Safeguarding public health



Ms H Farrant
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11/12/2012

Dear Ms H Farrant

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

 Our Reference:
 20363/0204/001-0035

 Eudract Number:
 2004-002197-34

 Product:
 Mabthera

 Protocol number:
 04/Q1104/27

Substantial Amendment Code Number: Substantial Amendment 29.10.12 (Main Protocol v8.0)

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 08/11/2012.

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