MHRA
Safeguarding public health

Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane, London SW8 5NQ

Direct Line: 0207 084-2327
Facsimile: 0207 084-2443
Room 12- 242

Dr M Spryer
University College London
Gower Street
London WC1E 6BT

CTA Number:
Eudract Number: 2004-002197-34

13 October 2004

Dear Dr Spryer

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 1031
Product Type: Medicinal Product with Special Characteristics
Product: MabThera
Protocol number: 04/Q1104/27

NOTICE OF ACCEPTANCE

I am writing to confirm that the Licensing Authority, acting under regulation 18(2)(b) or (c), or 19(2)(a) or (8), or 20(2)(a) or (5), of the Regulations and according to the type of medicinal product involved[1], accepts your request to carry out a clinical trial in accordance with your application received on 15 September 2004 which we acknowledged in our letter dated 13 October 2004 subject to you receiving a favourable opinion from the relevant ethics committee in accordance with regulation 15(1). You may therefore carry out the trial as notified, but I must remind you of the Authority's powers under regulation 31 to suspend or terminate a clinical trial if the conditions set out in regulation 31(1)(a) and (b) are satisfied.

Remark:
* A sample of the labelling should be provided.

The authorisation is effective from the date of this letter and may continue under this authorisation. In accordance with regulation 27, you must notify the Licensing Authority within 90 days of the conclusion of the trial, that it has ended.

Yours sincerely

pp **Mrs Salma Syed**
Clinical Trial Unit

[1] The Licensing Authority's authorisation powers for clinical trials are regulation 18 for those involving general medicinal products, regulation 19 for those involving medicinal products for gene therapy etc., and regulation 20 for those involving medicinal products with special characteristics.