AMERICAN
ASSOCIATION
OF BLOOD BANKS

May 7, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Docket No 97N-484P Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement

The American Association of Blood Banks (AABB) is pleased to comment on this proposed rule *Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement.* This proposed rule completes the set of proposals that would implement a comprehensive new system for regulating human cellular and tissue based products. The AABB is the professional society for over 8,000 individuals involved in blood banking and transfusion medicine and represents approximately 2,000 institutional members, including blood collection centers, hospital based blood banks, and transfusion services as they collect, process, distribute, and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country. For over 50 years, the AABB's highest priority has been to maintain and enhance the safety and availability of the nation's blood supply. The AABB also sets Standards and has a highly successful accreditation program that assesses programs against the appropriate Standards.

Current Good Tissue Practice (CGTP) sets forth the requirements governing "*the methods used in, and the facilities and controls used for, the manufacture of human cellular and tissue based products.*" The AABB notes that the proposed requirements are based on current good industry practice and are intended to address important minimum criteria for the manufacture of these products. We are particularly pleased that the industry standards reviewed in preparation for determining the provisions of the proposed regulation included AABB Standards. **The AABB supports the proposed rule** and is pleased to note that the proposed regulations set out general objectives rather than requiring specific procedures. The AABB strives to be certain that its Standards are compatible with regulations and that all of the minimum FDA requirements are included. As discussed throughout section VII, Analysis of Economic Impacts, the AABB Standards already encompass most of these proposed requirements, and those that are not specifically addressed will be considered at the next revision.

8101 Glenbrook Road ♦ Bethesda, MD 20814-2749 ♦ Phone: (301) 907-6977 ♦ Fax: (301) 907-6895
Web site: www.aabb.org ♦ Email: aabb@aabb.org

97N-484P

C24

The AABB strongly supports the requirement for a quality program. The AABB has required implementation of a quality program in collection and processing facilities for hematopoietic progenitor cells (HPC) as a condition of AABB accreditation since 1996. In 1996 the AABB separated the requirements for HPC facilities from those for blood banks and transfusion services and separately published the first edition of *Standards for Hematopoietic Progenitor Stem Cell Services.* The AABB is currently developing the first edition of *Standards for Cord Blood Banks* that will also require implementation of a quality program.

This proposed regulation has obviously been carefully considered and the information is comprehensive, well organized and easy to understand. The AABB, however, does wish to point out two minor concerns. Section §1271.200(e) Equipment, Records requires that *"records of recent maintenance, cleaning, sanitizing, calibration, and other activities shall be available at each piece of equipment."* The AABB believes that such records are necessary, but it may not be practical or even possible to have the records available "at each piece of equipment". **The AABB suggests that the wording be changed to require that records be readily available.**

Section § 1271.210 (e) Supplies and Reagents, Pooling states that *"human cells or tissues from two or more donors shall not be pooled (placed in physical contact or mixed in a single receptacle) during manufacturing."* While we understand that preparation of large pools is undesirable, it is quite possible that there may not be sufficient quantity from a single donor of hematopoietic progenitor cord blood cells to achieve therapeutic value. This is particularly of concern if practice evolves such that cord blood cells are used for adult therapy and it becomes desirable to pool two or more donor collections. Pooling of human cells or tissues could be considered to be analogous to pooling of platelets, a routine procedure in transfusion medicine. **We urge the FDA to reconsider the impact of prohibiting pooling.**

The agency requested additional comments on possible alternative inspection and enforcement provisions that would leverage agency resources, be cost-effective, and achieve the public goals of the proposed rule. **The AABB suggests joint agency- third party inspections modeled after the Health Care Finance Administration's (HCFA) program.** The AABB has had deemed status with HCFA for several years and has successfully integrated assessing for Clinical Laboratory Improvement Amendments (CLIA) requirements during the same inspection in which AABB requirements are evaluated. This would be cost-effective for both the facility undergoing inspection and the agency, and would leverage agency resources by requiring fewer personnel to conduct inspections. Because the third party must meet specified requirements and be given deemed status, the quality of the inspection would be maintained or enhanced. The agency would also be authorized to conduct verification inspections to be certain that the third party inspections are acceptable. The public goals of the proposed rule would therefore be achieved.

The AABB thanks the agency for this opportunity to comment. Should you have any questions or wish to discuss any of the comments further, please contact Kay Gregory, Director, Regulatory Affairs at 301-215-6522 or kayg@aabb.org.

Sincerely,

Karen Shoos Lipton, JD
CEO