AI000076

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AI000076

Roter

Health Care Limited

8614

To: C Bishop

From: A S Clark

Date: July 14, 1986

Subject: FACTORATE LABELLING

Ref: ASC/CL/1995/86

Copies to:
W Brzeski
E R James
R B Christie

We now have approval from the Department of Health and Social Security for the use of a label relating to HTLV III antibody testing on Factorate outers. The wording is as per that on the data sheet.

We still await approval from the National Drugs Advisory Board.

GRO-C

A S Clark

Inter-office memorandum

ARMOUR002997

ARMO0000556_0001

AI000077

6. Name of Product: FACTORATE HEAT TREATED Licence Number: 0231/0038

7. Address for reply:

AI000077

Miss A S Clark
Armour Pharmaceutical Company Limited
St Leonards House
St Leonards Road
EASTBOURNE East Sussex BN21 3YG

8. Give the present product 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.

Present	Proposed
un the outer, containing 10 vials, labelling as per attached sheet.	As at present but additionally a sticker with the following wording: "All units of source plasma are tested for antibodies to human T cell lymphotropic virus type III (HTLV III) and found to be negative." This wording has previously been approved for use on the data 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 June 17, 1986

Status Registration Officer

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 GRO-C Date: 9 JUL 1986

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

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

*Delete as appropriate

ARMOUR002998

ARMO0000556_0002

AI000078

Name of Product: HIGH POTENCY FACTORATE HEAT TREATED Licence Number: 0231/0044

7. Address for reply:

Miss A S Clark
Armour Pharmaceutical Company Limited
St Leonards House
St Leonards Road
EASTBOURNE East Sussex BN21 3YG

AI000078

8. Give the present product 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.

Present	Proposed
On the outer, containing 10 vials, the labelling as per attached sheet.	As at present but additionally a sticker with the following wording: "All units of source plasma are tested for antibodies to human T cell lymphotropic virus type III (HTLV III) and found to be negative." This wording has previously been approved for use on the data 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 June 17, 1986

Status Registration Officer

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: GRO-C Date:

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

*Delete as appropriate

ARMOUR002999

ARMO0000556_0003

AI000079

Name of Product: HIGH POTENCY FACTORATE HEAT TREATED Licence Number: 0231/0044

Address for reply:

Miss A. S. Clark
Armour Pharmaceutical Co. Ltd.,
St. Leonards House,
St. Leonards Road,
Eastbourne, East Sussex BN21 3YG

AI000079

Give the present product 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.

Present	Proposed
Under section on presentation : Presentation Dried Human Antihaemphilic Fraction Factorate Heat Treated is a stable lyophilised concentrate of Factor VIII AHF, AHG) prepared from pooled human plasma. Each vial contains the labelled amount of antihaemophilic activity in International Units (one International Unit is the activity equivalent to the average Factor VIII content of 1ml aliquots of 167 samples of fresh normal plasma, as cont'd/....	As at present but additionally the following information to be included : "In addition all units are tested for ALT (serum alanine aminotransferase) and found to be less than twice the established upper normal value for the test kit". Reason All units of source plasma are now ALT tested.

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 9/6/96

Status Registration Officer

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: GRO-C Date:

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

*Delete as appropriate

ARMOUR003000

ARMO0000556_0004