

Bayer UK Limited
Pharmaceutical Business Group
Bayer House
Strawberry Hill
Newbury
Berkshire
RG13 1JA

Telephone: Newbury (0635) 39000
Direct dialling: Newbury (0635) **GRO-C**
Fax: (0635) 39404
Telex: 847205 Baynew G

Dr. E. Greene,
Cutter Biological,
Miles Inc.,
4th & Parker Streets,
PO Box 1986,
BERKELEY, California 94701,
U.S.A.

TELEFAX

Your ref

Our ref

CDS/ER/177

Date 9 November 1989

Dear Eli,

I am now in a position to update you on the following:

KOATE HS

The Department of Health has considered our written response (submitted June 1989) and, having taken advice from NIBSC, still has reservations concerning the adequacy of the data on viral inactivation. Thus, they wish to refer the matter to the Committee on Safety of Medicines (CSM) for further advice. It is likely that the CSM will discuss the data during their meeting in January 1990.

If we consider it appropriate, we could arrange an informal meeting at the Department of Health to discuss the application prior to January. Dr. J. Purves (Pharmaceutical Assessor) has tentatively suggested 4 December 1989. As I will need to confirm this date within a few days, could you please determine whether or not the relevant experts would be available at such short notice. Please note, however, that such informal meetings usually involve only two or three company representatives at the most. Before proceeding with any arrangements, however, please note the following comments regarding Gamimune N.

GAMIMUNE N

As you are aware, lot number 40U052A will not be released by NIBSC as they found antibodies to HIV both in the finished product and in plasma pool PF 3282. Their presence was confirmed using four different immunochemical methods including immunoblotting. Robin Thorpe (NIBSC - Head of the Immunobiology Division) thought it might be helpful to arrange a small informal meeting to discuss the scientific and technical aspects of testing blood products and plasma pools.

However, since then, NIBSC have notified the Department of Health, and Dr. John Purves considers it more appropriate that we meet both NIBSC and Department of Health representatives at the same time. The Medicines Inspectorate are also being notified, but as yet it is unclear whether or not they will attend the meeting or contact us independently.

continued/

Dr. Purves stressed that we should not hold this meeting until all the necessary investigations into the possible causes of contamination are complete and we are in a position to offer some explanations. Thus, I would be grateful if you could inform me as soon as possible as to whether the data will be available in time to combine it with the Koate HS meeting or, if not, the earliest possible date thereafter.

I look forward to receiving your comments in the near future.

Yours sincerely,

GRO-C

Craig D. Simpson
SENIOR REGISTRATION OFFICER

cc: Dr. R. Wheywell
Dr. G. Macdonald
Mrs. J. Boulton