



BLOOD PRODUCTS LABORATORY

National Blood Transfusion Service

With the compliments of

10 OCT 1985

Norman

PRODUCT SERVICES DEPARTMENT

*A copy of a memo to Asmou
Pharmaceutical*

Elstree Hertfordshire WD6 3BX

Tel: 01-953 6191

15-259

52

	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 ISTH 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 ISTH 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.