BPL
BIO·PRODUCTS LABORATORY

Dagger Lane, Elstree, Herts. WD6 3BX
Telephone: 081 905 1818
Facsimile: 081 207 4824

Dr J Metters
Deputy Chief Medical Officer
Department of Health
Richmond House
79 Whitehall
London SW1A 7NS

3rd June 1993

Dear Dr. Metters

BPL Plasma Derivatives Compromised By

Positive Hepatitis C Donations

I am writing to advise you of an issue concerning BPL products in which two plasma pools have been compromised by the late notification of plasma donations being tested and found positive for Hepatitis C antibody. This late advice has resulted in substantial quantities of product valued at over £1m being manufactured from these compromised pools. The products include high purity and intermediate purity Factor VIII (8SM and 8Y) together with some normal and Anti-D Immunoglobulins and Albumin.

We are satisfied with the level of assurance of safety provided by our processes and the level of Hepatitis C antibody in the compromised pools is almost certainly less than that in pools processed prior to the introduction of Hepatitis C screening. There is no history of transmission of Hepatitis C with any of the products mentioned above. We therefore believe that the products do not pose a risk to patients, a view supported by three independent virologists.

However, following the CPMP recommendations on "Blood Products and the Testing of Donations for Hepatitis C Antibodies" and the resulting CSM recommendations which came into force on 1 January 1993, we advised the MCA, Dr J Purves, of the above issue and requested exemption from the recommendations. We were advised that the decision was ours to take within our product licences.

MHRA0000121_0001

We have now carefully considered the appropriate action having regard to the following :-

1. The strict letter of our product licences.

2. Ministerial commitments that BPL will fully comply with CPMP guidelines.

3. The necessary preservation of BPL's high reputation for safe products.

4. The draft Annex to the EC Guide to GMP for products derived from human blood or human plasma, particularly paragraph 11 on post collection measures.

5. The political sensitivity of the haemophilia population.

6. The difficulty of drawing a distinction in the public mind between HIV, Hepatitis B and Hepatitis C even though our processes deal equally effectively with all three.

7. The fact that the source of our current problem will almost inevitably become public.

We have concluded that, although a strict interpretation of the CPMP guidelines and the Annex to the EC Guide may not actually prevent us from releasing the compromised product, we believe that to do so would certainly breach the spirit of the guidelines and the Annex. We have therefore concluded that we should not and will not release the compromised products unless we receive the approval and support of the DOH and dispensation from the MCA. In normal circumstances such a decision would result in a financial and product loss but no market place disturbance. However the products compromised, with the exception of 8Y and Albumin, are those where we are a major supplier, have no stock and cannot make fresh supplies available for some weeks. We must therefore advise our customers of our supply problems and we are satisfied that it is highly likely if not inevitable the true source of our difficulty will become public. We believe the only sensible course is therefore to advise our customers of the full situation to enable them to take whatever action is necessary to try and secure supplies from elsewhere.

You should however be aware that while we believe there are adequate alternative supplies of high purity Factor VIII for haemophiliacs, even if manufactured from imported and paid plasma, this is not true for some sizes of normal immunoglobulin and Anti-D. In the latter case in particular we are the sole UK supplier of the 250 iu dose of Anti-D. The other UK supplier is believed to be short of material.

You should also be aware that batches of Albumin from both compromised pools have been issued and at least partially used. We have decided it would be inappropriate to institute a recall of these products. Additionally, Factor XIII, an unlicenced product, has been issued.

We felt it appropriate to warn you of the above position in view of the potential public concern and possible complaints of supply shortage. We would be content to issue the compromised products, because we believe they are safe, if we were given a dispensation from the constraint of the CSM recommendations and draft EC Annex but we cannot delay advising our customers of the true position beyond next Monday 7th June. I apologise for the short notice of this advice and we will be happy to provide any further information you require.

Yours sincerely

GRO-C

R C D WALKER
Chief Executive

CC:	Dr K Jones	MCA
	Dr J Purves	MCA
	Mr J Canavan	DOH
	Dr G C Schild	NIBSC
	Mr J Adey	NBA
	Dr H H Gunson	NBA