

12-15-2004 10:00 AM -8 10:20  
December 15, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Comments for the Docket: "Radio Frequency Identification Feasibility Studies and Pilot Programs for Drugs: Guidance for FDA Staff and Industry, Compliance Policy Guides (CPG), Section 400.210, November 2004"**

Secure Symbology, Inc. (SSI) is offering comments to the U.S. Food and Drug Administration (FDA) regarding the guidance document for FDA staff and industry titled, "Radio Frequency Identification Feasibility Studies and Pilot Programs for Drugs" published on November 22, 2004. By way of introduction, SSI is a global corporation specializing in innovative serialization and tracking solutions for a variety of supply chains vulnerable to counterfeiting and diversion, including pharmaceutical products at all packaging levels. SSI's technology utilizes bar coding with Reduced Space Symbology (RSS) and Composite Symbology (CS), which is a proven technology with a track record for success and can also provide the electronic pedigree that the FDA is seeking under the call for RFID feasibility studies and pilot programs. SSI is the bar code track, trace and anti-counterfeiting partner to Cardinal Health's pharmaceutical distribution chain.

The purpose of the following is to: (1) seek clear FDA identification of broader track and trace feasibility studies and field guidance in this industry (e.g., bar coding); (2) request public clarification of specific statements in the November 22, 2004 guidance document and; (3) raise issues not addressed by the guidance document that were key issues in the FDA report, "Combating Counterfeit Drugs, A report of the Food and Drug Administration," published February 2004.

**The use of bar coding to satisfy the requirements of the applicable statutes and regulations.**

The opening statement of the November 22, 2004 document states, "This guidance represents the Food and Drug Administrations (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. "

First, although the FDA may not intend to confer rights on any person or operate to bind the public, the approach taken in this document creates a de facto standard of RFID for the electronic pedigree as applied to anti-counterfeiting track and trace applications. SSI's bar code technology also provides an electronic pedigree. SSI has met with many companies in the U.S., Canada and Europe to discuss securing the pharmaceutical supply chain. Many firms, both large and small, have expressed concern regarding the use of RFID given its high costs for infrastructure, data synchronization, and middle ware. At present, the Return on Investment (ROI) for many companies would be negligible, possibly even non-existent. While RFID is almost certain to be the technology of the future, that future is anywhere from 3-5 years away or more.

Until RFID is more widely implemented with lower costs and key issues regarding the lack of ISO standards, privacy, hacking, radio frequency interference and other consumer group concerns are resolved, there will continue to be segments of the industry reluctant even to invest in feasibility studies for RFID.

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Second, the use of the term “alternative approach” is ambiguous. Does it mean that industry has the option to do feasibility studies and pilot programs using alternate technologies such as bar coding (which provides the same level of public protection as RFID) and by doing so, seeks FDA discretionary enforcement? Or does it mean that industry can apply different approaches to the use of RFID studies and programs? If it is the former, then the FDA should publish parameters for compliance standards for two dimensional bar coding similar to those of RFID. Many pharmaceutical companies, including R & D firms, small generic firms, and firms doing clinical trials, have expressed an interest in using SSI’s technology solution, the Electronic Sequence Code™ (ESC™) as a stepping stone to the RFID technology for the next two to ten years. The FDA should not create a de facto standard with an unproven technology whereby it prevents equally effective, alternative approaches from being utilized.

For the afore-mentioned reasons, SSI respectfully requests that the FDA clarify in a published document what is meant by the opening statement in the November 2004 guidance document and that FDA consider non-RFID technologies that lead to and support RFID in the future for case-by-case approaches to anti-counterfeiting and supply chain security.

### **The goals of the Compliance Policy Guide (CPG)**

As identified in the CPG document, the FDA’s goal is to facilitate the performance of RFID studies and allow the industry to gain experience with the use of RFID. SSI can immediately provide track and trace capabilities and an electronic pedigree throughout the entire pharmaceutical distribution and supply chain, from the production line to the end retail or institutional pharmacist user. It also affords the highest degree of product integrity and safety, as we previously communicated in our comments to the docket on the Importation of Drugs.

SSI is concerned that by focusing solely and exclusively on RFID, a technology that is currently a work in progress with severe limitations (i.e. interference from water and metal, problems with lack of ISO standards, data synchronization, expensive infrastructure and middle ware, lack of consumer validation, privacy and hacking issues), the FDA is:

- Denying industry the opportunity to use more cost-effective alternatives that presently deliver the same level of consumer and public protection today. Our experience in meeting with pharmaceutical companies, government officials, and supply chain associations is that RFID may provide a ROI to some substantial companies with products that have a large profit margin; however, smaller and medium sized companies with products that do not have that margin are very reluctant to go down that path until RFID has more experience, comes down in cost, and has solved other problematic aspects.
- Exposing patients and the public to unnecessarily potential counterfeit drugs as the Agency collects data on RFID over the next several years. Clearly we recognize that RFID is the way of the future, but until that future date arrives, leaving the public vulnerable should not be an option. In addition, the November/December 2004 issue of the Journal of the American Pharmacists Association reported that pharmacists want a role in drug importation, according to a study conducted by pharmacists at the University of Illinois at Chicago and the University of Michigan. In this article, pharmacists express concern about safety, liability and the economic ramifications if imported drugs are channeled into the U.S. (a likely scenario in the near future).

RFID tags that are limited to the case and pallet level without data synchronization and privacy at the pharmacy level leave the pharmacist in a precarious position. This profession should not be left vulnerable until 2007 while there are current means to reduce the pharmacist’s and the public’s exposure to risk and liability. Why not choose an interim pathway that protects a pharmacist’s ability to protect the public while seeking the long term vision of RFID?

For the reasons stated above, SSI respectfully requests that the FDA reconsider the goals of the CPG to facilitate the performance of RFID, as well as available and emerging technologies that also offer a demonstrable and cost-effective solution toward providing the same level of consumer protection while still guaranteeing the safety of domestic and imported drugs.

**Issues in the February 2004 Report from the FDA on Combating Counterfeit Drugs that should be addressed by facilitating industry experience with track and trace technologies.**

- Page 3 of the February 2004 report states, "Radio Frequency identification (RFID) appears to be the most promising approach to reliable product tracking and tracing. Significant feasibility studies and technology improvements are underway to confirm that RFID will provide cost-reducing benefits in areas such as inventory control, while also providing the ability to track and trace the movement of every package of drugs from production to dispensing." This statement is factually inaccurate. RFID will not be cost effective for many company's products unless there is a significant profit margin on the product being tagged and inventoried. Many pharmaceutical and consumer products in general will not be able to apply RFID tags in a "cost effective" manner to the end product level for at least three to five years, not to mention beginning to address issues such as read rates, privacy concerns and kill tags.
- As we have previously stated to the FDA, SSI's ESC™ System provides the supply chain with a method for serializing individual products, cases, pallets and/or containers. Thus, this technology now provides industry the ability to uniquely mark items with a machine readable serialized bar code with corresponding human readables that easily communicates data to a database that is password protected and encrypted on drugs as small as unit dose, and containing such variable data as: NDC, lot number, expiration date, and unique serial number. To accomplish this, the technology uses in-line laser, ink-jet and/or thermal transfer printers without sacrificing production line speeds.
- On page 3 as described in the report, "The FDA is working with RFID product developers, sponsors and participants of RFID feasibility studies to ensure that the FDA's regulations facilitate the development and safe and secure use of this technology." SSI urges FDA to work with bar code serialization as a strategic partner in steps that do lead to a truly cost effective pathway to RFID of the future.
- Page 5 of the February 2004 report describes the issue of drug counterfeiting as "a global challenge to all nations." Yet RFID tags, writers, readers, and data synchronization have their own challenges and many of these globally unresolved issues will remain well past 2007.
- On page 12 of the February 2004 report, the FDA makes a very brief statement about the use of two dimensional bar codes for some products, and then endorses RFID for inventory control, correct dispensing, and transmission of key data. Again, this is clearly years away from becoming a reality on a global basis.
- Pharmacists and drug store chains have commented publicly to the Drug Importation Docket that pharmacist and consumer authentication of drugs in real time is a significant aspect of a track and trace system. The feasibility studies and pilot programs under consideration in the November 22 Compliance Policy Guide will not be a factor for the next two to three years.

**Summary**

Companies need to be able to move their products easily through the global supply chain with the utmost security while maintaining the integrity of all their products. The ultimate solution is an effective track and trace technology utilizing an electronic pedigree for products throughout the growing global marketplace. There is no question that RFID is the ultimate technology of choice. We



recognize that the ultimate goal of RFID through its data carrier, the Electronic Product Code (EPC™), is to serialize every manufactured product down to the item level. However, due to the huge infrastructure costs, high tag costs, questions concerning ISO standards, hacking and privacy concerns, and implementation of RFID to the items level, RFID is by most estimates three to five years or more away. The public, patients, and consumers can not afford to wait.

Although a wide discrepancy exists among current cost estimates for implementation of RFID to the product level, we have seen estimates associated for a billion dollar company to set up an RFID infrastructure to just tag at the pallet level range from \$30-\$40 million dollars and \$11-\$12 million dollars per year for the tags. SSI's technology can be installed for a fraction of the cost and with minimum production intrusion because there are no server, software, or maintenance costs to the wholesaler, distributor, or end user pharmacist. The savings to the entire supply chain by use of this technology would pay for the lower cost RFID of the future as it works its way down to the end user level.

Finally, the FDA's February 2004 document on Combating Counterfeit Drugs indicated that there is no "silver bullet," and that a multi-layered approach with overt and covert technologies was the pathway of choice. Yet, the CPG published on November 22, 2004 would appear to contradict that approach by singling out RFID as the optimal choice, the de facto standard if you will, without options for other cost-effective approaches, short term priorities, or any multi-layering. We respectfully submit that this approach is short-sighted and denies consumers truly affordable access to safe products in circulation.

I urge the FDA to (1) consider these comments and recommendations, (2) strategically work with two dimensional serializing bar code technology, (3) revise and/or clarify the November 22, 2004 CPG, and (4) allow companies to conduct pilot programs with this type of technology and offer them the same enforcement discretion as those companies who choose to test RFID.

Thank you again for the opportunity to comment on this timely and important health issue.

Sincerely,

Ron Barenburg  
President

cc: Paul M. Rudolf M.D., J.D.  
Steve Niedelman