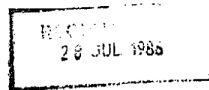


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Rorer



Health Care Limited

To: Miss A Clark
From: P B Lloyd
Subject: ALT Testing of Factorate

Date: July 27th, 1986.
Ref: PBL/AMW

Copies to:
C J Collins
PA Harris
E R James
C R Bishop
R ~ Christie
N. Randall
File:
1. PBL
2. Reader

Further to your memo of June 16th, in order to get more definitive information on the rationale for the statement it has been proposed to make on Factorate labels, we have obtained a copy of the test procedure used by Plasma Alliance. I attach a copy which I suggest you retain in your registration files for factorate. Plasma donations having an ALT titre above 70 units per ml at 30 degrees C are excluded from plasma pools for Factorate production. This is consistent with the label text proposed because the test kit cites the upper normal value at 30 degrees C as being 35 units per ml. The latter value is lower than that cited in the Alter et al paper (44u/ml) but the methods and kits are probably not identical.

GRO-C

P B Lloyd

Inter-office memorandum

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