



INTER-OFFICE CORRESPONDENCE

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TO C. R. Bishop	FROM	Fred Feldman
	CO.	Armour Pharmaceutical Co.
	CITY	Kankakee, IL
THIS IS IN REPLY TO YOUR LETTER DATED		DATE
		July 24, 1985
SUBJECT ALPHA THERAPEUTIC HEAT TREATMENT - YOUR MEMO OF JUNE 25, 1985		

In my previous comments to you, I have made observations on Alpha's heat treatment process and their publication's reference to the heating of dry product. As we discussed at the ISTD meeting in San Diego, I learned from the committee reports (Dr. Manucci's session) that the Alpha Therapeutic process heats the AHF with the product in a dry state. During the heating Alpha floods the powder with heptane. This does not solubilize the powder, and Alpha merely makes a slurry of the dry powder with the solvent. Alpha calls this a "wet heat process" because even though they have dry powder, they consider the heptane to be a liquid and therefore "wet." This is by no stretch of the imagination equivalent to a liquid pasteurization process such as carried out by Behringwerke on their AHF or by all manufacturers on Albumin. Until Alpha has demonstrated the equivalence of their process with liquid pasteurization, customers should understand the distinction.

At the ISTD meeting, Dr. Manucci gave a presentation on Wednesday called, "The Prevalence of Post Transfusion Hepatitis in 27 First Exposure Hemophiliacs After Giving Treated Clotting Factor Concentrates" (#0-743). In this session Dr. Manucci reported seeing a high level of transaminitis not only after dry heat treatment, but also after dry heat treatment and chloroform extraction. If dry heat treating and the chloroform is insufficient to disrupt the Non-A Non-B Hepatitis virus, then it is likely that Alpha's heat treatment plus heptane process will not be Non-A Non-B safe. Dr. Manucci further pointed out in the committee meetings on Saturday and Sunday that the Alpha study protocol for Hepatitis is inadequate in its sampling intervals for assessing Non-A Non-B Hepatitis (testing at two weeks and six weeks). This could be responsible for explaining some of their results. As you indicated, Dr. Kernoff, with a more rigid protocol, has already seen three patients with Non-A Non-B Hepatitis.

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FF/cd

cc: A. Bessler
M. Hrinda
L. Lucas
M. B. Rodell
A. Sheppard
C. Swartz
W. Terry

Production Director