

11/17



NATIONAL INSTITUTE FOR BIOLOGICAL STANDARDS AND CONTROL

Blanche Lane South Mimms Potters Bar Hertfordshire EN6 3QG

NATIONAL BIOLOGICAL STANDARDS BOARD

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

telex 21911 Nibsac G
fax no. 0707 48730
telephone Potters Bar (0707) 54753

SLJ/FF/89.454

FACSIMILE MESSAGE

No. of pages: 1

For the attention of: Mr Clive Wilson
Medicines Control Agency
Department of Health
Market Towers

Dear Clive

Re: Profilate

Not final as HIV Ab is correct is in the fraction may find virus

Following our telephone conversation this morning and an analysis of the data and commentary faxed by Mr Booth, we have come to these conclusions:

1 There is no evidence suggesting that the product is unsafe. Batches of Profilate have been tested here in accordance with the Product Licence, found to meet specifications and released to the market. This testing has included tests for antibodies to HIV and for the presence of HBsAg on both the final product and the plasma pools.

2 The Inspectorate has made pertinent criticisms of the manufacturing process that reveal breaches of GMP. However, we feel that the company are responding to the criticisms made (as evidenced by the letter of 2nd November) and that IAG is perhaps over-hasty in its recommendations.

3 We feel that your own commentary deals with the essential points extremely clearly.

4 Dr Duncan Thomas has had a lengthy discussion with Frances Rotblat. We don't feel that it is necessary for us to be present at your meeting tomorrow.

With best wishes.

Yours sincerely

No clinical data

GRO-C

S L Jeffcoate