



**Department of Health and Social Security**

Medicines Division

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27 JAN 1988

Mr I Bryant  
Regulatory Officer  
Travenol Laboratories Ltd  
Caxton Way  
THETFORD  
Norfolk IP24 3SE

Your reference IJB/MES

Our reference CTX/0116/0181A

Date 27<sup>th</sup> January 1988

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 using Hemofil M in accordance with your notification dated 7 December 1987. You may therefore carry out the trial as notified, but I must remind you of the conditions set out in my letter of 14 December 1987 to which you should now attach this confirmation of exemption.

1. Please note that the following assumptions have been made

1.1 Process variables that would affect viral inactivation are adequately controlled.

1.2 The CPMP guidelines on the use of MAbs have been followed re-use of the immunoaffinity column and use of an alternative MAbs have been adequately controlled.

15B || 2. A new page 8 of MLA 164, showing the correct finished product specification should be submitted.

In accordance with Article 5(1) of the Order, this exemption is effective from 20 January 1988 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 EXT 3377