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MEMORANDUM

DATE: February 8, 2002

TO: Mr. Wilson

FROM: Dr. Appelbaum

SUBJECT: FDA Warning Letter

On December 31, 2001, we received a warning letter from the Food and Drug Administration concerning studies involving an investigational new drug. The concerns of the Food and Drug Administration were essentially limited to issues of documentation. Studies of investigational new drugs overseen by the Food and Drug Administration have unique requirements for the development of case report forms, documentation and reporting that differ from most other clinical research. Further, the Food and Drug Administration's monitoring policies are evolving. Our institutions are working closely with the Food and Drug Administration to modify aspects of our system of documentation so as to be in full compliance with their requirements. The actual clinical trials involving the investigational new drug in question are encouraging, resulting in some of the highest cure rates for acute myeloid leukemia ever reported.