AI000097/15

Department of Health and Social Security
Medicines Division
Market Towers 1 Nine Elms Lane London SW8 5NQ
Telex 883669 Telegrams Healthmin London SE1
Telephone 01-720 2188 ext

AI000097
REGI[illegible]
2 AUG 1984

Mr C J Collins
Regulatory Affairs Manager
Armour Pharmaceutical Company Limited
Hampden Park
Eastbourne
East Sussex BN22 9AG

Your reference
Our reference PL/0231/0038
Date 31 July 1984

Dear Sir

MEDICINES ACT 1968: PART II LICENSING

In accordance with Section 24 of the Medicines Act, authority has now been given for the renewal of the following product licence:

Product	Licence Number
Factorate	PL/0231/0038

The formal documents are enclosed. If you consider they contain information which is incorrect or is not in accordance with your application please return them with brief details.

In relation to the above licence you will wish to note and consider the following:

1. The licence is subject to standard provisions which are contained in the schedule to the licence.

2. All products are subject to review by the Committee on Review of Medicines.

3. If any new data sheets for the product covered by this licence are to be issued, will you please arrange for copies to be sent to this office. The particulars to be included in such sheets are set out in the Medicines (Data Sheet) Regulations 1972 (SI 1972 No 2076).

Yours faithfully

GRO-C

ENC

ARMOUR002323

ARMO0000320_0001

AI000098/15

AI000098/1

M E D I C I N E S A C T 1 9 6 8

RENEWAL OF PRODUCT LICENCE

PRODUCT LICENCE No 0231/0038

Granted to: Armour Pharmaceutical Company Limited
St Leonards House
St Leonards Road
Eastbourne
East Sussex, BN21 3YG

Date of grant 25 March 1976

The Licence granted under the above reference number in respect of the product, particulars of which are set out in Part 1 of the attached Schedule, is hereby renewed, subject to the further provisions set out or referred to in Part 2 of the said Schedule.

The Licence, as now renewed, will, unless previously suspended, revoked or varied as to the period of its validity, continue in force until the end of a period of five years from the date of renewal given below.

Date of renewal: 25 MARCH 1981

GRO-C: Lucas

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

31 July 1984

Department of Health and Social Security
Medicines Division
Market Towers
1 Nine Elms Lane
LONDON SW8 5NQ

ARMOUR002324

ARMO0000320_0002

M E D I C I N E S A C T 1 9 6 8

Product Licence No. 0231/0038

SCHEDULE

Part 1 - PARTICULARS OF THE PRODUCTS TO WHICH THE LICENCE RELATES

1.	Name of Product:	Factorate (Factor VIII)
2.	Pharmaceutical form:	A white to pale yellow lyophilised cake in vial with vacuum for intravenous administration to human beings after reconstitution.
3.	Active constituents:	Antihaemophilic Factor (Human): Each vial contains a minimum of 125 AHF units and provides a minimum of 5 AHF units per ml when reconstituted with 25 ml water for injection.
4.	Uses:	In therapy of classical haemophilia (Haemophilia A)
5.	Recommended dose and dosage schedule:	Antihaemophilic Factor (Human)-FACTORATE® is for intravenous administration only. Although dosage must be individualized according to the needs of the patient (weight, severity of hemorrhage, presence of inhibitors) the following general dosages are suggested:

1. OVERT BLEEDING - Initially 20 units per kg. of body weight followed by 10 units/kg. every eight hours for the first twenty-four hours and the same dose every twelve hours for 3 or 4 days.

2. MUSCLE HEMORRHAGES -

a. Minor hemorrages in extremities or non-vital areas: 10 units per kg. once a day for 2 or 3 days.

b. Massive hemorrhages in non-vital areas: 10 units per kg. by infusion at 12 hour intervals for two days and then once a day for two more days.

c. Hemorrhages near vital organs (neck, throat, subperitoneal), 20 units per kg. initially, then 10 units per kg. every 8 hours. After two days the dose may be reduced by one-half.

MEDICINES ACT 1968 AI000098/3

Product Licence No. 0231/0038

SCHEDULE

Part 1 - PARTICULARS OF THE PRODUCTS TO WHICH THE LICENCE RELATES

5.	Recommended dose and dosage schedule cont'd:	3. JOINT HEMORRHAGES - 10 units per kg. every eight hours for a day; then twice daily for one or two days. If aspiration is carried out, 10 units per kg. just prior to aspiration with additional infusions of 10 units per kg. eight hours later and again on the following day. 4. SURGERY - Dosages of 30 to 40 units per kg. body weight prior to surgery are recommended. After surgery 20 units per kg. every eight hours should be administered. Close laboratory control to maintain the blood level of AHF above 40% of normal for at least ten days postoperatively is suggested. As a general rule one unit of AHF activity per kg. will increase by 2% the circulating AHF level. Adequacy of treatment must be judged by the clinical effects - thus the dosage may vary with individual cases.
6.	Contra-indications, Precautions and Warnings:	Antihemophilic Factor (Human) - FACTORATE® is prepared from human plasma, each donation of which has been found negative for Hepatitis B Surface Antigen (HBsAg) by the radioimmuno-assay (RIA) method. In addition, this lot, after reconstituiton has been tested and found negative by the RIA method. However, since no completely reliable laboratory test is yet available to detect all potentially infectious plasma donations, the risk of transmitting viral hepatitis is still present. FACTORATE® contains low levels of groups A and B isohemagglutinins. When large volumes are given to patients of blood groups A, B, or AB the possibility of intravascular hemolysis should be considered. There are no known contraindications to antihemophilic factor.
7.	Legal Category:	PRESCRIPTION ONLY MEDICINE.
8.	Method of retail sale or supply:	For supply to hospitals.

AI000101

AI000098/4

MEDICINES ACT 1968

Product Licence No. 0231/0038

SCHEDULE

Part 1 - PARTICULARS OF THE PRODUCTS TO WHICH THE LICENCE RELATES

9.	Manufacturer of dosage form:	Active consituent and Dosage form: Armour Pharmaceutical Company PO Box 511 Kankakee Illinois 60901 USA Active consituent only Metrix Clinical and Diagnostics Division Armour Pharmaceutical Company Chicago Illinois 60616 USA
10.	Dates of letters of variation to original licence:	16 July 1976, 9 February 1977, 15 June 1977, 15 October 1977, 12 November 1979, 19 September 1980, 18 August 1981, 30 July 1982, 23 August 1982, (2 letters) 30 September 1982. 12 April 1984, 26 April 1984

ARMOUR002327

MEDICINES ACT 1968

Product Licence No. 0231/0038

SCHEDULE

Part 2 - FURTHER PROVISIONS SUBJECT TO WHICH THE LICENCE HAS BEEN GRANTED

1. All the provisions of Part I of Schedule 1 of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (SI 1971 No 972) as amended by the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1972 (SI 1972 No 1226), the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1974 (SI 1974 No 1523) and the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1977 (SI 1977 No 1039) shall apply.

2. Leaflets issued with proprietary medicinal products shall comply with the requirements of the Medicines (Leaflets) Regulations 1977 (SI 1977 No 1055). Labels of medicinal products shall comply with the Medicines (Labelling) Regulations 1976 (SI 1976 No 1726) as amended by the Medicines (Labelling) Amendment Regulations 1977 (SI 1977 No 996).

3. The product(s) shall not be recommended to be used for any purposes other than those specified in Part 1 of this Schedule as Uses.

4. The specification of the constituent and of the finished product shall be in accordance with the information contained in the application for this product licence.

5. The product shall be manufactured by the person named in Part I of the Schedule to this licence or by any other person who is licensed to manufacture products of that description in the United Kingdom.

AI000103

AI000098/6

MEDICINES ACT 1968

PRODUCT LICENCE No. 0231 /0038 **has been granted under and subject to the provisions of the Medicines Act 1968 to**

Armour Pharmaceutical Company Limited
Hampden Park
Eastbourne
Sussex

in respect of the products, particulars of which are set out in Part 1 of the attached Schedule. The Licence is subject to the further provisions set out or referred to in Part 2 of the said Schedule.

This Licence, unless previously suspended, revoked or varied as to the period of its validity, shall continue in force until the end of a period of five **years from the date on which it was granted.**

Date granted : 25 March 1976

GRO-C

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

GRO-C 1976

Department of Health and Social Security,
Finsbury Square House,
33/37A, Finsbury Square,
London, E.C.2.

ARMOUR002329

ARMO0000320_0007

AI000104

MEDICINES ACT 1968

AI000098/7

Product Licence No. 0231 / 0038

SCHEDULE

Part 1 - PARTICULARS OF THE PRODUCTS TO WHICH THE LICENCE RELATES

1.	Name of Product:	Factorate (Factor VIII)
2.	Pharmaceutical form:	A white to pale yellow lyophilised cake in vial with vacuum for intravenous administration to human beings after reconstitution
3.	Active constituents:	Antihaemophilic Factor (Human): Each vial contains a minimum of 125 AHF units and provides a minimum of 5 AHF units per ml when reconstituted with 25 ml water for injection.
4.	Uses:	In therapy of classical haemophilia (Haemophilia A)
5.	Recommended dose and dosage schedule:	As specified in the application
6.	Method of retail sale or supply:	For supply to hospitals
7.	Manufacturer:	Active constituent and Dosage form: Armour Pharmaceutical Company PO Box 511 Kankakee Illinois 60901 USA Active constituent only Metrix Clinical and Diagnostics Division Armour Pharmaceutical Company Chicago Illinois 60616 USA

ARMOUR002330

ARMO0000320_0008

AI000105

MEDICINES ACT 1968

Product Licence No. 0231 / 0038 AI000098/8

SCHEDULE

Part 2 - FURTHER PROVISIONS SUBJECT TO WHICH THE LICENCE HAS BEEN GRANTED

1. All the provisions of Part I of Schedule 1 of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (S.I. 1971 No. 972) as amended by the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1972 (S.I. 1972 No.1226) and the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1974 (S.I. 1974 No.1523) shall apply.

2. The number of the Licence shall appear on all containers or packages in which the product(s) is packed, on any package inserts or accompanying literature and on any data sheets issued in connection with the product.

3. The product shall not be recommended to be used for any purposes other than those specified in Part 1 of this Schedule as Uses.

4. The specification of the constituent and of the finished product shall be in accordance with the information contained in the application for this product licence.

5. The product shall be manufactured only in accordance with the method given in the application for this product licence.

6. Information shall be provided by the licence holder on the number of donations from which plasma is pooled for the manufacture of each batch of the product, and the reasons for and the rate of rejection of donors or donations centre by centre.

7. Plasma shall be obtained only from donor centres in the United States of America or in other countries specified in respect of which the licensing authority is satisfied as to the donation arrangements being premises in respect of which the licence holder has provided an undertaking that they may be inspected by or on behalf of the United Kingdom licensing authority.

MEDICINES ACT 1968

Product Licence No. 0231 / 0038

AI0000979

SCHEDULE

Part 2 - FURTHER PROVISIONS SUBJECT TO WHICH THE LICENCE HAS BEEN GRANTED

8. The potency of the product shall be expressed in international units.

9. The product shall be stored at a temperature of 6° Centigrade or below.

10. Product labelling shall be in accordance with the British Pharmacopoeia for dried human Antihaemophilic Fraction.

11. The licence holder shall on request furnish to the Licensing authority from every batch of the product or from such batch or batches as the licensing authority may from time to time specify, a sample of such amount as the licensing authority may consider adequate for any examination required to be made and the licence holder shall, if required by the licensing authority, furnish full protocols of the tests which have been applied.

12. If the licensing authority so direct the licence holder shall not sell or supply any batch in respect of which a sample is or protocols are furnished under paragraph 11 until a certificate authorising the sale or supply of the batch has been issued to him by the licensing authority.

13. The licence holder shall, on being informed by the licensing authority that any part of any batch of the product has been found not to conform as regards strength, quality and purity with the specification of the product and on being directed so to do, withdraw the remainder of that batch from sale or supply and, so far as may be practicable, recall all issues already made from that batch.

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

7. **Address for reply:**

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

AI000098/10

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
Presentation Dried Human Antihaemophilic 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 determined in an international /cont	Presentation As at present but additionally the following information to be included: "All units of source plasma are tested for antibodies to human T cell lymphotropic virus type III (HTLV III) and found to be negative." Proposed data sheet text attached. Reason This test is now being carried out routinely on all plasma collected.

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** 9 January 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:** - 4 MAR 1986

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

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

*Delete as appropriate

ARMOUR002333

ARMO0000320_0011

AI000108

Page 2

7. Licence number: 0231/0038 Your reference: R80/147

8. Name of Product: FACTORATE

REGISTRATION 16 APR 1984

9. Address for reply:

AI000098/11

Armour Pharmaceutical Company Limited,
St. Leonards House,
St. Leonards Road,
Eastbourne,
East Sussex,
BN21 3YG
Attn: Mr. W. J. Tarbit

16 APR 1984

10. 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):

Present	Proposed
Shelf-life	
Shelf-life of 2 years when stored at a temperature between 2° and 8°C.	Shelf-life of 3 years when stored at a temperature between 2° and 8°C.
Within this period Factorate may be stored at a temperature not exceeding 30°C for up to six months.	Within this period Factorate may be stored at a temperature not exceeding 30°C for up to six months.

11. Reasons for change: Development of additional stability data.

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

Signed GRO-C Date 11th March, 1982

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

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

Signed: GRO-C Date: 12 APR 1984

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

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

ARMOUR002334

ARMO0000320_0012

oduct: FACTORATE Licence Number: 0231/0038

7. Address for reply:

FD
PHSS
KBS/24

MISS L. J. NEWTON,
REGISTRATION OFFICER,
ARMOUR PHARMACEUTICAL COMPANY LIMITED,
ST. LEONARDS HOUSE, ST. LEONARDS ROAD,
EASTBOURNE, EAST SUSSEX, BN21 3YG

AI000098/12

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
SEE COPY OF DATA SHEET OVERLEAF.	AS AT PRESENT WITH ADDITIONAL INFORMATION CONCERNING RECONSTITUTION VOLUME. THE PROPOSED DATA SHEET TEXT IS ATTACHED.

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 22ND JANUARY, 1985

Status C/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: 5 JUL 1985

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

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

*Delete as appropriate

AI000110

Form MLA 221
R.82

NOTIFICATION ONLY

APPLICATIONS FOR CHANGE OF PRODUCT LICENCE AI000098/13

1. **PRODUCT NAME:** FACTORATE 1000 iu/vial **LICENCE NUMBER:** 0231/0038

2. **Name and Address of Licence Holder** Armour Pharmaceutical Company Ltd.,
St. Leonards House,
St. Leonards Road,
Eastbourne, East Sussex. BN21 3YG

Telephone Number: (0323) 21422 **Name of Contact:** Mr. W. J. Tarbit

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

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

4. **Reasons for change**

Desire for smaller capacity presentation to facilitate manufacture and storage in use.

For Licensing Authority use only:

5. **Application dated** ..... **Route**

Received ..... **Pharm:**

Stats ref ..... **Med:**

Code .....

ADP

Application Approved*/Refused
(See M-)

____ no copies required ____ MLA 221 and flagged pages only

Pharmacist:
Date:

____ MLA 221 only ____ Complete data

Doctor:
Date:

*Delete as appropriate

R.I

6. Name of Product FACTORATE 1000 iu/vial Licence Number: 0231/0038

7. Address for reply:

Mr. W. J. Tarbit,
Regulatory Affairs Department,
Armour Pharmaceutical Company Ltd.,
St. Leonards House,
St. Leonards Road,
Eastbourne, East Sussex,
BN21 3YG

REGISTRATION
15 JUL 1985

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*
Supply in 125 ml vial of glass to USP Type I specification.	Supply in 100 ml capacity vial of glass to USP Type I specification. The bulk liquid will be concentrated by ultra filtration before filling into vials to reduce the volume of liquid containing the required amount of Factorate activity.

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 26th March, 1984

Status Assistant Regulatory Affairs Manager

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 17 JUL 1985

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

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

*Delete as appropriate

AI000099 . CW11

Department of Health and Social Security
Finsbury Square House Medicines Divisi[illegible]AI000099
33-37a Finsbury Square London EC2A 1PB
Telex 883669 Telegrams Healthmin London SE1
Telephone 01-638 8020 ext
LP2

MEDICAL DEPT.
21 JUL 1976

Armour Pharmaceutical Company Limited
Hampden Park
EASTBOURNE
Sussex
BN22 9AG

Your reference

Our reference
PL/0231/0038

Date
GRO-C 1976

FOR THE ATTENTION OF S G BROOKS ESQ

Dear Sir

NOTIFICATION OF CHANGE IN PARTICULARS RELATING TO
PRODUCT LICENCE No: 0231/0038
NAME OF PRODUCT: FACTORATE

1. Thank you for your letter of 17 May 1976 detailing changes in particulars relating to the above product licence. This is to let you know that the licensing authority has no objection to the proposed changes. Please retain this letter with the formal documents relating to product licence number 0231/0038 as evidence of the approval of the change.

The formal documents relating to this licence are returned herewith, they have not been amended as you suggested because it is not usual practice to do so.

2. I am sorry to say that we cannot undertake to check data sheets in draft form. Copies of printed data sheet should be sent to us as when available.

Yours faithfully

GRO-C

MG The firm Metrix Division is deletes from th.

ENCS

AI000100

R80/165 Dose Factorate Formol Does

Page 2 AI000100

7. Licence number: PL 0231/0038 Your reference: R80/165

8. Name of Product: FACTORATE

9. Address for reply:

REGISTRATION 25 AUG 1982

Mr. W. J. Tarbit,
Armour Pharmaceutical Co. Ltd.,
St. Leonards House,
St. Leonards Road,
Eastbourne,
East Sussex,
BN21 3YG

10. 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):

Present	Proposed
RECONSTITUTION Factorate Single Fill: 'Reconstitute Factorate using 20 ml Sterile Water for Injections BP using standard aseptic precautions'. Factorate Double Fill: 'Reconstitute Factorate using 40 ml Sterile Water for Injections BP using standard aseptic precautions.'	Factorate Single Fill: 'Reconstitute Factorate with sterile Water for Injections BP using standard aseptic precautions. Reconstitution with 20 ml sterile Water for Injections BP will give a solution which complies with the BP. In some circumstances, where a small volume is required, it may be preferable to reconstitute Factorate with 10 ml sterile Water for Injections BP: however the conten of sodium and citrate ions will not comply with the BP. Factorate Double Fill: As above but substitute 20 ml for 10 ml in third paragraph and 40 ml for 20 ml in second paragraph.

11. Reasons for change: See MLA 221, page 3

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

Signed GRO-C Date 8th April, 1982

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

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

Signed: GRO-C Date: 23.8.82

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

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

ARMOUR002339

ARMO0000320_0017

AI000101

81/83 Diss Feedback Formal Docs

Page 2

7. Licence number: 0231/0038 AI00010 Your reference: 81/83

8. Name of Product: FACTORATE

9. Address for reply:

Armour Pharmaceutical Co. Ltd.,
St. Leonards House,
St. Leonards Road,
Eastbourne,
Sussex.
BN21 3YG

10. 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):

Present	Proposed
Single and double fill presentations with nominal 250 and 500 iu/vial respectively.	Additional presentation containing nominal 1000 iu/vial, reconstituted in 60 ml of water for Injections BP for user convenience.

11. Reasons for change: See MLA 221 Page 3

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

Signed GRO-C Date 30th July 1982

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

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

Signed: GRO-C Date: 23.8.82

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

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

ARMOUR002340

ARMO0000320_0018

7. **Licence number:** 0231/0038 **Your reference:**

8. **Name of Product:** FACTORATE 1000 iu/vial presentation

9. **Address for reply:**

Mr. W. J. Tarbit,
Regulatory Affairs Department,
Armour Pharmaceutical Co. Ltd.,
St. Leonards House,
St. Leonards Road,
EASTBOURNE,
East Sussex, BN21 3YG

REGISTRATIC
30 APR 1984

10. **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):**

Present	Proposed
1000 iu/vial Reconstitution in 60 ml Water for Injections B.P.	See MLA 221, page 3.

11. **Reasons for change:** Standardisation of product range.

12. **I hereby make application for the above licence to be changed in accordance with the proposals given above:**

Signed GRO-C **Date** 30th September, 1982

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

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

Signed: GRO-C **Date:** 26 APR 1984

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

AI000103

Licence Number: 0231/0039

Name of Product: FACTORATE 1000 iu/vial presentation

PROPOSED

In addition low volume reconstitution in 30 ml Water for Injections B.P. with following wording:

'Reconstitute Factorate with Water for Injections B.P. using standard aseptic precautions.

Reconstitution with 60 ml Water for Injections will give a solution which complies with the B.P.

In some circumstances, where a small volume is required, it may be preferable to reconstitute Factorate with 30 ml Water for Injections B.P., however the content of sodium and citrate ions will not comply with the B.P.'.