# COMMITTEE ON SAFETY OF MEDICINES

Market Towers,
1 Nine Elms Lane,
London, SW8 5NQ
*Telephone:* 01-720 2188
Ext GRO-C

*Your reference:*
*Our reference:*

Miles Laboratories Ltd
PO Box 37
Stoke Court
Stoke Poges
Slough
SL2 4LY

24 October 1985

FOR THE ATTENTION OF : MRS M. W. TATT

Dear Madam

PRODUCT : KONYNE-HT PL No. 0055/0108

The Committee on Safety of Medicines have been consulted by the Licensing Authority about your application for a Product Licence for Konyne-HT. The Committee have directed me to inform you, in accordance with Section 21(1) of the Act, that they have reason to think on grounds relating to safety, quality and efficacy (see Section 20(3) of the Act), that they may be unable to advise the Licensing Authority to grant a Product Licence.

The Committee have provisionally concluded that:-

1. Inadequate information had been provided on the manufacture and control of the sterile water for injection vials.

2. Inadequate information had been provided on the fractionation and control procedures.

3. Information should be provided on the standards used in finished product testing.

4. Inadequate evidence had been provided of virus inactivation.

5. Insufficient evidence had been provided of the clinical safety and efficacy of the product or of the product on which it is based.

If you wish to discuss any of these points please do not hesitate to contact Dr Duncan, the Medical Assessor, on Ext GRO-C or Mr Betts, the Pharmaceutical Assessor, on Ext GRO-C

The Act provides that before the Committee advise the Licensing Authority about your application, you shall be afforded an opportunity of appearing before and being heard by them, or of making representations in writing to them, with respect to the grounds referred to above. Please let me know within 28 days if you wish to take up either of the above options and, if so, which of them you have chosen. If you request a hearing you will be contacted by a member of the Secretariat regarding the date of the hearing and any other relevant matters.

You should submit 23 copies of any additional information you wish to be presented to the Committee. This should be as concise as possible and directly relevant to the grounds referred to above.

Please inform me if there will be some delay in the submission of the additional material. Where the delay is likely to exceed one year from the date of this letter, it would be helpful if you would consider withdrawing the present application and re-applying at a future date. This option is put to all companies whose applications are the subject of the proceedings under Section 21(1) of the Act.

Please acknowledge receipt of this letter promptly. I look forward to an early reply advising me of your future intentions.

Yours faithfully

GRO-C

KEITH FOWLER
Assistant Secretary CSM