

[REDACTED]

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

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

10/05/2007

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 NON-ACCEPTANCE

I refer to your request for authorisation 20/04/2007 which we acknowledged in our letter dated 26/04/2007 relating to a Clinical Trial identified by the above Eudract number.

The Licensing Authority has carefully considered your request but has decided, in accordance with regulation 18(2)(a), or 19(2)(b) or 20(2)(b), according to the type of medicinal product involved¹, not to accept it.

Grounds for non-acceptance:

- * It is assumed that, in the absence of stability data, the drug substance is tested to and complies with its specification prior to its use in manufacture of the drug product.
- * Since the method of production is considered to be manufacture, a copy of the MA(IMP) for the sites of manufacture of the oral active and placebo solutions should be provided.

You may respond to the above grounds for non-acceptance, in accordance with regulation 18(5), or 19(6) or 20(3) according to the type of medicinal product involved, within 15 days of the date you receive this notice otherwise your application will be deemed to have been refused.

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.

Comments:

Yours sincerely

[REDACTED]

Head of Clinical Trials Unit