

The next step will be to draw up recommendations for using RFID or other auto-ID technologies to identify and track medical devices and supplies.

By Beth Bacheldor

Jan. 16, 2007—The [U.S. Food and Drug Administration](#) (FDA) is making progress on its efforts to determine whether it will require companies to use a unique device identification (UDI) system to track and trace medical devices they manufacture and supply.

The agency recently finished reviewing public comments it received after requesting information about such a UDI system. Back in August, the FDA published a notice in the Federal Register, seeking ideas on how the use of a UDI system might improve patient safety (see [FDA Seeks ID System for Medical Devices and Supplies](#)). The main purpose of a UDI system would be to reduce medical errors by providing more automated ways to collect such device information as the manufacturer, make and model, along with unique attributes, serial numbers, identifying lot, manufacturing numbers and expiration dates. In addition, a UDI system could facilitate device recalls, improve reporting on devices and identify incompatibilities or potential allergic reactions.

Larry Kessler, director of the FDA's Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, says his department found "virtually nothing new" during its review of all the comments received. "We were hoping for some new wrinkle," he says. "There was nothing in the comments that said, 'Oh, this is fabulous,' and nothing that put the fear of God in us either."

Within the next four to six weeks, Kessler hopes to brief his bosses—including Daniel Schultz, director of the [Center for Devices and Radiological Health](#) (CDRH), and two other FDA officials. If those briefings go well, Kessler says, the next step will be to draw up recommendations for a UDI system.

Each year, the FDA receives more than 180,000 "adverse-event" device reports about malfunctioning or otherwise problematic medical devices. A UDI system could help address and resolve these issues. At present, it can be difficult to track down a specific device because the reports often lack the necessary information. A UDI system would provide a standard method of collecting identification data on each device being recalled or reported on.

The FDA does not expect to dictate the kinds of automatic identification technologies that might be used, though in August 2006, Kessler told *RFID Journal* that the agency was interested in radio frequency identification.

The FDA is currently investigating the use of RFID to protect the U.S. pharmaceutical supply chain against counterfeit drugs (see [FDA Will Issue Drug-Pedigree Guidelines](#)). Its efforts to promote the use of RFID for pedigrees, which document the chain of custody of drug products moving through distribution channels, got a shot in the arm last week when [EPCglobal's](#) board of governors ratified an electronic-pedigree (e-pedigree) standard.

The e-pedigree standard is designed to provide the pharmaceutical industry with a common format that supply chain partners can utilize to collect pedigree information. and upon which providers of pedigree solutions can base their e-pedigree software offerings. The standard is expected to make it easier for companies to create pedigrees (see [EPCglobal Ratifies E-Pedigree Standard](#)).