



INTEROFFICE CORRESPONDENCE

FROM: BIOLOGIC PRODUCTS
REGULATORY AFFAIRS

M. Carr

DATE: August 27, 1982

4-BIG-1

TO: E. Colton
T. C. Drees, Ph.D.
C. McAuley, M. D.

cc: E. Fedor, Ph.D.
M. Hainski, Ph.D.
B. Hartin
K. Martinet
E. Mealey, Ph.D.
B. Olivarez

Re: Request from OOB Regarding Cryoprecipitate Paste
or AHF Obtained from HBIG Donors

During my meetings at OOB August 25, 1982, Dr. Donohue asked to speak to me for awhile alone. The subject of his discussion was Cryoprecipitate or AHF obtained from the manufacture of Hepatitis B Immune Globulin. He explained that at OOB they had discussed the possibility of sending letters to the manufacturers of HBIG, requesting them to not use material from HBsAb donors for the manufacture of AHF. The reason for this is because of the possibility that ASID is a transmissible agent that is transmitted as hepatitis B is, by AHF. Their request would be that this material not be used for the time being, but that we should stockpile the cryoprecipitate paste on the chance that AHF would be eventually exonerated. Dr. Donohue, however, wanted to explore the possibility of our sending a letter to the Bureau, in which we voluntarily state that we would not use such material in AHF manufacture. The reason he would like to see the manufacturers do this is that if the manufacturers did this voluntarily rather than OOB requiring it by a letter to the manufacturers, there would not be the eventual difficulty of them reversing themselves. In addition, this is a very delicate subject at the moment and OOB wishes to avoid alarming the hemophilic community and any other segment of the population.

Dr. Donohue said that Dr. Meyer had suggested the possibility of all manufacturers amending their License Applications to delete the use of plasma from HBIG donors in the manufacture of AHF. However, Dr. Donohue did not want to go to such lengths, and would rather have a voluntary halt "for the time being". Dr. Donohue noted that we probably would want to explore the liability issues too, since he was sure the manufacturers were sensitive on this subject. I told him I would call him after discussing this with Dr. Drees.

GRO-C
MC:ad

30-1-1983

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