

Protocol number:

UCL/08/0167

Substantial Amendment Code Number:

Amendment 2/Protocol 2.0_PIS 2.1_Pregnant Partner PIS &

CF/20may10

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to inform you that the Licensing Authority accepts the proposed amendment to your clinical trial authorisation (CTA), received on 24/05/2010.

This amendment may therefore be made.

You are reminded that where it is appropriate, the Ethics Committee should also be notified of amendments.

Yours sincerely,

Clinical Trials Unit MHRA