Safeguarding public health



Paul Smith

University College London

Lymphoma Trials Office, 222 Euston Road London NW1 2DA CTA number:

20363/0204/001

EudraCT number:

2004-002197-34

24 August 2006

Dear Mr Smith,

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

Product: Rituximab

Protocol number: 04/Q1104/27

NOTICE OF ACCEPTANCE OF AMENDMENT (Version 2)

I am writing to confirm that the Licensing Authority, in accordance with regulation 24(5)(b) accepts the proposed amendments contained in your notice of amendments received on 1 August 2006 relating to the Clinical Trial Authorisation identified by the above CTA number, subject to the relevant ethics committee giving a favourable opinion in accordance with regulation 24(9).

This trial may therefore proceed accordingly.

Yours sincerely

Dr Carolyn Greenwood

Medical Assessor Clinical Trials Unit

Direct Line: 020 7084 2327, Facsimile: 020 7084 2443, Room: 12-242

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