Safeguard ng public health

MHRA

Dr P Bat
UNIVER SITY OF NOTTINGHAM
TEAM F Q, PAYMENTS CENTRE, FINANCE DEPARTMENT
KING'S MEADOW CAMPUS
NOTTIN GHAM
NG7 2N R
UNITED KINGDOM

Duplicate Copy
13/10/2008

27/02/2(08

Dear Dr P Bath

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

Our Ref rence:	03057/0020/001-0001
Eudract Number:	2007-004766-40
Product	NITRO-DUR 0.2MG/H (5MG/24H) TRANSDERMAL PATCH
Protocol number:	30592

NOTICE OF GROUNDS FOR NON-ACCEPTANCE

I refer t your request for a clinical trial authorisation (CTA), received on 28/01/2008. The Licensing Authorit has carefully considered your request in accordance with regulations 18-20, but has decided not to a cept it on the following grounds:

Ground for Non-Acceptance
Pharma eutical Points
*A sam le of the labeling to be used in the proposed trial should be provided.
For furth er information on the above points, please contact Dr Martin O'Kane on 0207 084 2659.

You ma respond to this letter by making an amended request for a clinical trial authorisation within the time scales set out in regulations 18-20, otherwise your application will be deemed to have been refused The amended request should cover all the issues raised in this letter.

Yours s ncerely,

Clinical Trials Unit
MHRA

Proposed label for RIGHT STUDY

RIGHT STUDY (Rapid Intervention with GTN in Hypertensive Stroke Trial)

For external use only

Glyceryl trinitrate 5mg patches (NITRO-DUR 0.2 mg/hr) x 7

Apply ONE patch DAILY for seven days as directed.

Patient randomisation number.....

Name.....Date.....

BN.....EXP.....

Clinical Trial use only *Investigator Prof P Bath*

KEEP OUT OF THE REACH OF CHILDREN Store between 15-30^{0}c

Pharmacy Dept, City Hospital Campus, NUH, Hucknall Rd, Nottm NG5 1PB

0115 9691169. Eudract no 2007-004766-40

Randomisation number, patient name, date to be added at the point of dispensing