FORM MLA 221
R.82

NOTIFICATION OF CHANGE OF PRODUCT LICENCE

1. PRODUCT NAME: ANTIHAEMOPHILIC FACTOR (HUMAN) METHOD FOUR, HEAT-TREATED, HEMOFIL HT
LICENCE NUMBER: PL0116/0150 RA.191A

2. Name and Address of Licence Holder:
Travenol Laboratories Ltd.,
Caxton Way,
Thetford,
Norfolk
IP24 3SE

Telephone Number: Thetford (0842) 4581
Name of Contact: D.M. Barrow

3. Please indicate if you have changed or propose to change any of the following:

___ Name of Product
___ Pharmaceutical Form
___ Specification of container, shelf life and storage precautions
_X_ Manufacturing process where change affects the quality of the product
___ Site of Manufacture
_X_ Finished product specification
___ Ingredients
___ Uses, directions for use, route of administration
___ Dosage and dosage schedule
___ Contraindication, precautions and warnings
___ Manufacturing process where changes do not affect quality
___ Manufacturer or assembler
___ Supplier of active ingredients
___ Quality control procedure
___ Method of retail sale or supply
___ Activities covered by the licence
___ Labels, leaflets, data sheets
___ Cancellation of licence
___ Other

4. Reasons for change: Specification that product is manufactured exclusively from individual plasma donations screened for HTLV-III antibodies, obtained only from donors with normal ALT levels.

For Licensing Authority use only:

5. Application dated .....
Received .....
Stats ref .....
Code .....

Route
Pharm:
Med:

ADP

___ no copies required
___ MLA221 and flagged pages only
___ MLA 221 only
___ Complete data

Application Approved*/Refused
(See M-)

Pharmacist:
Date:

Doctor:
Date:

*Delete as appropriate

6. Name of Product: ANTIHAEMOPHILIC FACTOR (HUMAN) METHOD FOUR, HEAT-TREATED, HEMOFIL HT LICENCE NUMBER: PL0116/0150 RA.191A

7. Address for reply:

Mr. D.M. Barrow,
Senior Regulatory Officer,
Travenol Laboratories Limited,
Caxton Way,
Thetford,
Norfolk IP24 3SE

8. Give the present particulars and proposed change. If the change refers to particulars on the Schedule of the product licence you should give them exactly as they currently appear on the licence and how you propose they should be stated (continue on a separate sheet if necessary). Please attach supporting evidence to the application and indicate the number of volumes and copies.

Add specificication that product is manufactured exclusively from individual plasma donations screened for HTLV III antibodies obtained from donors with normal ALT levels.
(See attached sheet)

9. I hereby make application for the above licence to be changed in accordance with the proposals given above and certify that the changes will not adversely affect the quality of the product.

Signed GRO-C Date 13th February 1987

David M. Barrow, BSc., C.Biol., M.I.Biol.

Status Senior Regulatory Officer
Scientific and Regulatory Affairs

10. The licensing authority *consents to/acknowledges your request to change the product licence as outlined at 8 above.

Please retain this form with the formal documents relating to the product licence as evidence of *approval/notification of the change.

Signed: Date:

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

* Delete as appropriate

Name of Product: ANTIHAEMOPHILIC FACTOR (HUMAN) METHOD FOUR, HEAT-TREATED, HEMOFIL HT

Licence Number: PL 0116/0150
RA 191A

PRESENT	PROPOSED
Part II Pharmaceutical Data on The Dosage Form	Part II Pharmaceutical Data on The Dosage Form
3. Quality Control	3. Quality Control
3.1.2 Constituents not in Pharmacopoeia	3.1.2 Constituents not in Pharmacopoeia
(a) Source Plasma (Human)	(a) Source Plasma (Human)
... each unit of Source Plasma (Human) is tested for the presence of Hepatitis B Surface Antigen (HBsAG) using third generation reagents licenced by the Bureau of Biologics.	... each unit of Source Plasma (Human) is tested for the presence of Hepatitis B Surface Antigen (HBsAG) using third generation reagents licenced by the Bureau of Biologics. In addition each unit of Source Plasma (Human) has been tested and found non-reactive for HTLV III antibody. Plasma is collected only from donors found to have normal levels of Alanine Aminotransferase (ALT)...
	3.3 Finished Product Specification Source Plasma
	Each unit of Source Plasma (Human) used in manufacture has been tested and found non reative for Hepatitis B Surface Antigen (HBsAg) and HTLV III antibody. Plasma is collected only from donors found to have normal levels of Alanine Aminotransferase (ALT).
	3.3.2 Analytical Methods
	The Methodology for determination for the presence of Hepatitis B Surface Antigen (HBsAg) and HTLV III antibody and plasma levels of Alanine Aminotransferase (ALT) are included as attachments 1 - 3 respectively.