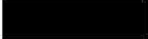




Our Reference: 27280/0002/001-0001
Eudract Number: 2007-001036-31



PFIZER LIMITED
RAMSGATE ROAD
SANDWICH
KENT
CT13 9NJ
UNITED KINGDOM

26/04/2007

Dear 

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

Product: PF-00446687
Protocol number: A8361011

ACKNOWLEDGEMENT

Thank you for your request received on 20/04/2007 for a Clinical Trial Authorisation (CTA) under the above Regulations.

The information you have provided to support your request is complete and therefore your request is valid.

It is the Authority's intention, where appropriate, to send a letter confirming that they have no objection to the trial. If they find grounds for not accepting the application they will send a notice within 30 days from the 20/04/2007 setting out those grounds for non-acceptance as well as setting a time period of no less than 14 days from the date you receive the notice in which you may respond to those grounds. The authority will then consider the amended request and within 60 days from the date the original request was received notify non-acceptance, acceptance or acceptance subject to specified conditions, as the case may be.

If your request for authorisation involves a general medicinal product then, in accordance with regulation 18, if we do not notify you within 30 days from the date we received your request the clinical trial will be treated as authorised by regulation 18(3) of the Regulations.

I draw your attention to 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.

If you have any queries about this letter please do not hesitate to contact me.

Yours sincerely

A solid black rectangular box used to redact a signature.

Head of Clinical Trials Unit