HYLAND THERAPEUTICS DIVISION
TRAVENOL LABORATORIES, INC.

→ Monoclonal AHF

Interoffice correspondence

to: S. Holst

from: M. Lee

GRO-C

subject: Method M Registration - U.K.

RECEIVED
30 SEP 1986
Ans'd.....

date: September 22, 1986

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Mark Philip, Gillian Taylor, and I met briefly with Doctor Duncan Thomas of the NIBSC in London on September 9 to discuss Method M registration in the U.K. A few salient points of the meeting follow:

1) We probably will not be able to register the product as an amendment to the current HEMOFIL® T file. Instead, an abridged new license will need to be submitted to the DHSS.

2) Mark Philip will meet with the DHSS next month to clarify and confirm exact requirements.

3) They would like some samples to test in order to familiarize themselves with the product. This will expedite future passage of lots.

4) We reviewed the clinical trials to be performed. Their opinion was that the half-life and recovery study in Oakland plus some of the Phase IIa data (safety/efficacy in previously treated hemophiliacs) would be sufficient for registration. This will have to be confirmed by the DHSS. We will have to submit a CTX if Dr. G. Savidge and others in the U.K. participate in the Phase IIb study ("virgin" study).

5) They suggested collecting data in hemophiliac dogs. We indicated that such a study was currently not anticipated.

6) We hope to present some clinical data during the next meeting in mid-November. This may expedite the registration process.

7) Finally, the idea of using the Method M process for the next WHO F.VIII standard was discussed and will be taken under consideration.

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