# FDA Clears Way for RFID Tagging

The U.S. Food and Drug Administration lifts some labeling requirements and gains support from two major pharmaceutical manufacturers.

By Jonathan Collins

Nov. 15, 2004—In a move to spur the testing and deployment of RFID in the United States pharmaceutical supply chain, the U.S. Food & Drug Administration has lifted a range of labeling and manufacturing practice regulations that it believes had been hampering RFID trials.

“Today we are issuing a compliance program that makes clear to the [pharmaceutical] industry that studies involving the use of RFID tags, chips and antennae on drug containers can be conducted without special request for FDA authorization,” Dr. Lester M. Crawford, acting FDA commissioner, said during a conference call with reporters.

According to the FDA, the primary goal of its action is to boost adoption of RFID technology, which it believes will help reverse a rise in recent years of counterfeit drugs entering the supply chain. “The goal of this policy is to enable industry to gain experience in this new technology to ensure the long-term safety and integrity of the U.S. drug supply,” said Crawford.

According to the agency, adoption of RFID will enable detailed electronic history of product shipments to be automatically produced, making it harder for counterfeit goods to enter that supply chain. Adding RFID should also raise the complexity and cost of trying to make counterfeit products appear to be genuine.

In its February 2004 report "Combating Counterfeit Drugs," the FDA said RFID was an important technology in ensuring the long-term safety and integrity of the U.S. drug supply (see FDA Endorses RFID Technology). But existing regulations have impeded some RFID trials by pharmaceutical companies.

“We had received numerous questions over the last year as to whether putting radio frequency tags on bottles impacted any of our labeling requirements or any of our good manufacturing requirements, as well as whether there were any concerns at the FDA that exposure to electromagnetic energy could affect product quality, and certain pilot studies were inhibited or delayed,” said Dr. Paul Rudolf, senior advisor for medical and health policy at the FDA.

Regulations will be lifted until December 2007, by which time the FDA says it expects to have been able to learn from RFID pilot studies to understand what labeling and good manufacturing issues emerge when using RFID, so all these issues can be addressed in a more definitive way. The FDA has posted online a new Compliance Policy Guide.

In addition to lifting restrictions, the FDA is also setting up a Counterfeit Drug Task Force, which it says will work with pharmaceutical companies and standards bodies–including EPCglobal, which is commercializing EPC technology—to provide a way for the results from pilot studies to be shared directly with the FDA.

Coinciding with the FDA's announcement, several major pharmaceutical manufacturers announced pilots to incorporate RFID into pharmaceutical packaging. Purdue Pharma said its pilot program would see RFID tags placed under labels for 100-tablet bottles of its OxyContin prescription pain killer tablets starting this week. The company will label all product shipments to Wal-Mart and drug wholesaler H.D. Smith.

Pzifer announced it has begun planning for an RFID project with the goal of shipping cases and retail packages of Viagra with passive RFID technology by the end of 2005. The pilot will run for a year with the aim of defining the benefits and challenges of deploying on other products and shipments.

GlaxoSmithKline (GSK) said it will begin using RFID tags in the next 12 to 18 months on at least one product deemed susceptible to counterfeiting, in order to more effectively monitor its progress from the company to the patient. In its Consumer Healthcare division, GSK already tags all pallets shipped to a central distribution center for Metro, a German retailer, and plans to tag pallets and cases shipped to Wal-Mart's Texas distribution centers by late January.

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