MEMORANDUM OF MEETING: Regarding FDA Requirement for Summary of Records

Date: April 20, 1998

Attending for American Association of Tissue Banks (AATB)
Gail Javitt, Michael Joyce, Jeanne Mowe, Richard Russo

Attending for FDA:
David Feigal, Jay Epstein, Elizabeth Waltrip, Phil Noguchi, Ruth Solomon, Jerome Davis, Paula McKeever

AATB had requested this meeting and opened the meeting, according to the agenda provided by AATB by defining the issue, clarifying the public health issues (clinician needs and current clinical practice), and presenting their proposal for addressing the issues. They expressed the concern of the organization regarding tissue safety and that relation to the AATB's difficulties regarding the Final Rule for Human Tissue for Transplantation (21 CFR Part 1270) with the requirement for a summary of records. The AATB did provide comments and clarification to the FDA at the publication of the interim rule during the comment period.

AATB leaders have contacted the users of the tissue regarding the information needed on the label. There is reliance on the tissue banking industry with the suppliers accepting responsibility for complete background information available on short notice.

The requirements of Section 1270.21 of the regulations was discussed in detail. AATB asserted the general equivalence of CLIA certified laboratories, handling of tissues by different laboratories for various processing, and case of access to records should contamination or infection result. FDA requested a brief review of the information supplied to users at this time. AATB explained that the laboratory will follow an SOP for procedures to examine and test the tissue specimen, the detail of background screening records, including next of kin, health records, coroner's records, and autopsy, if any.

FDA explained the focus of the rule and the thinking behind it. They expressed interest in sharing the public health concerns of the AATB. The issue of having all records travel with the tissue would be to ensure its immediate access. FDA understands that AATB concurs with the standards required by FDA, but does not concur with the information FDA has required to travel with the label. C

] The AATB is requested to concentrate on the identity of the laboratory, list of the tests performed, the name of the person performing and/or reviewing the tests; and the name of the responsible head of the laboratory. The rule as stated must be followed. There may possibly be room to develop agreement on the scope of the "summary of records". There was agreement to re-examine the requirements for particularization regarding the testing performed. FDA is not in a position to violate its own regulations and must, therefore, discuss the issue with General Counsel to determine the flexibility allowed in the regulation.

There was additional discussion of the current degree of compliance among tissue establishments which varies broadly.

FDA responded that they will review the entire matter and proceed with internal discussions.