



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

RE: Comments for the Task Force on Drug Importation [Docket No. 2004N-0115]

Secure Symbology, Inc. is offering comments to the U.S. Food and Drug Administration (FDA) and the Task Force on Drug Importation as charged by HHS Secretary Tommy G. Thompson to study what it would take in terms of oversight and resources to safely import drugs. We are aware that the comment period has closed but we are requesting consideration of our comments as you move forward to conclude your study by December 2004.

Secure Symbology, Inc. is a global corporation specializing in providing innovative serialization and tracking solutions for a variety of supply chains vulnerable to counterfeiting and diversion, including pharmaceutical products at all packaging levels. The purpose of our comments is to respond to key questions raised in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) and provide important information about our new technology because it offers a demonstrable and cost-effective solution toward guaranteeing the safety of imported drugs.

Anti-counterfeiting technologies that could improve the safety of products in the domestic market as well as those products that may be imported.

Although bar coding technology is not new, not all bar codes applications have the same capabilities as our technological solution, which can now provide track, trace and an electronic pedigree throughout the supply chain from production line to end retail or institutional pharmacist user, and afford the highest degree of product integrity and safety.

Our company's ESC™ System provides the supply chain with a method for serializing individual products, cases, pallets and/or containers. Thus, the technology now provides the ability to uniquely mark items with a machine readable bar code (with corresponding human readables) which becomes a portable database on drugs as small as unit dose, with such variable data as: NDC, lot number, expiration date, AND a unique serial number. To accomplish this, the technology uses in-line laser, ink-jet and/or thermal transfer printers without sacrificing production line speeds.

We provide a solution for assuring greater safety of domestic and imported drug products because it can now encode, encrypt and cross-reference both the Uniform Code Council's (UCC) Global Trading Information (GTIN) and tomorrow's Electronic Product Code (EPC™) formats in separate or combined bar codes. Using recognized global standard bar codes such as Reduced Space Symbology, (RSS) with composites for small unit-dose pharmaceutical products, and UPC-A and EAN with composites for OTC drug products, the ESC™ System, because of its unique serialization process can provide legitimate supply chain members with real time product validation, all using off the shelf and readily available bar code scanners.



Furthermore, significant amounts of variable data besides what was previously available, such as country of origin, contraindications, "red flag" warnings, best use by dates, and in the case of containers, entire manifests with URL links to entire shipping information and chain of custody for expedited port and border control can now be encoded. It's also important that the Task Force be aware that our company has also developed an imager that can read all these codes, is RFID-ready, wireless to the Internet and has a cell-phone built in, specifically for port of entry security.

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. But because of the huge infrastructure costs, high tag costs, questions concerning ISO standards, hacking and privacy concerns, implementation to the items level is, by most standards, 5 – 10 years away. The ability to track, trace and provide an electronic database and an electronic pedigree cannot wait 5-10 years for item level serialization while U.S. states, counties and it's citizens bring pharmaceutical products in from Canada and other foreign countries. DOD and Wal-Mart driven mandates may elicit some success in the next few years at the container and/or pallet level, but even at this level, data synchronization still is a major issue.

Costs associated with the implementation of technologies.

What is especially important for the Task Force to recognize is that our technology can accomplish today most of what RFID states it can do years from now and at a fraction of the cost. For our technology, the capital costs would be incurred by: (1) installing on the production line ink-jet, laser, or thermal transfer printers to print the variable data on top of the pre-printed linear bar code at production line speeds and (2) installing verifiers, cameras and a controller, all under a 21CFR11 structure. This would be the one-time capital cost. And, we provide this service for pennies per label to the manufacturer, and at no charge to the packager, wholesaler, distributor or pharmacist. There are virtually no additional label costs initially, because the pharmaceutical manufacturer, as is currently practiced, pre-prints the label with the now prescribed NDC in a machine readable linear bar code like RSS limited or RSS stacked for small unit items, or UPC-A or EAN for OTC products

Current cost 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. Our company's technology can be installed for a fraction of the cost and with minimum production intrusion. Again, as previously stated, there are no server, software or maintenance costs to the wholesaler, distributor or end user pharmacist.

Short and long term financial impact on drug prices, drug manufacturers, pharmacies, wholesalers, and patients.

The short term and long term net financial impact on pharmaceutical stakeholders is threefold: (1) There is a demonstrable ROI to the manufacturer. (2) There is no financial impact to mid-level distributors. (3) And consumer protection would be enhanced while the costs of drugs is kept down. Unsafe pharmaceuticals, including diverted, contaminated, unapproved or counterfeit products would be kept out of the supply chain and public confidence in oversight agencies increased-- all with virtually no impact on drug prices to the consumer.



Because Secure Symbology's serialization technology system is far less of a financial burden than RFID to start up, smaller, qualified and reliable foreign pharmaceutical companies could—within the appropriate regulatory framework-- implement and benefit from serialization (i.e., track and trace, anti-counterfeiting, brand security, better inventory control, ease of recall, validation of returns and the ability to maintain an electronic data base and provide an electronic pedigree on the life cycle of the product). Thus, imported pharmaceuticals would provide a higher degree of assurance of safety and integrity.

In the U.S. market, 3-5 percent of manufactured pharmaceuticals are returned, virtually with no validation. With serialized products, manufacturers would know if product strayed out of the authorized supply chain—or if inappropriate imported drugs strayed into the supply chain-- and could then validate authorized or approved drug products and returns, thereby saving tens of millions of dollars per manufacturer. With serialization, recalls could target specific NDC, lot, expiration date and serial number range, instead of a broad based recall, which saves time, money, and keeping safe products in circulation and keeping pharmaceuticals affordable and accessible to the American public.

Summary

In summary, Secure Symbology, Inc. believes that if the importation of foreign pharmaceuticals is legalized, it is done so within a regulatory framework that provides a safety net where current gaps exist and relies heavily on a serialized supply chain with appropriate options for companies to choose from, including serialized bar code technology. Since FDA's regulatory structure is the gold standard in many countries around the world, we also believe that FDA "raising the bar code" as a significant track and trace tool will enable developing countries and emerging markets to consider the solution where they have no capacity, resources or infrastructure to have a verification system that protects their own citizens from unsafe drugs.

If I can provide any additional information, please contact me. Thank you again for the opportunity to comment on this timely and important health issue and your consideration of these comments.

Sincerely,

Ron Barenburg
President