



UK
CERN General

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8th March 1988
PJC/BMC

Dr. O.F. Schwarz,
Immuno AG,
Vienna.

Dear Dr. Schwarz,

Following our discussions last week concerning the new steam treatment process for Tisseel, I have decided after discussions with Mr. Berry, Mr. Nicholson and Mr. Sloggem from the DHSS, we should proceed with the Medicines Commission Appeal for Tisseel dry heated.

Mr. Sloggem is aware that dry heated products with less than 1% moisture are suspect, but he feels that he would certainly consider an application for a dry heated product and would assess it on its merits. He will shortly be starting the pharmaceutical assessment for the Appeal.

If we wait for the Tisseel steam treated, it will take some time to accumulate enough clinical data and we, therefore, have nothing to lose by continuing with the Tisseel dry heated Appeal. If we lose the Appeal, then we would certainly give consideration to a completely new Application for Tisseel steam treated. If we were to apply for Tisseel steam treated, Mr. Sloggem has said that we will need exactly the same information that is required for the steam treated coagulation concentrates.

It would, I am sure, help if we could have additional inactivation studies on further batches available prior to the Appeal, as I am sure this will be required.

We would also like assurance that if we are successful in obtaining a Licence at the Appeal, that you will continue to supply us with the Tisseel dry heated product, even if other countries change over to Tisseel steam treated.

I could ask Professor Preston for his opinion on this subject, but I feel that as he has no knowledge of the complexities of the licensing procedures, he would be unable to provide us with any additional information.

Kind regards,

Yours sincerely,
for IMMUNO LTD.

GRO-C

P.J. Coombes
Managing Director