18.

Baxter

Interoffice Memorandum – For Internal Use Only

To: R. Feakes
J. O'Sullivan

cc: J. Adey
A. Whitaker

Date: May 3 1990

From: D. Galliford

Granting of licences - estimated timings

A. Gammagard

We are currently awaiting S. Holst to inform us what additional work Hyland are proposing to carry out to provide data on outstanding questions raised by the DH in consideration of our licence application.

It is probable that this work will take 3-4 months to carry out.

Review of this work and other amendments to the application by the DH is likely to take in the region of six months.

We may therefore expect to receive licence approval for Gammagard Jan-Feb 1991.

B. Hemofil-M

The national application submitted in the UK was refused on the basis that at European level it had been decided the product falls within the definition of a High Technology Product and therefore subject to Directive 87/22/EEC. Licence application must therefore be considered via the Community Concertation Procedure. ~ Bio

This "European" application is being put together in Glendale; a copy of their time plan is attached from which you will see that they are proposing submission of the application September to November 1990.

Experience with the Concertation Procedure so far has shown that approval time takes in the region of 15 months.

We would thus expect to obtain licence approval for this product between December 1991 and February 1992.

GRO-C

B02