

FDA Will Issue Drug-Pedigree Guidelines

Associate FDA commissioner Randall Lutter says the pharmaceutical industry needs to move quickly toward adopting RFID for verifying a drug's chain of custody.

By Beth Bacheldor

Aug. 8, 2006—The U.S. Food and Drug Administration (FDA) announced today plans to issue technical guidelines in the next several weeks, designed to help pharmaceutical manufacturers, distributors and retailers implement drug-pedigree programs as part of an FDA-led effort to stem the amount of counterfeit drugs entering the U.S. pharmaceutical supply chain. Pedigrees, either electronic or paper-based, document the chain of custody of drug products as they move through distribution channels.

In addition, the FDA reports, it will issue its final compliance policy guide before year's end for the Prescription Drug Marketing Act (PDMA) of 1987, which takes effect Jan. 1, 2007. In early June, the FDA lifted a temporary hold on the PDMA, initiated because some members of the pharmaceutical industry were concerned that pedigrees would have a negative impact on small wholesalers (see FDA Issues New 'Counterfeit Drug Task Force' Report).

The compliance policy guide will provide the pharmaceutical industry with information about how the FDA will enforce the PDMA during its first year in effect, explains Randall Lutter, associate FDA commissioner for policy and planning, and cochair of the FDA Counterfeit Drug Task Force. For more than two years, the task force has been investigating the use of pedigrees, RFID and other tools to combat counterfeit drugs.

The draft PDMA compliance policy guide has been available for public comment since June, and Lutter says the FDA is now reviewing those comments as it develops the final compliance guide. The technical guidelines will be written in the form of questions and answers, he adds, and will provide information and guidance “about how pedigrees would work in practice after the Prescription Drug Marketing Act takes effect.”

During the FDA's disclosure about its plans regarding the compliance policy guide and technical guidelines, Lutter reiterated the FDA's continued interest in fighting counterfeit drugs.” He pointed to the June 9 announcement, when the PDMA stay was lifted, as a “key initiative to continue efforts to fight counterfeit drugs and promote track and trace, including RFID, as a way of enhancing the security of the U.S. drug supply.”

According to Lutter, the agency hopes the reinstatement of the PDMA regulation will spur the pharmaceutical industry's efforts to combat counterfeit drugs and begin testing RFID. “Our announcement is based on the view that [pharmaceutical industry] stakeholders have been too slow relative to our earlier expectations,” he says. “The June announcement was intended to jumpstart the stakeholders—provide a kick in the pants, if you will—to recognize that this is a real problem and deserves real attention. And the pedigree requirement of the PDMA, we believe, is best implemented through electronic track and trace capabilities.”

The FDA's update this week coincides with a new product introduction from IBM (see IBM Markets RFID Suite for Tracking Drugs). The vendor unveiled its IBM RFID System for Pharmaceutical Track and Trace,

which leverages IBM software and services so companies can collect and share all the information necessary to create a drug pedigree.

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