



Worldwide Pharmaceutical Operations

9th May 2008


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Dear Sir or Madam,

NOTIFICATION OF SUBSTANTIAL AMENDMENT (FOR INFORMATION ONLY)

PF-00446687 200mg Powder for oral Solution
EudraCT Number: 2007-001036-31
Protocol Number: A8361011

Protocol Title: "A 2-Cohort, Multi-centre, Randomised, Double-blind (Third Party Open), Placebo Controlled 4-way Crossover Study to Assess the Efficacy of Single Oral Doses of PF-00446687 on Erectile Dysfunction in Men Suffering from Erectile Dysfunction, Using 100mg Sildenafil as a Positive Control"

Please find enclosed documentation in CD-ROM relating to notification of substantial amendment to an ongoing clinical trial study with PF-00446687. The amendment does not involve the addition of new information but to correct the data previously submitted in the original application.

The original data in the application (initial CTA) for A8361011 recorded that the packaging and final release of the sildenafil citrate tablets and placebo for sildenafil citrate tablets were the responsibility of Pfizer Sandwich. The packaging and final release is not performed by

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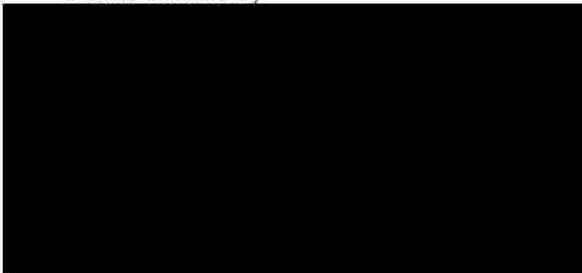
Pfizer but by the contract research organisation (CRO). The process that has been in place involves the CRO sites packaging and releasing sildenafil citrate tablets and its placebo from bulk tablet supplies and packaging materials supplied by Pfizer. The IMPD has been updated accordingly.

As this type of amendment to the application is considered an administrative change only, assessment is not necessary and hence, a fee is not applicable.

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I trust that you find everything in order. Should you require further information, please do not hesitate to contact me.

Yours faithfully



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