MEMORANDUM

Subject: Meeting with Dr Schwarz on 24.11.1976
KRYOBULIN England

Present: Dr Schwarz, Dr Elsinger, Mr Lendvay
Dipl.Dolm. Diernhofer

In a telephone conversation with Dr Schwarz, Mr Berry asked why, after a change to a reduced solvent content in the registered KRYOBULIN (explanation: refer to letter 2064/DI/Em dated 05.02.1976), no changes were made to the label regarding the fibrinogen and protein contents. The question came from Dr Thomas, the new head of the National Institute for Biological Standards & Control.

Response:

Mr Schwarz will inform Mr Berry that the labels were not changed because the listed limits of 2.5% fibrinogen and 3.0% total protein are required by pharmacopeia. Because we plan to adhere to these limits or remain below as in the case of fibrinogen, in our dealings with the British health authorities, we saw no need to change the pharmacopeia-defined limits.

It is likely that Dr Thomas will now look into the composition of the concentrate. For this, Dr Elsinger was contracted to study the actual protein content of the concentrate to allow us to prepare for possible dialogue or a possible change in the composition.

Note for the Registration Department:

In the future, two types of KRYOBULIN concentrate will be sold - KRYOBULIN 1 and KRYOBULIN 2.

KRYOBULIN 1 = Made from European plasma (with a lower hepatitis risk - publication by [illegible]

KRYOBULIN 2 = Made from US Licenced Source Plasma (proven to have a significantly higher hepatitis risk - publication by [illegible]

KRYOBULIN 2 will be significantly cheaper than KRYOBULIN 1 because the British market will accept a higher risk of hepatitis for a lower-priced product. In the long term, KRYOBULIN 1 will disappear from the British market.

The respective label information has not been definitively determined and will be announced by Mr Lendvay from the Registration Department.

Registration Department

Vienna, 25/11/1976 *[Signature]*

Dipl.Dolm. I.Diernhofer

Copy: Dr Schwarz
Dr Elsinger