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Lægemiddelstyrelsen
1 Axel Heides Gade
DK-2300 Copenhagen
Denmark

4th December 2008

Dear Sirs

**Re: End of Trial Notification for rhASA-04 (EudraCT No. 2007-007165-20),
DKMA ref: 2612-3646**

On behalf of Shire Pharmaceuticals Ireland Limited, the company wishes to notify the agency that the above-mentioned study did not start. The company notices that from the approval letter of this trial dated 29th January 2008 approval was given for the trial until 1st November 2008, no patients have been recruited into this trial.

Please do not hesitate to contact me should you have any questions.

Yours faithfully,

A handwritten signature in blue ink that reads 'Justine Revell'.

Justine Revell
Associate Director, EU Regulatory Affairs