6 Name of Product: KOATE-HT Licence Number: PL0055/0107

7. Address for reply:

MRS. M.W. TATT,
MILES LABORATORIES LIMITED,
STOKE COURT, STOKE POGES,
SLOUGH, SL2 4LY, BERKSHIRE.

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 |
|---|---|
| SOURCE PLASMA (HUMAN)<br>Source plasma is collected according to the Cutter System of Plasmapheresis which incorporates all the FDA requirements for Source Plasma (Human). | SOURCE PLASMA (HUMAN)<br>Source plasma is collected according to the Cutter System of Plasmapheresis which incorporates all the FDA requirements for Source Plasma (Human) including testing of samples from all donors for antibodies to HTLV III.<br>Reason<br>The procedure for screening of donors has been updated in accordance with FDA requirements. |

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: Marie W Tatt Date 30th May 1985.

Status 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: C Q Knight Date: 31 JUL 85

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

DEPARTMENT OF HEALTH AND SOCIAL SECURITY

*Delete as appropriate