

CTA number: 27280/0002/001-0001

EudraCT number: 2007-001036-31

**PFIZER LIMITED
RAMSGATE ROAD
SANDWICH
KENT
CT13 9NJ
UNITED KINGDOM**

25 July 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 letter dated 4th July 2007.

The information provided is acceptable.

Yours sincerely

Pharmaceutical Assessor
Clinical Trials Unit

9



4th July 2007

Regulatory Lead Women's Health/ Sex Health
Worldwide Regulatory Strategy - Europe
Direct Line: [REDACTED]
Fax Line: +[REDACTED]
Email: [REDACTED]

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 5NO

Response to Remarks (Your Ref: 27280/0002/001-0001)

Compound: PF-00446687 up to 2mg/mL Oral Solution
EudraCT Number: 2007-001036-31
Protocol Number: A8361011
Internal SAN Number: 5547

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

Thank you for your notice of acceptance of amended request dated 15th June 2007, in respect of the title Eudract number. Please find enclosed a CD containing the Company's responses to the remarks from the Agency.

The acceptance notification had four remarks for the Company to address and response the first three remarks are provided in the attachment (INQS-2007-126-GB file on the CD). With respect to the fourth remark (further data on the sildenafil placebo), clarification from the MHRA ([REDACTED] 's letter of 25th June 2007) is that

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Page 1 of 2

Registered in England: No 536209
Registered Office: Ramsgate Road
Sandwich, Kent CT13 9NL, UK

Registered in England: No 526209
Registered Office: Ramsgate Road
Sandwich, Kent CT13 9NJ, UK

06 JUL 2007

REQUEST FOR DESPATCH OF MATERIALS (HOME AND EXPORT)

One copy to accompany the goods to the Despatch Dept;

One copy to the Supply Point (687)

Date: 05 July 07	Department: Worldwide Regulatory Operations	Int. Tel No. 46959
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Description of Items: CTA Response PF-00446687 2mg/mL Oral solution Response to MHRA Remarks Eudract Number: 2007-001036-31 Protocol: A8361011 ----- CDROMS: 1 CDROMs x 1 copies = 1 TOTAL CDROMS = 1 ----- TOTAL ITEMS = 1		Consignee (No P.O. Box numbers): 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 <table border="1"> <tr> <td>Tele:</td> <td></td> </tr> <tr> <td>Fax:</td> <td></td> </tr> <tr> <td>E-mail:</td> <td></td> </tr> </table>		Tele:		Fax:		E-mail:	
Tele:									
Fax:									
E-mail:									
		CHARGEABLE: YES ☐ NO ☒ IF CHARGEABLE: Terms of Sale: Payment terms: IF NON-CHARGEABLE: Cost Centre: 5002606/A836/CTA Response Value for Customs: £3							
Country of Origin (if not U.K.): Dangerous Goods (This section MUST be completed) Are the materials dangerous for SUPPLY under CHIP 2 regulations? YES ☐ NO ☒ If YES, you must attach a Safety Data Sheet Are the materials dangerous for CARRIAGE under UN regulations? YES ☐ NO ☒ For guidance, refer to introductory notes.		Insurance: Special Valuation: Buyer (if different from consignee): Additional Instructions (if any): JTS: eSAN: 5547 Please Despatch on: 5 th July 2007							
Signature of Sender: Scheduled Substances (This section MUST be completed to meet possible legal requirements) If the above item(s) is a chemical compound, is it a SCHEDULED SUBSTANCE? YES ☐ NO ☒ If YES, state CAS number Please note that the export of some SCHEDULED SUBSTANCES require to be pre-notified to the appropriate authority and a delay in shipment anticipated		For Supply Point Dept. use only: For Despatch Dept. use only:							
Signature of Sender: Delivery required by: 3rd July 07 Insert a DATE and remember unnecessary cost may be incurred if your instruction is not realistic. Approved by Requisitioner: Name: XXXXXXXXXX Signe: XXXXXXXXXX Staff Number: Date: 05 July 07									



CTA RESPONSE

PF-00446687

Response to MHRA Remarks

2mg/mL Oral solution

Eudract Number: 2007-001036-31

Protocol: A8361011

Date: JULY 2007

TO OPEN THE FILES:

INSERT THE DISC INTO YOUR CD/DVD DRIVE

CLICK ON START

SELECT RUN

TYPE: X:\

NOTE: REPLACE X: WITH ACTUAL CD/DVD DRIVE LETTER

CLICK ON OK

THIS ELECTRONIC MEDIA HAS BEEN VERIFIED AS VIRUS FREE, HAVING BEEN CHECKED WITH MCAFEE VIRUSSCAN ENTERPRISE 8.0.0 (VIRUS DEFINITIONS 19TH FEB '07 OR LATER).

PFIZER GLOBAL RESEARCH AND DEVELOPMENT

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CTA RESPONSE

06 JUL 2007

PF-00446687

Response to MHRA Remarks

2mg/mL Oral solution

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PF-00446687

Date: JULY 2007

SAN-5547-GB