-9 MAY 1991

BJC 9MC

M E M O R A N D U M

To: Dr. R.S. Lane

From: Dr. D.P. Thomas

c.c. Mr. B.J. Crowley

7th May, 1991.

I would like to suggest that there are some outstanding items that we need to clarify as soon as possible with the MCA. We seem to be acting on the assumption that our new products will receive full marketing authorisation on the basis of clinical data supplied by either Baxter or Kabi. I think we need to establish, as a matter of urgency, that the secretariat at the MCA view this in the same way that we do, namely that we will be able to use the Baxter and Kabi clinical data for obtaining a product licence for both 8SM and Vigam. As you know, we have no clinical data of our own to support the safety of the product in relation to freedom from contamination with viruses. Are the MCA likely to take the view that both these products, <u>when manufactured at Elstree</u>, will require full viral validation locally, both in vitro and in long term clinical studies? I hope very much that this will not be the case, but it is important that we ask the question of the MCA. *

The situation with 9MC is even more problematical. This is an entirely new product, developed in-house. I feel sure that the MCA will require us to show that the solvent detergent process invalidates a range of viruses in vitro, and I understand that these studies are already in hand. But will they also require that we demonstrate in clinical trials, by long term follow-up, that 9MC is free of the risk of transmitting AIDS or hepatitis before a product licence is given to us? *

I am sorry if I seem pessimistic, but it is vital that we get as much guidance as we can from Dr. Purves and colleagues about the likely view of the MCA when they eventually review our product licence applications.

GRO-C

CENTRAL BLOOD LABORATORIES AUTHORITY
DATE REC'D - 8 MAY 1991
ACTION

* certainly worth clarifying

We should take the line that Baxter and Kabi data is adequate and relevant to the products to be made at Elstree