FDA issues new rule on tissue safety

The Food and Drug Administration (FDA) on Nov 18 issued its long-awaited third rule tightening oversight of the tissue processing industry. The final “good tissue practice” rule regulates manufacturing of human tissue products such as musculoskeletal grafts, corneas, and cellular therapies. The rule will be effective May 25.

Two earlier rules cover registration of tissue establishments and donor screening. The rules are intended to prevent incidents such as the 2001 death of 23-year-old Brian Lykins of Minnesota from an infection associated with a contaminated knee allograft.

The Lykins family has been “tireless in their advocacy for tissue safety,” the FDA’s director of biologics, Jesse Goodman, MD, said at a press conference announcing the rule. He noted that the rules are needed to keep up with rapid growth in the tissue industry. About 1 million tissue transplants were performed in 2004, a dramatic increase from 350,000 in 1990.

The rule requires manufacturers who recover, process, store, label, package, and distribute tissues to use safeguards to prevent introduction, transmission, or spread of communicable diseases.

Each step in the process needs to be controlled, the FDA notes. Among problems that can arise are errors in labeling, mix-ups of testing records, and failure to adequately clean work areas.

The rule does not require tissues to be sterile but says recovery and processing must be done in an aseptic manner. Any tissue manufacturer that represents its processing methods as reducing the risk of disease transmission, inactivating pathogens, or sterilizing tissue must back that with “a fully verified or validated process,” the FDA says.

Impact on health care facilities

Hospitals and surgery centers that simply transplant tissue do not fall under the rule, Dr Goodman said. They would come under the rule only if they procure and “manufacture” tissue.

Two requirements are of particular interest to hospitals and surgery centers:

- tissue tracking
- adverse event reporting.

Under the tracking requirements, tissue manufacturers must label each piece of tissue with a distinct identification code for tracking purposes. (There is an exception for autologous or directed donations.) Manufacturers also must have a method for tracking the tissue from the donor to the “consignee” (generally the entity the tissue is distributed to, such as the health care facility or surgeon.) The FDA cannot mandate how tissue is tracked within a hospital or surgery center. Instead, it requires manufacturers to have a labeling method that “facilitates effective tracking.” For example, the label could say: “Important notice to end user: Please record this distinct identification code in your records and in the patient’s file.”

Separately, laboratory standards of the Joint Commission on Accreditation of Healthcare Organizations require keeping records allowing tissue to be tracked to the recipient.

The FDA says tissue tracking is needed to locate recipients in case contaminated tissue is discovered. For example, if an infection is traced to faulty tissue processing, the manufacturer would be able to contact facilities or physicians that received tissue from the same donor or lot.
Tissue manufacturers will have to investigate any adverse reactions involving a communicable disease that happen in tissues they have distributed. They must report to the FDA within 15 days any such event that is fatal, life threatening, or results in permanent functional impairment or permanent damage to a body structure or needs medical or surgical treatment.

The rule and Q&A are at http://www.fda.gov/cber/rules.htm#gtp