

27280/0002/001-0001
CTA number: N/A
EudraCT number: 2007-001036-31

[REDACTED]
Worldwide Regulatory Strategy
Pfizer Global Research and Development Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ

25 June 2007

Dear [REDACTED]

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS
2004 S.I. 1031
Product: PF-00446687
Protocol number: A8361011

Thank you for your e-mail dated 25th June 2007.

The information provided is noted.

Remarks:

- Unfortunately, the version of the IMP dossier used for the assessment was missing the relevant pages. The data on the placebo have now been reviewed and are acceptable.

Yours sincerely,

[REDACTED]
Pharmaceutical Assessor
Clinical Trials Unit

[REDACTED]

From: [REDACTED]
Sent: 25 June 2007 17:15
To: [REDACTED]
Subject: Compound: PF-00446687. EUDRACT Ref: 2007-001036-31

Dear [REDACTED]

PROTOCOL: A8361011

The Company received an acceptance letter dated 15th June 2007 for the title Eudract Number today.

With respect to the remarks, we would ask for clarification on remark 4, as this needs to be addressed before the study can start.

Remark 4:

Further information on the composition, method of manufacture and release testing of the placebo tablet (placebo for sildenafil) should be provided before the study commences.

Having reviewed the IMPD, can the MHRA clarify what information is required in addition to that already supplied.

The Company is planning to start the study within the next two weeks and we would like to ensure that responses to all remarks have been lodged with the MHRA before then. For ease of reference I attach a copy of the MHRA communication. With thanks in advance for your kind assistance in this matter.

Yours sincerely

For Pfizer Global Research & Development

[REDACTED]
Worldwide Regulatory Strategy
Pfizer Global Research & Development Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ

[REDACTED]

This email was received from the INTERNET and scanned by the Government Secure Intranet Anti-Virus service supplied by Cable&Wireless in partnership with MessageLabs. (CCTM Certificate Number 2006/04/0007.) In case of problems, please call your organisation's IT Helpdesk. Communications via the GSi may be automatically logged, monitored and/or recorded for legal purposes.

25/06/2007