NOTES ON A MEETING BETWEEN JB AND MR. HEATH OF SPEYWOOD LABORATORIES CONCERNING THE PRODUCT LICENCE FOR KOĀTE ON 19/8/76

Mr. Heath visited me to personally collect the letter of authorisation (a copy of which is attached) from Bayer to the DHSS allowing Speywood to refer to the Bayer Product Licence application for Koate when they make their application since Cutter have now decided that they will hold the Product Licence for Koate in the UK. I also gave Mr. Heath a copy of our Product Licence application but deleted all mention of the manufacture of Koate as requested by Mr. Ryan of Cutter on the telephone on Tuesday. So, in File I, Supplementary Particulars, I deleted paragraph 3.2a which was a summary of the manufacturing process and in File 2, pages 025 to 048 inclusive were omitted which was all the details of the preparation of Koate including the sources of the plasma used. I handed over a complete copy of File 3 which was a report of the clinical trials. I also included copies of the letters which passed between us and the DHSS concerning labelling and the standardisation of the Cutter house standard for Factor 8, together with notes about the batch release procedure as discussed with Dr. Bangham in June. Since, only yesterday, we received a letter from the DHSS asking us to agree to the inclusion of certain additional provisions in the Product Licence, I handed over a copy of this letter which is the one mentioned in the letter of authorisation. Following his meeting with me, Mr. Heath was going to the Medicines Division at Finsbury Square to meet Mr. Deveney, Miss Rosemary Smith, Mrs. Cooke and Dr. Andrews. He did say he would let me know, as a matter of interest, the result of the meeting.

GRO-C

JB/jm/19.8.76