CUTTER *Laboratories* Inc.
MEMORANDUM

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TO: Lowell Crow
FROM: J. Kris Piper
DATE WRITTEN: February 23, 1976
SUBJECT: Koāte™ Registration - Bayer U.K.

The following is in response to Mrs. Boult's telex of February 18, 1976. Her requests are restated followed by our answers.

1. *Can you confirm that on-going information will be provided on the reasons for, and the rate of, rejection of donors or donations, centre by centre.*

We do not collect information of this nature. Such information would be of dubious value in evaluating a plasma derivative product's safety or efficacy. In the manufacture of Koāte™, all Source Plasma (Human) used as the starting material is collected and handled according to regulations described in Title 21 of the U. S. Code of Federal Regulations. Similarly, all plasmapheresis donors must be acceptable according to the criteria described in these regulations. All plasmapheresis centers from which our source material is obtained are licensed by the U. S. FDA. Thus, the FDA insures that all donors and units of Source Plasma (Human) are handled according to the regulations. Copies of the specific U. S. regulations covering Source Plasma (Human) and plasmapheresis donors are attached for your reference. As can be seen only HB_sAg negative units of Source Plasma (Human) from healthy donors can be used in the manufacture of licensed biological products such as Koāte™.

2. *Does Cutter agree to the imposition of the batch release procedure, if the licensing authority apply it.*

We do not feel that the batch release procedure should be applied to Koāte™. Antihemophilic Factor (Human) is a stable, lyophilized product which has been licensed in the U. S. for nearly ten years. The safety and efficacy of this drug are well known and have been substantiated in the scientific literature. In the case of Koāte™ in particular, each lot is subjected to rigorous chemical and biological testing by both Cutter and the U. S. Bureau of Biologics before being released to distribution. This is true of material to be exported as well as that sold in the U.S. For these reasons we feel that any additional routine testing would be redundant and would result in unnecessary waste of this valuable drug. If required, we would provide complete summaries of all testing performed on Koāte™ prior to release on a lot by lot basis. However, we do object to the batch release procedure.

JKP:jw GRO-C

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