MEDICINES ACT 1968, 1971 APPLICATION FOR CHANGE TO MARKETING AUTHORISATION

Form MLA 221 (Revised 1/4/87)

1 PL number: PL 0055/0107

Product name: KOATE HT

Name and address of PL holder: Miles Laboratories Ltd
Stoke Court
Stoke Poges
Slough SL2 4LY

Active constituent(s): (quantitative): Coagulation Factor VIII - heat treated

Dosage form: Lyophilised powder for reconstitution with Water for Injection for intravenous infusion.

Method of sterilisation: Sterile filtration through 0.2 micron filter. Final product heat-treated at 68°C for 72 hours.

Telephone no: 02814 5151 Ext GRO-C
Person to contact: Mrs M W Tatt
Applicant's ref: MWT/kp

2 Proposed change involving [please tick box(es)]

2A ☐ NAME OF PRODUCT

2B ☐ MANUFACTURER ☐ ASSEMBLER ☐ DISTRIBUTOR
☐ STORAGE ARRANGEMENTS

2C ☐ INDICATIONS ☐ CONTRAINDICATIONS / WARNINGS / PRECAUTIONS
☐ DOSAGE ☐ DATA SHEET ☐ PACKAGE INSERT

2D ☐ FORMULATION - "ACTIVE(S)" ☐ SUPPLIER OF ACTIVE INGREDIENTS ☐ FORMULATION - "EXCIPIENT(S)"
☐ INGREDIENT SPECIFICATIONS ☐ METHOD OF MANUFACTURE ☐ FINISHED PRODUCT SPECIFICATION
☐ QUALITY CONTROL PROCEDURES ☐ CONTAINERS ☐ PACK SIZE
☐ SHELF LIFE ☐ STORAGE PRECAUTIONS ☐ METHOD OF RETAIL SALE / SUPPLY
☐ "OWN LABEL" SUPPLIER ☑ OTHER (PLEASE SPECIFY): Notification of change in screening ~~of donations - ALT testing.~~

3 On page 2 (use additional pages if necessary) please give full details of (a) present particulars, etc; (b) proposed change and (c) reason for change; any supporting evidence should be attached to the application. Two sets of Form MLA 221 are required. In addition, two sets of the appropriate pages of MLA 201, 231 or 201R amended in accordance with the proposed change should be submitted.

FOR OFFICIAL USE ONLY:

Route:

Application dated .....

Form 2A action .....

Received .....

Form 2B action .....

Stats. No .....

Pharmaceutical Secretariat:

Code .....

Medical / Dental Secretariat:

Data: registered / attached to file / in blue pouch / in data store

Labelling etc: .....

Application: APPROVED / REFUSED Pharmaceutical Secretariat: Date:

APPROVED / REFUSED Medical / Dental Secretariat: Date:

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PL number: PL 0055/0107
Product name: KOATE HT

Mrs M W Tatt
Miles Laboratories Limited
Stoke Court
Stoke Poges
Slough SL2 4LY

For the attention of:
Name and address for reply:

5 Give the present product particulars and proposed change, and the reason for change. Differences not immediately apparent should be underlined or otherwise highlighted. If the change affects particulars on the Schedule to the Product Licence these should be given exactly as they appear in the Schedule and exactly how it is proposed they should be stated. Continue on separate sheets if necessary. Attach any supporting evidence. Two copies of Form MLA 221 and the additional pages referred to in Section 3 should be submitted.

Present	Proposed
Source Plasma (Human) Source plasma is collected according to the Cutter System of Plasma-pheresis which incorporates all the FDA requirements for Source Plasma including testing of samples from all donors for antibodies to HTLVIII.	Source Plasma (Human) Source plasma is collected according to the Cutter System of Plasma-pheresis which incorporates all the FDA requirements for Source Plasma including testing of samples from all donors for antibodies to HIV.

continued...

Reason for change: The ALT screening procedure has been introduced by Cutter as an additional safety measure following recommendations by the U.S. authorities.

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

Signed GRO-C Date 10/8/87

Status Regulatory Affairs Manager

FOR OFFICIAL USE ONLY

The Licensing Authority consents to your request to change the Product Licence as outlined in 5 above. Please retain this form with the formal documents relating to the Product Licence as evidence of approval of the change.

Signed: Date:

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

Present

Proposed continued

In addition Cutter test each donation for A levels. Only units found to have an ALT level less than twice the upper limit of normal for the test are used in the manufacture of KOATE HT.

NBSB
NATIONAL BIOLOGICAL STANDARDS BOARD

A W.H.O. International Laboratory for Biological Standards

NATIONAL INSTITUTE FOR BIOLOGICAL STANDARDS AND CONTROL
Blanche Lane, South Mimms, Potters Bar
Hertfordshire, EN6 3QG

telegrams Nibsac Potters Bar
telex 21911 Nibsac G
telephone Potters Bar (0707) 54753 & 54763

MEDICINES ACT 1968

BATCH RELEASE CERTIFICATE No H 0051 A

PRODUCT LICENCE/ ~~CLINICAL TRIAL CERTIFICATE~~ No PL 0055/0107

PRODUCT KOATE HT (Heat treated Factor VIII)

In accordance with the provisions of the above Product Licence ~~Clinical Trial Certificate~~

held by Miles Laboratories Ltd

THIS IS TO CERTIFY THAT protocols and samples of

Batch No/s	Filling Lot/s
5050391A	

received from Miles Laboratories

have been examined and that sale or supply is hereby authorised with the consent of the Licensing Authority of the Department of Health and Social Security.

Dated this 24th day of August 19 87

Signature. GRO-C: Rhinehall .....
NATIONAL BIOLOGICAL STANDARDS BOARD

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MEDICINES ACT 1968

BATCH RELEASE CERTIFICATE No H 0051 A

PRODUCT LICENCE/
~~CLINICAL TRIAL CERTIFICATE~~ No PL 0055/0107

PRODUCT KOATE HT (Heat treated Factor VIII)

In accordance with the provisions of the above Product Licence ~~Clinical Trial Certificate~~

held by Miles Laboratories Ltd

THIS IS TO CERTIFY THAT protocols and samples of

Batch No/s	Filling Lot/s
5050291	

received from Miles Laboratories

have been examined and that sale or supply is hereby authorised with the consent of the Licensing Authority of the Department of Health and Social Security.

Dated this 24th day of January 1987

Signature.. GRO-C: Rhinehall .....
NATIONAL BIOLOGICAL STANDARDS BOARD