

[REDACTED]  
PFIZER LIMITED  
RAMSGATE ROAD  
SANDWICH  
KENT  
CT13 9NJ  
UNITED KINGDOM

15/05/2008

Dear [REDACTED]

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

|                                    |                     |
|------------------------------------|---------------------|
| Our Reference:                     | 27280/0002/001-0003 |
| Eudract Number:                    | 2007-001036-31      |
| Product:                           | PF-00446687         |
| Protocol number:                   | A8361011            |
| Substantial Amendment Code Number: |                     |

**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 09/05/2008.

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**