Cutter MILES

TO: M. Sternberg GRO-C DATE: 10/5/84

FROM: S. J. Ojala

SUBJECT: Meeting with FDA, Oct. 2, 1984

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I met with Dr. Aronson, Dr. Gerety and Ann Hoppe to review our core antibody testing program. The meeting was scheduled at their request because of concerns over what effect this testing might have on the resultant products. I explained that it seemed a little late to be voicing concerns about product implications as we had been screening plasma since February. Dr. Gerety countered that it was our responsibility to inform them of process changes that might have product implications. I explained that I thought we had kept them informed since discussions on the subject began in December of 1983, and had been widely reported in the lay press (Wall Street Journal, JAMA) subsequently. Ann Hoppe told Gerety that the Division had been informed of our testing program, and perhaps the communication problem was internal in the FDA. I feel that we have been responsible in keeping Aronson and Petricciani informed, so I don't really know why the recent interest and concern has surfaced. Gerety then explained he felt that the entire plasma industry had an obligation to keep the FDA informed of any changes that could have product implications. I promised to pass the word to the rest of the industry.

The discussion then moved to the subject of product safety in terms of utilizing core negative plasma. I explained our 30% core positive blending program for Fraction II products and Gerety remained concerned that products (particularly ISG) that had a demonstrated efficacy based on traditional donation patterns would be different even with our blending scheme. He asked that we measure the titers of anti-HBs and anti-HAV and insure that they are above 1:100 and 1:500 (RIA) respectively. He also wants to know the starting pool titers for anti-HBs for both core negative and positive pools.

Both Gerety and Aronson expressed concern that using only core negative cryo for AHF production would reduce anti-HBs levels as well and result in a Hepatitis risk. I countered that our action was only taking the next available step in excluding high risk donors (as requested by the FDA) to minimize any potential AIDS risk. They explored the possiblity of a label change to indicate to the user that we were using only core-negative plasma, and I argued that the

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product already carried a boxed Hepatitis warning. The FDA suggested that we needed amendments to the product licenses for all products to use screened plasma. I pointed out that we were still using source plasma (human) and that our plasmapheresis operating protedures had been amended to show the change. I further indicated that an amendment would take too long to approve for our production schedules. I mentioned that even as we spoke final product lots were being produced by the techniques mentioned earlier. Then Gerety and Aronson got into an esoteric discussion of potential risk from AHF and eventually Gerety decided our product might even be safer than non-screened production. (So much for concensus on hepatitis risk.)

We left the discussion with an agreement that we would inform the agency in writing of our production changes (but not a license amendment) and secure something back in writing from them acknowledging the changes. We will include some of the information on titers indicated above.

I believe the subject is generally resolved in that the FDA will not delay any product lot release or take other action which would be detrimental to our production and marketing plans.

Gerety mentioned in a hallway conversation that he believed that they had identified a new strain of Hepatitis-C that was, in fact, the same as non-A/non-B and had some kind of assay for it available. Some kind of publication will follow.

The HTLV-III study was in progress, with the seeded samples going to the freeze drier on Oct. 1, 1984 and initial results expected next week.

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