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to:

Gillian Traynor - Thetford

Method M - Licence Submission

date

20th October 1987

from:

subject:

John Brooks - Egham

copies:

D. Galliford - Thetford

R. Feakes - Thetford

I. Bryant - Thetford

A. Whitaker - Egham

J. Wynne - Egham

With reference to your memo of 12th October 1987.

- 1. Hyland believe that FDA licence could be issued by end Nov 1987.
- Hopefully UK customers will commence usage on a 'named-patient' basis once 'M' has FDA approval, premium price makes this very limited.
- Hemofil-T (Heat-treated) not accepted by market place poor solubility and record on viral safety.
- 4. 'Armour' (major competitor is Monoclonal productions) do not have FDA licence either one customer using this product is Bradford. * STOP PRESS GOT LICENCE TODAY * GRO-C

In view of the above, we must submit our licence application without delay once data collated (is FDA data suitable?) to enable us to stay ahead of the competition and meet our customers requirements for a concentrate free of viral contaminants.

Regards

GRO-C

JOHN R. BROOKS Product Marager Blood Products

JR/02966