BPL

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From: Terry Snape

Total pages: 2 including this page

Date: 27 November, 1997

Subject: Amerscan Pulmonate II

Your ref:	Our ref:	Direct Line:	E-mail:
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Dear Dr Brewis,

Further to our telephone conversation this morning, I attach a copy of the NBA briefing note developed in respect of the recall of Pulmonate II. I hope this assists you in developing local policy.

Bearing in mind your specific concerns I have left a message for Dr Angela Robinson (National Medical Director, NBS), asking that she contact you. Whilst I believe that she will confirm my observations to you, it is possible that Dr Robinson will be in a better position to discuss the circumstances of the advice from the ethical committee.

I confirm for the record that the attached briefing note, and the texts prepared in respect of the associated recall of BPL products, were reviewed with and cleared by the Defect Medicines Report Centre of the UK MCA before they were issued.

Please do not hesitate to contact me if I can be of further assistance.

Yours sincerely,

GRO-C

Terry Snape,
Technical Director (BPL).

20th November 1997

Background to the recall of BPL Zenalb, used to prepare Nycomed Amersham "Amerscan Pulmonate II"

Bio Products Laboratory withdrew a batch of Human Albumin Solution (Zenalb) on 4 November 1997. The recall was a precautionary measure, undertaken on MCA recommendation, following the confirmation that one of the blood donors whose plasma was used to manufacture the albumin had developed new variant Creutzfeldt-Jakob disease (nv-CJD).

There is no evidence that Creutzfeldt-Jakob disease (CJD) has ever been transmitted by blood or blood products. However, the new variant form of the disease seems to behave differently from the classical form and, on the basis of current evidence, we cannot be certain that it is not transmitted by blood or blood products. Against this background, recall of the affected batch of albumin was therefore considered to be a sensible precaution.

The batch of albumin in question was used by Nycomed Amersham in the manufacture of those batches of Amerscan Pulmonate II, and it is this association that led to the MCA recommendation that Nycomed Amersham recall those batches.

There is presently no diagnostic test for CJD infection (any type); there is no prophylaxis against, or treatment for, CJD infection; the incubation period for the disease is variable and long. The ethical committee advising on CJD surveillance in the UK has recommended that, given this situation, patients previously treated with plasma products derived from an affected donor should not be informed.

For further information, please contact Sue Cunningham on GRO-C.