

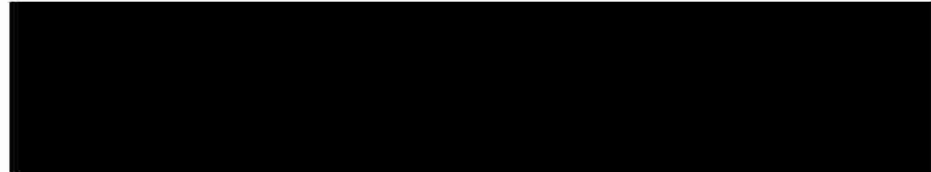
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Global Research & Development

17th April 2007



Information Processing Unit
Area 6 – Clinical Trial Applications and Related Responses to RFIs
Medicines & Healthcare Products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Initial Application

PF-00446687 200 mg Powder for Oral solution
EudraCT Number: 2007-001036-31
Protocol Number: A8361011
Internal SAN number: 3800

Protocol Title: A 2-Cohort, Multi-Centre, Randomized, Double Blind (3rd Party Open), Placebo Controlled 4-Way Crossover Study to Assess the Efficacy of Single Oral Doses Of PF-00446687 on Erectile Function in Men Suffering from Erectile Dysfunction, Using 100 MG Sildenafil AS a Positive Control..

Dear Sir / Madam

Please find enclosed a clinical trial application for a Phase 2a study in respect of the title compound, a melanocortin agonist. PF-0044687 is in development for both male erectile dysfunction (MED) and female sexual dysfunction (FSD), it is the former target indication that is the subject of this clinical trial application.

A full quality component of the IMPD is provided for PF-0044687, its placebo and the sildenafil placebo. Active sildenafil has been sourced as Viagra® that is commercially available in the European Union.

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1

Page 1 of 2

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AWARDED TO PFIZER LIMITED

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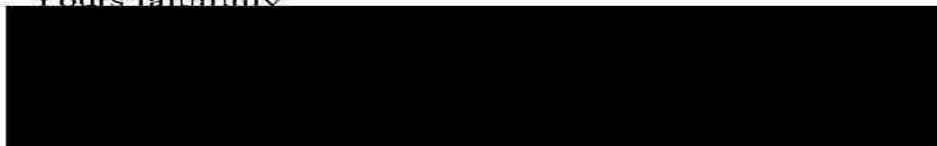
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The currently approved Summary of Product Characteristics (SmPC) for Viagra® is included as part of this application. Pfizer proposes that the quality data with the exception of the final packaging step (labelling only) are identical to that approved for marketing authorization numbers EU/1/98/077/009-012 and that the non-clinical and clinical data that support the approved marketing authorization numbers are applicable to the patient to be recruited to the study. Therefore an abridged IMPD comprising the Viagra® SmPC is included with respect to sildenafil.

Please note this Clinical Trial Application has been submitted for review with the draft label appended, the actual approved UK label will be forwarded appropriately when available and prior to regulatory approval.

I trust that the above is satisfactory. However, please do not hesitate to contact me if I can be of further assistance.

Yours faithfully



Encl.: Clinical Trial Application

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