

IMMUNO LTD

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DATE: 21st July 1987

TO: Mrs. Henninger

FROM: Mr. Coombes

SUBJECT: For your information - a copy of my letter to  
Dr. Schwarz.

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# Immuno Ltd



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

20th July 1987  
PJC/BMC

Dear Dr. Schwarz,

I have spoken by telephone to the Medical Assessor concerning our Licence Variation for Kryobulin. It would appear that when we receive the letter from the DHSS it will simply say that it has been turned down. As it is a variation no explanation will be given. She has given me her comments and feels that there would be no point in arranging a meeting with her as her comments to me are self explanatory. We do feel we should have a meeting with the Pharmacist as we do need more information from him on the deficiencies of the Variation.

It would appear that the Variation only just failed and the consensus of opinion from the Members of the Committee was that we should have applied for an abridged application as there were so many changes to the production. We would also then have had the right to appeal. We should now, therefore, start to prepare an abridged application.

The main points which did not satisfy the Biological Sub Committee were:-

1. They were not convinced that the Hepatitis B cases were not related to the product, particularly as it was only one batch. We should have submitted full details of the patients who contracted Hepatitis, their ages, where they lived etc. and argue the point as to how they may have contracted the virus. The chimpanzee work did not convince them.
2. The inactivation data supplied they felt was too simplistic. They have seen HIV conversion in products with good inactivation data.
3. They are currently looking at products heated at 80°C for 72 hours and, therefore, products heated for 10 hours at 60°C they look upon with great suspicion. They know that dry heat products at 60°C for 30 hours have caused sero conversion in the U.K.
4. They were not convinced that the conditions of the steam treatment process were properly controlled. They needed evidence to show that steam treatment was able to penetrate all the powder.

There may have been other minor pharmaceutical points, but we would have to discuss these with the pharmacist. I would, therefore, suggest the following:

1. We visit the pharmacist as soon as possible to obtain his detailed comments. If you wish to send someone over who has knowledge of the development and validation of the process, this may be helpful.