GRO-C

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Department of Health and Social Security
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RECEIVED 18 JUN 1975

G. Hardy Esq. PH.D, ARIC
Scientific Services Manager
Traverol Laboratories Ltd.
Caxton Way
Thetford
Norfolk IP24 3SE

Your reference
RA 191
Our reference
PL 0116/0011
Date
June 1975

Dear Sir/~~Madam~~

NOTIFICATION OF CHANGE(S) IN PARTICULARS RELATING TO PRODUCT LICENCE(S) No(s): 0116/0011
NAME(S) OF PRODUCT(S):

Hemofil Antihaemophilic Factor

Thank you for your letter of 30 May 1975 detailing changes in the particulars relating to the above product licence(s).

The licensing authority agrees to amend the particulars specified in the application as detailed in the attached documents.

Please retain this letter with the formal documents relating to product licence(s) number(s) 0116/0011 as evidence of approval of the change.

Yours

GRO-C

P. W. OTLEY

A person authorised to sign on behalf of the Secretary of State for Social Services

PLN 1

Licence Number: 0116/0011 Your reference: PA. 191

Name of Product: HEMOFIL ANTIHAEMOPHILIC FACTOR (HUMAN) METHOD FOUR

Give the present particulars and the change or proposed change. If the particulars appear on the licence document itself, you should give them exactly as they are given on the licence, or as you propose they should be given. (The items in the lefthand column of (3) are usually specified on product licences.)

Present	Proposed
11.4 Finished Product Specification	I i) Hepatitis Add:-
I i) Hepatitis	Each LOT of product, after reconstitution as for use, is tested for the presence of Hepatitis B antigen by the radioimmuno-assay technique, using Ausria kit 2. A nonreactive test result must be obtained for each LOT of product before it can be released for sale.
The concentrate is prepared from large pools of fresh human plasma. Such plasma may contain the causative agent of viral hepatitis. However, each unit of plasma has been found to be negative for Hepatitis Associated Antigen by counterelectrophoresis.	

(continue on a separate sheet if necessary)

Reason for the change

The radioimmuno-assay technique for the detection of Hepatitis B Antigen is more sensitive than the counterelectrophoresis technique previously used.

Each unit of plasma is tested for HBAg by counterelectrophoresis and the final product is again tested for HBAg using the radioimmuno-assay technique.

I hereby make application for the above licence to be varied in accordance with the proposals given above.

Signed: GRO-C Date: 30th May 1975