Cutter

MILES

TO: BMC

DATE: 5/30/85

FROM: S.J. Ojala

SUBJECT: Non-Heat Treat License

COPIES TO: L Ambrus
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Dr. Harry Meyer called this special meeting of all producers of coagulation products to discuss the use/production/license of non-viral inactivated products. The attendees included:

FDA	Industry
Dr. Meyer	S. Ojala (Cutter)
Dr. Petricciani	S. Holst (Hyland)
Anne Hoppe	P. Carr (Alpha)
Dr. Esber	D. Marcus (Armour)
Dr. Donahue	E. Vanderelst (Hoechst)
Dr. Aronson	L. Baum (Hoechst)
Dr. Murano	G. Trimin (Immuno)
Don Hill	J. O'Malley (ARC)
Mr. Falter	B. Reilly (ABRA)
M. Crouch	

Dr. Meyer explained that the major manufacturers of coagulation products (AHF and PTC) had been approved for a viral inactivation process for some time, and the data demonstrated reasonable performance for eliminating HTLV-III virus from the final product. He questioned the utility for a non-treated process given the current situation and requested that we uniformly send letters to the FDA stating we would no longer produce or distribute non-heated product to preclude negative reaction from the medical community and the general public. He indicated that everyone spoke as though heat treating processes had eliminated the potential for HTLV-III viral exposure from these products, and no one had really focused on the fact that the ability to produce non-treated products still remained possible with the current licenses. He explained that although the FDA could revoke these through the regulatory process, he did not want any attention paid to the fact that the FDA had allowed this situation to continue for so long, and he would like the issue quietly solved without alerting the Congress, the medical community and the public. Implicit in the discussion was the concern that the FDA felt that this action was long overdue. He wanted a date (such as June 1) for the letters from us.

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Industry responded with a list of reasons why they had particular problems with the proposal, including the value of the inventory in our control, the lack of inhibitor indication for PTC, Alpha's pending dry-heat approval, Hyland's non-approval for Autoplex, etc. Everyone had a reason and Hyland mentioned an 18 million unit AHF inventory that would have to be reworked to heat-treat product.

The industry position was that we would need rapid review of pending submissions and some time to review the situation with our management. Several proposed a staggered elimination of non-heat license, starting with AHF and moving into other areas as feasible, and the international situation was reviewed extensively.

Meyer replied that he understood the situation and could sympathize with the difficulties but that did not remove the overriding concern that no one anywhere in the world should be allowed continued exposure to HTLV-III for any of the reasons mentioned. He specifically mentioned that the Japanese registration would soon occur, and he would assist with rapid review and approval for submissions, but the de-licensure of all products had to occur soon.

I spoke with Aronson following the meeting and he reported the problem with the review was that "there are those who seek to license heat treating processes with low temperatures and short times, which the FDA finds unacceptable. This was briefly reviewed during the meeting and Hyland (Holst) stated that Cutter had made it difficult for the rest of the industry by using such "extreme" temperatures for so long a duration, and thus established precedent. I could only respond that we had arrived at the time and temperature following extensive development work, and that our process was satisfactory for our product. I sense that Hyland is seeking to increase the severity of their inactivation step, the FDA is concerned about the limitations of both the Alpha dry heat and N.Y. Blood inactivation processes. The FDA will meet internally during the interim to review the special situations.

We agreed to review this internally and meet again with him on June 17 to finalize our actions and the timetable. It is clear that Meyer intends to solve this problem quickly, with or without our cooperation.

Meyer also wants us to insure that all plasma we receive is tested for HTLV-III, whether from internal operations, contract centers, recovered plasma, short supply agreements or brokers. He wants confirmation on this by June 17, 1985.

I suggest that we review this item at the BMC on Friday, May 31, 1985.