

FDA Endorses RFID Technology

Feb. 18, 2004—The U.S. Food and Drug Administration released its final report today on ways to reduce the counterfeiting of prescription drugs. The report's recommendations include the use of RFID technology to create a "pedigree"—a secure record documenting that the drug was manufactured and distributed under safe and secure conditions.

The report says it should be feasible to use RFID to track all drugs at the unit level by 2007.

"This is a significant step forward in deploying RFID down to the item level," says Jack Grasso, a spokesperson for EPCglobal, the organization charged with commercializing Electronic Product Code (EPC) technology. "We look forward to working with the FDA to do it in a responsible way."

The number of FDA counterfeit-drug investigations has increased to more than 20 per year since 2000, after averaging only five per year through the late 1990s. RFID is increasingly seen within the pharmaceutical industry as the answer to a growing problem. The report falls short of mandating the use of RFID, but industry observers say that FDA guidelines are usually followed very closely.

The agency has been studying ways to combat counterfeiting since July 2003, when FDA commissioner Mark McClellan created the Counterfeit Drug Task Force. More than 70 meetings were held to discuss various topics, including ways to improve the collection of data to create pedigrees. EPCglobal made presentations about the potential of RFID technology to fulfill this requirement. The task force's final report draws on input from security experts, federal and state law enforcement officials, technology developers, manufacturers, wholesalers, retailers, consumer groups and the general public.

"Because the capabilities of counterfeiters continue to evolve rapidly, there is no single 'magic bullet' technology that provides any long-term assurance of drug security," says the report, entitled *Combating Counterfeit Drugs*. "However, a combination of rapidly improving track-and-trace technologies and product authentication technologies should provide a much greater level of security for drug products in the years ahead."

The report says that adoption and common use of RFID as a reliable track-and-trace technology is feasible in 2007. The technology would help secure the integrity of the drug supply chain by providing an accurate drug pedigree.

"Reliable RFID technology will make the copying of medications either extremely difficult or unprofitable," the report concludes. "FDA is working with RFID product developers, sponsors, and participants of RFID feasibility studies to ensure that FDA's regulations facilitate the development and safe and secure use of this technology. FDA is also working with other governmental agencies to coordinate activities in this area."

The report says there was "universal support" for using RFID technology to create electronic pedigrees, and it spells out a timetable for adoption. This year, the industry will conduct feasibility studies using RFID on

pallets, cases and packages of pharmaceuticals. Next year, some manufacturers, large wholesalers and some large chain drugstores should begin to put individual serial numbers on pallets and cases of pharmaceuticals likely to be counterfeited. By 2006, tagging should be at the individual unit level of all drugs likely to be counterfeited, and by 2007, the FDA envisions all drugs being tagged at the pallet, case and unit levels.

The report doesn't specifically endorse EPC technology, but makes clear that the FDA envisions the use of a serialization system and the kind of network technology that EPCglobal is building to support the tracking of goods in open supply chains.

"We've been talking to FDA about this, and they have come to the same conclusions we have," John Roberts, director of healthcare for the Uniform Code Council, which together with EAN International, created EPCglobal. "It starts with pilots and feasibility studies, then tagging pallets and moving down to the consumer level. We think this is the right path."

Roberts says EPCglobal is eager to work with the FDA. Results of pilots conducted by EPCglobal subscribers will be made available to the FDA.

"This is an important driver," Roberts says. "Everyone's been waiting for this. The pharmaceutical industry is among the largest in the United States, and it will see far faster [adoption of EPC technology] than other verticals."

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