Safeguarding public health



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Our Reference: 20363/0204/001-0029 Eudract Number: 2004-002197-34

Mr P Mouncey
UNIVERSITY COLLEGE LONDON
LYMPHOMA TRIALS OFFICE
222 EUSTON ROAD
LONDON
NW1 2DA
UNITED KINGDOM

28/08/2007

Dear Mr P Mouncey

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

Product: Mabthera

Protocol number: 04/Q1104/27

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to confirm that the Licensing Authority, in accordance with regulation 24(5)(b) accepts the proposed amendment contained in your notice of amendment received on 31/07/2007, relating to the Clinical Trial Authorisation identified by the above Eudract 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

, Malcolm Barratt-Johnson

me Co

Clinical Trials Unit