

Heat Treated Factorate

Notes on an informal meeting held at the DHSS, Market Towers, London on  
19th December 1984

Present: Dr. M. Duncan, Medical Assessor, Biological Products, DHSS  
Mr. R.B. Christie )  
Mr. C.J. Collins ) Revlon Health Care (UK) Ltd.

Background: RBC had attended a recent talk by Dr. Hill, Consultant Haematologist, Birmingham Childrens Hospital on the subject of HTLV III antibody screening in his patients, carried out as part of a research programme in connection with AIDS. The significance from our viewpoint of the work is that this centre uses only Armour Factorate together with some DHSS material. A copy of some very informal notes from RBC on the meeting are attached.

Discussion: The information contained in the notes was made known to Dr. Duncan since in our opinion they constitute material information on our product which relates to its safety in use. A short general discussion of the overall situation ensued. Dr. Duncan was not overly surprised but was most interested especially as Dr. Hill intends to treat negative cases with the heat treated product in the hope that they continue negative.

CJC then discussed the CDC/HTLV III viral inactivation studies and reported that they have got to be repeated due to viral assay difficulties. Results are now not expected until mid- to late January 1985. This is very disappointing. However, CJC provided a copy to Dr. Duncan in confidence (at her request) of the available data from Dr. B.L. Evatt of the CDC (letter to Fred Feldman dated 29th November 1984) giving some results on viral inactivation work. The possibility of making a PL variation application for the heat treated product was discussed in the light of this work and our other data bases (CTX for the IP product and PL Application (refused) for the HP Product) for heat treated product. Dr. Duncan's view was that we should submit an application as soon as possible on the basis of the available evidence. Clearly the additional CDC data will become available in the not too distant future to add to the information.

GRO-C

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