PB-75A

Safeguarding public health

MHRA

1 7 JAN 2011

Dr P Bath
UNIVERSITY OF NOTTINGHAM
CLINICAL SCIENCES BUILDING
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UNITED KINGDOM

14/01/2011

Dear Dr P Bath

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference:

03057/0033/001-0003

Eudract Number:

Protocol number:

2007-004766-40

Product:

NITRO-DUR 0.2MG/H (5MG/24H) TRANSDERMAL PATCH

30592

Substantial Amendment Code Number:

Amendment 002, Protocol version 1.3 dated 08 December 2010

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to inform you that the Licensing Authority accepts the proposed amendment to your clinical trial authorisation (CTA), received on 21/12/2010.

This amendment may therefore be made.

You are reminded that where it is appropriate, the Ethics Committee should also be notified of amendments.

Yours sincerely,

Clinical Trials Unit MHRA