

**CBER's PLAN OF IMPLEMENTATION TO THE  
RECOMMENDATIONS ON THE OIG REPORT  
“ Oversight of Tissue Banking” – OEI-01-00-00441**

**The Food and Drug Administration should expedite the publication of its regulatory agenda that requires registration of tissue banks, enhanced donor suitability screening and testing, and use of good tissue practices.**

**Response:**

FDA published the final rule entitled, “Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing” on January 19, 2001. In addition, the Agency has published two proposed rules: 1) “Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement” (January 8, 2001) and, 2) “ Suitability Determination for Donors of Human Cellular and Tissue Based Products” (September 30, 1999). The comment period for the proposed rule concerning good tissue practices ends on May 8, 2001. On April 18, 2000 FDA reopened for 90 days the comment period for the proposed rule concerning suitability determinations for donors of human cellular and tissue-based products. This action was taken in response to requests for an extension to allow interested parties, including State and local officials, additional time for review and to submit comments. The agency is currently evaluating comments received on the proposed rule.

When finalized, these three rules would together establish a comprehensive regulatory program for human cellular and tissue-based products, to be contained in part 1271 (21 CFR part 1271).

**Within its existing regulatory authority, FDA should take two steps to enhance oversight of tissue banking:**

**FDA should set a realistic, yet aggressive, date by which it would complete an initial inspection of all tissue banks.**

**Response :**

We are currently evaluating available resources and program priorities to develop a plan. As the OIG report recognizes, however, FDA has not received adequate funding for inspection of tissue banks and "related cell and tissue" product establishments. With currently available resources, the agency continues to be faced with difficult choices in regard to its oversight in other areas of comparable or greater public health significance in order to increase its activity in the tissue banking area.

**FDA should determine an appropriate minimum cycle for tissue bank inspections.**

**Response:** The Agency supports FDA biennial inspections to determine a baseline of industry compliance with the regulations. Depending on availability of resources and a firm's history of compliance, inspection cycle could vary. Our current tissue inspection program provides a risk-based prioritization system for selecting firms for inspection. Two of the many factors considered in scheduling inspections are whether or not the firm has a violative history of FDA-conducted inspections and whether it is accredited by a recognized organization.

**FDA should work with States and with professional associations that have inspection and accreditation programs to determine in what areas, if any, oversight activities could be coordinated.**

**Response:**

FDA recognizes that States and professional associations have an important impact on the quality of tissue available. However, states and professional associations may have different concerns and interests than FDA's. Accrediting organizations and state-regulated programs may cover fewer types of human cells, tissues, and cellular and tissue-based products and may set standards that would not cover the entire spectrum of products. Moreover, the goals of professional organizations differ in several critical ways from regulatory oversight programs. Such accrediting organizations often work with tissue establishments to attempt to bring them into compliance with their standards, but lack enforcement authorities. FDA's goals are to protect the public from unsafe tissue products and the Agency uses a variety of enforcement tools to help assure public health and safety.

In other product areas, FDA has entered into mutually beneficial contracts with States to perform FDA inspections. This has been successful in areas where the state law parallels the federal law and there has been sufficient experience with the regulatory program to standardize inspections. When these elements are present in the tissue area, FDA plans to seek ways to establish similar partnerships with such States.

The issue of how to best implement a comprehensive, resource efficient program of on-site inspections of tissue establishments is complex. We are aware of tissue recalls and market withdrawals conducted by firms which are accredited, so accreditation can not be seen as an absolute guarantee of safety and suitability. The FDA is carefully evaluating the recommendations of the HHS' Office of Inspector General concerning the overall regulatory framework for tissues, including how to best assure adequate inspectional coverage.

Because of divergent interests, and the different and less comprehensive standards and laws administered by organizations other than the FDA, the Agency believes that FDA biennial surveillance inspections are necessary to determine whether establishments are complying with FDA regulations. FDA could not obtain this information through accrediting bodies or state inspections at this time. We will continue to explore ways to exchange information with accrediting bodies and states.