Safeguarding public health



Ms H Farrant
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13/05/2010

Dear Ms H Farrant

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

Our Reference:

20363/0204/001-0034

Eudract Number:

2004-002197-34

Product:

Mabthera

Protocol number:

04/Q1104/27

Substantial Amendment Code Number:

Amendment 7: Protocol V6.0, 26.03.2010

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 08/04/2010.

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