

Dr J Grigg
BARTS AND THE LONDON NHS TRUST
2 NEWARK STREET
LONDON
E1 2AT
UNITED KINGDOM

22/02/2010

Dear Dr J Grigg

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

Our Reference: 21313/0024/001-0001
Eudract Number: 2009-015626-11
Product: Singulair Paediatric 4mg Granules
Protocol number: 006983 QM

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 12/02/2010.

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**