

[REDACTED]

Our Reference: 27280/0002/001-0001
Eudract Number: 2007-001036-31

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

15/06/2007

Dear [REDACTED]

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

Product Type: General Medicinal Product

Product: PF-00446687

Protocol number: A8361011

NOTICE OF ACCEPTANCE OF AMENDED REQUEST

I am writing to confirm that the Licensing Authority, acting under regulation 18(6)(b) or (c), or 19(7)(a) or (8), or 20(4)(a) or (5), according to the type of medicinal product involved¹, accepts your amended request to carry out a clinical trial in accordance with your application 25/05/2007 subject to you receiving a favourable opinion from the relevant ethics committee in accordance with regulation 15(1). You may therefore carry out the trial as notified, but I must remind you of the Authority's powers under regulation 31 to suspend or terminate a clinical trial if the conditions set out in regulation 31(1)(a) and (b) are satisfied

Remarks:

- * An annotated structure and assignments should be provided for the NMR spectral data.
- * It is assumed that polymorphic form is controlled in the drug substance specification.
- * No batch analysis data have been included for the reference standard. These should be provided.
- * Further information on the composition, method of manufacture and release testing of the placebo tablet should be provided before the study commences.

¹ The Licensing Authority's authorisation powers for clinical trials are regulation 18 for those involving general medicinal products, regulation 19 for those involving medicinal products for gene therapy etc., and regulation 20 for those involving medicinal products with special characteristics.

The authorisation is effective from the date of this letter and may continue under this authorisation. In accordance with regulation 27, you must notify the Licensing Authority within 90 days of the conclusion of the trial, that has ended.

Yours sincerely

A solid black rectangular box used to redact the signature of the Head of Clinical Trials Unit.

Head of Clinical Trials Unit