



# Department of Health and Social Security

Medicines Division

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Mrs. M. W. TATT.  
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Your reference

MWT/SVS.

Our reference

CTX 0055/0112.

Date

9th February 87.

Dear Sir

## THE MEDICINES (EXEMPTION FROM LICENCES) (CLINICAL TRIALS) ORDER 1981

I am writing to confirm that the Licensing Authority raises no objection to your carrying out a clinical trial in accordance with your notification dated 22nd August 86. You may therefore carry out the trial as notified, but I must remind you of the conditions set out in my letter of 26th August 86 to which you should now attach this confirmation of exemption.

In accordance with Article 5(1) of the Order, this exemption is effective from 30th January 87 and will continue for a period of 3 years providing that the conditions referred to as above are fulfilled.

Notes on the role of Ethics Committees in relation to clinical trials under the Medicines Act 1968 can be found in the "Guidance Notes on Applications for Clinical Trial Certificates and Clinical Trial Exemptions". This publication is available from Her Majesty's Stationery Office.

Copies of data submitted in connection with this application are held by us. We will need to retain two copies for our records, but if you wish us to return the balance we will do so. If we have not heard from you within two weeks of the date of this letter the balance of data will be disposed of as classified waste.

It will assist us to have a positive indication of your decision and for this purpose an advice slip is attached.

Yours faithfully

GRO-C

MRS Kim Freeman