Safeguarding public health



Mr P Mouncey
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UNITED KINGDOM

06/10/2008

Dear Mr P Mouncey

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

Our Reference:

20363/0204/001-0033

Eudract Number:

2004-002197-34

Product:

Mabthera

Protocol number:

04/Q1104/27

Substantial Amendment Code Number:

Protocol 5.0/AM6/Change in main protocol and PET sub

protocol/07.07/2008

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 27/08/2008.

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

