Safeguarding public health

NEWCASTLE-UPON-TYNE HOSPITALS NHS FOUNDATION TRUST

[redacted]

15/08/2012

Dear

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

Our Reference: 17136/0261/001-0001
Eudract Number: 2012-000145-12
Product: MabThera
Protocol number: 5997

NOTICE OF ACCEPTANCE OF AMENDED REQUEST

I am writing to inform you that the Licensing Authority accepts your amended request for a clinical trial authorisation (CTA), received on 09/08/2012.

Authorisation of your clinical trial is subject to the following condition(s):
*The normal saline used as the placebo comparator is a UK marketed product.
If these conditions are met, the trial is authorised and you do not need to respond to this Jetter. If your trial does not meet these conditions, your trial does not have authorisation and therefore you can not proceed with the trial. You must inform the MHRA immediately if the trial does not meet the above conditions. All changes to the terms and conditions of this trial must be made as a request for a substantial amendment to this clinical trial authorisation.

The authorisation is effective from the date of this letter although your trial may be suspended or terminated at any time by the Licensing Authority in accordance with regulation 31. You must notify the Licensing Authority within 90 days of the trial ending.

Finally, you are reminded that a favourable opinion from the Ethics Committee is also required before this trial can proceed; changes made as part of your amended request may need to be notified to the Ethics Committee.

Yours sincerely,

Clinical Trials Unit
MHRA