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November 3, 2003

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

Re: Docket 2003N-0361
Submitted electronically to http://frwebgate.access.gpo.gov/cgi-bin/leaving.

Attention: Anti-Counterfeit Drug Task Force

Thank you for the opportunity to present and demonstrate track and trace technology, RFID, and anti-counterfeit technology at your public meeting held on October 15, 2003. Zebra has considerable experience in bar code printing and systems, has been a leader in the development of standards for the blood bagging industry, and has implemented secure systems for the Department of Defense. Our over thirty years of experience in bar code technology and leadership in the pharmaceutical industry make us uniquely qualified to comment on some of the important issues surrounding the drug supply chain today.

Attached is Zebra Technologies' submission of comments to docket 2003N-0361. The first attachment, *Comments to FDA 10/15/03*, are the final comments presented to the FDA on 10/15/03. Below, we have also answered questions in the federal register (Federal Register: September 5, 2003 (Volume 68, Number 172, Notices, Pages 52772-52775) that we felt were most relevant to our area of expertise. Finally, we have also attached two whitepapers developed by Zebra—one that details the benefit of bar coding within the pharmaceutical supply chain and one that details secure media solutions.

We would welcome the opportunity to speak with you directly about any of the matters presented.

Respectfully,

Deborah H. Murphy
Life Sciences Market Development Manager

James O'Hagan   **2003N-0361**   **C 29**
Director, Technology Transfer

A: Technology

1. Secure operational methods that make it more difficult for criminals to obtain access to genuine drugs and genuine packaging, more difficult to replace those drugs with convincing counterfeits, and more difficult to divert drugs into inappropriate channels are key to the success of any anti-counterfeit measures. Technology can play a valuable role in helping detect when the supply chain has been compromised. It can also play an important role in quickly gathering information that is critical to our ability to limit the detrimental effects of the bogus medications and to prosecute criminals. Some technologies can also make it more difficult for criminals to produce convincing counterfeit packaging.

Both track and trace technologies and authentication technologies should be used in fighting counterfeit drugs. Track and trace technologies are most useful for quickly identifying the extent to which the supply chain has been compromised by counterfeiters or diverters. Track and trace technologies have the added benefits of streamlining supply chain operations, thus reducing handling costs and reducing the amount of outdated medication within the supply chain.

This level of specificity requires a consistent, widely used, and easily automated taxonomy for both medications and suppliers. The 14 digit Global Trade Identification Number maintained by UCC.EAN is an excellent platform on which to build a communication system for medications because it is specific, consistent, widely used, and easily automated. Similar EAN.UCC keys exist for tracking individual shipments. In addition, the FDA should endorse the creation of a similar, authenticable identity for use by manufacturers, pharmacists, and supply chain partners. This could be extended by the industry to develop secure operational practices as well as procedures, including communications that would occur when those practices are compromised.

Track and Trace Technologies

Track and trace technologies span a wide range of operational methods and technologies, including:

Technology	Overview	Benefits	Drawbacks
Paper manifest	Printed piece of paper listing each handler of a shipment from point-of-origin.	Provides details for a shipment that allows the tracking of the shipment from origin. Negligible up-front investment and easy implementation.	Easy to create fraudulent documents unless secure paper technologies are widely used. Lack of centralized data depository makes it difficult to quickly and accurately identify problems.
Technology	**Overview**	**Benefits**	**Drawbacks**

Bar code labels	Tracking information is standardized by the industry. An adhesive label carrying this information is created for each individual shipment and permanently affixed to each shipping carton. Access to the database for the purpose of updating the status of product is required.	Tracking information is encoded into a bar code, improving reading accuracy and improving productivity. Minimal up-front investment and on-going maintenance costs. Lowers operating costs within the supply chain. Wide availability of experienced integration partners.	Requires industry agreement on informational content and format. Adding authentication requires allowing access to centralized data.
Electronic Product Codes	Identity is affixed to packaging as a low-cost passive RFID tag. Information on that package is stored in databases accessible by approved trading partners.	Identity can be read remotely through some types of packaging. Relies on integrated data throughout the supply chain, which can provide additional supply chain benefits.	Evolving standards, limited industry experience, higher cost than bar code labels. State of current technology requires some customization for each type of product and related packaging.
Passive Radio Frequency Identification	Identity is affixed to packaging as a passive rewritable RFID tag. Information regarding each handler is written to the tag as the item moves through the supply chain, allowing an auditor to identify times that a shipment may have been compromised.	Allows paper manifest system to be automated for improved accuracy, reduced handling costs and quick access to data.	Proprietary protocols and limited implementation expertise requires each application to be developed as a custom program. Hardware and tags are just beginning to appear on the market.
Active Radio Frequency Identification	Similar to passive RFID, but larger tags allow longer-range reading and additional information storage and functionality, such as locating a shipping container or monitoring temperature.	Currently used by U.S. Customs for tracking international shipping containers. Provides near real-time data, encompassing a broad range of handling activities.	Proprietary protocols and limited implementation expertise requires each application to be developed as a custom program. Costs are significantly higher than passive RFID.

Costs for these technologies vary with respect to implementation costs and tracking costs. Implementation involves agreement on what data will be shared and how it will flow, creating processes and computer networks at each trading partner, acquiring and testing hardware, and training personnel. Tracking costs include on-going software maintenance fees, media costs (paper, labels, RFID tags), and equipment service and maintenance. The costs for services and software vary widely, depending on the sophistication of the network and the chosen solution. Hardware and media costs also vary widely based on the size and complexity of the implementing company, but common industry estimates are that 20% of implementation costs are data acquisition and printing hardware and annual media costs are four times the cost of the printers. Hardware estimates include:

Technology	Hardware cost	Media Cost
Paper manifest	Standard business printers and copy machines, probably already installed.	3 cents per page, or 7 cents per label
Bar code labels	Industrial bar code printers range from $1000 to $4500 each.	2 to 4 cents per label
Electronic Product Codes	Hardware depends on how tag is integrated into packaging. EPC compliant shipping labels may be printed on an RFID printer-encoder ranging from $3000 to $8500 each.	30 to 50 cents per EPC label Individual chips may be under 15 cents in quantity
Passive Radio Frequency Identification	RFID printer-encoder ranging from $1500 to $8500 each.	35 to 75 cents per smart label
Active Radio Frequency Identification	Hardware costs vary widely on how tags are integrated with container or packaging.	$3.50 to $25 per tag and up

Anti-counterfeit Technologies
In addition to track and trace technologies, there are also many anti-counterfeit technologies available. These technologies are all built on the same premise—allowing easy authentication by trusted members of the supply chain, while raising the costs for counterfeiters. Typically, multiple layers of authentication are used, some for consumers, some for retailers or pharmacists, some for trusted enforcement personnel, and some that can only be identified and authenticated with proprietary laboratories. This results in the most robust system for both quickly identifying suspect medications and keeping secure the most proprietary authentication techniques.
Anti-counterfeit technologies serve to:

- Alter physical characteristics of the medication or its packaging,
- Digitally encrypt data about the medication or its packaging, then store that data in a database or on the item itself in a bar code or RFID tag, or
- Restrict access to the medication or its packaging.

The most secure system will use multiple layers of technology to integrate all three technology categories. A technology ideally suited to physically authenticating an individual pill may be cost-prohibitive if it requires breaking down a pallet of packaged medication to determine whether or not it includes counterfeit drugs. Restricting physical access to a shipment may be as simple as a padlock or as sophisticated as biometric confirmation used as a PIN on a secure computer network. Clearly there are benefits to layering technologies, which combine authentication with track and trace capability.

2. While there have been some efforts by individual pharmaceutical manufacturers to track shipments and to implement authentication technologies into medication and packaging, we are unaware of any industry-wide efforts. Barriers include:

- A highly regulated industry accustomed to high product margins from new product innovations has resulted in slow adoption of supply chain tracking technology, compared to lower margin industries seeking profitability through lower costs and greater efficiency, where we see industry wide adoption,
- Reluctance to publicly admit susceptibility to counterfeiting and diversion,
- Lack of knowledge by industry leaders regarding the extent of counterfeiting, leading to underestimating the probability of being negatively impacted by counterfeiting activities,
- Difficulty in assessing the detailed costs associated with an investment in equipment and processes to make counterfeiting more difficult,
- Rapidly changing individual layers of security is a successful method for staying ahead of counterfeiters, but this is not conducive to industry-wide standards in a highly regulated industry, nor is it cost effective.

3. The FDA should play an important role in facilitating the use of anti-counterfeit technologies by:
- Encouraging discussions between drug manufacturers, drug distributors, pharmacists, consumer groups, technology providers, and government enforcement personnel to disseminate information regarding the extent of the counterfeiting problem, understanding the associated costs, and evaluating potential solutions.
- Enabling the creation of a method to provide unique, authenticable, and automation-friendly identities to individual manufacturers, drug distributors, pharmacists, and their employees. This can then be used as a framework for development of an industry-wide standard for tracking pharmaceutical shipments.

- Dedicating some limited amount of FDA resource to streamlined approval of new pharmaceutical packaging, allowing drug manufacturers or packagers to test new anti-counterfeit technologies.

4. Pharmaceuticals, commanding a high market price and in high demand, can be inexpensively imitated at low risk of prosecution. Potential FDA interventions include:

- Aggressively promote known counterfeiting cases. This would serve to increase the probability of detection, making drug counterfeiting less attractive. This would also increase the perceived cost of counterfeiting to drug manufacturers and pharmacists, encouraging the use of anti-counterfeit technologies.
- Encourage increased government enforcement efforts and higher penalties for counterfeiting medications specifically for those medications with higher risk to the patient resulting from not taking authentic medications. This would serve to discourage counterfeiters from targeting specific high-margin medications because the risk of detection would be higher and the associated punishment would be more severe.
- Provide real and perceived benefits to opting in to a secure supply chain arrangement similar to the U.S. Customs' Customs Trade Partnership Against Terrorism (C-TPAT), thus endorsing industry efforts to secure its supply chain and allowing scarce enforcement resources to be focused on the small portion of pharmaceutical shipments at highest risk to counterfeiting and diversion. This could serve to accelerate industry movement toward safe, secure, supply chain tracking at lower costs. This raises the cost to counterfeiters trying to penetrate the U.S. pharmaceutical supply chain, while also lowering the reward to successful counterfeiters.

B: Regulatory and Legislative Issues

Implementing a more secure supply chain system with an ability to track product throughout the supply chain, through multiple trading partners, will essentially give the industry an electronic pedigree for product. This process would dramatically affect PDMA, and the requirements of manufacturers and distributors to comply.

C: Public Education

The usefulness of information disseminated by the FDA, other government agencies, and private stakeholders is based largely by how targeted it can be to the specific needs of an individual stakeholder. A patient on a daily regimen of Lipitor may willingly subscribe to e-mail or phone calls alerting him of a specific case of counterfeiting that could effect him, while that same patient may be unwilling to spend time reading a simple brochure or website on the general issue of drug counterfeiting. A busy pharmacist is likely to more closely inspect shipments from a specific supplier if she knows there has been an immediate threat in that particular area.

This level of specificity requires a consistent, widely used, and easily automated taxonomy for both medications and suppliers. The 14 digit Global Trade Identification Number maintained by UCC.EAN is an excellent platform on which to build a communication system for medications because it is specific, consistent, widely used, and easily automated. Similar EAN.UCC keys exist for tracking individual shipments. In addition to these, the FDA should endorse the creation of a similar, authenticable identity for use by manufacturers, pharmacists, and supply chain partners. This could then be extended by the industry to develop secure operational practices as well as procedures, including communications that would occur when those practices are compromised.

D. Industry and Health Professional Issues

All participants and providers in the healthcare industry have a role in preventing and minimizing the damages from counterfeit and diverted drugs. The FDA has already created a forum, through the Anti-Counterfeit Task Force, for increased exposure to the issues and future dialog to address the problems. Manufacturers, wholesalers, distributors, repackagers, GPO's, pharmacies, health care providers and consumers need to all participate in the creation of a stronger, more secure U.S. drug supply. The issues facing us today in counterfeiting and diversion can be minimized with technology—and it requires the cooperative work of the stakeholders listed above to implement a robust solution—through technology, reporting and accountability, and public education.

Thank you. My name is Jim O'Hagan, I am Director of Technology Transfer for Zebra Technologies Corporation, a leading manufacturer of on-demand printing solutions used for Supply Chain Tracking, business improvement, and security. Zebra is publicly traded and headquartered near Chicago.

Zebra provides automatic identification solutions to both small suppliers and worldwide corporations, including pharmaceutical manufacturers, contract packagers, drug distributors, retail pharmacies, and hospitals. We've assisted these firms in complying with the FDA's proposed unit-of-use labeling requirements, and we've also assisted several health care organizations, including the VA hospitals, with leveraging unit dose data and positive patient ID for patient safety. In addition, Zebra has participated on several committees and sub groups assisting in the development of patient safety and security, including the HDMA and their Industry Coalition for Patient Safety.

Zebra solutions are an integral part of supply chain tracking systems, not only in life sciences, but also in automotive manufacturing, parcel shipping, retail distribution systems, the U.S. Department of Defense, and in other industries where tracking and tracing individual items is essential to efficient and dependable operations. These businesses use bar codes to improve the security of their supply chains. Each item, case, or pallet is bar coded with the information that needs to be shared between two trading partners. Since these bar codes follow industry standard formats, that information is easily shared, with or without access to an electronic database. In addition, each tracked item has a unique identifier, allowing each item to be linked to other, more specific information made accessible only to trusted partners with a need to know. Since each item has a unique identity, each item can be tracked to and from each trusted partner. Because this identity is encoded in a bar code, or an RFID tag, tracking is extremely reliable at very high speed, and therefore, at very low cost.

In addition to supply chain tracking, Zebra's printers and supplies print authenticable identities including state drivers' licenses, airline boarding passes, event tickets, consumer electronics, computer software, and tax stamps. Custom materials, holographic films, magnetic strips, covert marks, and invisible bar codes are used widely but discreetly by Zebra's customers. But these anti-counterfeit technologies are worthless without secure operational methods including hiring practices, access control, and controlled access to information.

All these technologies depend on differentiating between trusted partners in an unsafe world. The FDA already plays an important role by confirming that certain manufacturers can be trusted to manufacture certain pharmaceuticals and that certain pharmacists can be trusted to dispense pharmaceuticals. Adding the ability to confirm that a trading partner is who and what he says he is can go a long way toward addressing both counterfeiting and diversion problems within the supply chain. Giving each partner a unique, authenticable, and automation-friendly identity is key to doing this in an effective but cost-efficient manner.

Creating an authenticable identity and tracking it through the supply chain is proven technology, and Zebra Technologies is an experienced, trusted advisor. Over 90% of the Fortune 500 use Zebra products in over 90 countries worldwide.

Thank you for the opportunity to work with you on this important issue. More detailed information and specific comments on the interim report will be submitted to the docket. Some of our products are on display next door with personnel available for further discussion.