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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852



Recommendation of SupplyScape Corporation

Docket No. 2005N-0510

**Submitted for the FDA Anti-Counterfeit Drug Initiative Public Workshop
Held on Feb. 8-9, 2006**

The FDA has successfully led the industry to increase, enhance and sustain patient safety for all Americans. Since 2003, the FDA provided leadership, guidance and support for the development of Electronic Pedigree, Serialization and RFID in order to secure the pharmaceutical drug supply from counterfeits.

At SupplyScape we believe patient safety is the first priority for all stakeholders. Patient safety should not be held secondary to the availability of specific technologies. Pharmaceutical supply chain security is an evolving achievement and we believe it is imperative to adopt the most secure measures attainable today and to augment this security with additional measures as quickly as possible.

Since the FDA's report on Combating Counterfeit Drugs in February 2004, industry has developed a better understanding of the various technologies and their roles in the development of an anti-counterfeit solution. SupplyScape reached a key conclusion:

RFID ≠ Electronic Pedigree ≠ Serialization

Therefore, time-tables for the deployment of RFID, Electronic Pedigree and Serialization will not be the same. Electronic Pedigrees are being implemented already without RFID or Serialization and by themselves will immediately provide a layer of protection against counterfeit drugs.

SupplyScape recommends the FDA should undertake these specific steps:

1. Develop new rules for the PDMA which support universal electronic pedigrees at a national level. Support state initiatives for electronic pedigree and accelerate the adoption of electronic pedigrees at a national level by leveraging work already done by many states. The industry has developed a universal Pedigree Messaging Format and is implementing it today to support state pedigree laws.
2. Establish a national drug serialization structure for cases and items. The structure should address the key issues of privacy, security and efficiency, such that it can be implemented immediately with barcodes and with RFID.
3. Actively support industry initiatives to implement RFID without mandating specific technologies. Provide guidance on the key issue of product stability and support migration plans.

Electronic Pedigree

SupplyScape believes universal adoption of Electronic Pedigree by all stakeholders is the most secure approach. The purpose of an Electronic Pedigree is to provide a certifiable transaction

history for a product in the supply chain. Industry, state regulators, technology vendors and standards organizations have converged on a Universal electronic pedigree model which is being implemented today in order to meet the Florida July 1, 2006 deadline. The Universal solution can be implemented once by a company and it will meet the requirements of all the state laws as well as the PDMA.

Multiple software technology vendors support the universal electronic Pedigree Messaging Format standard and have committed to interoperability. Large and small companies in the industry are implementing a universal solution in manner that is economically optimal for their business. Florida has finalized the rules for “self-authenticating” Electronic Pedigree and the standard supports them.

The FDA should update 21 C.F.R 203.50 to reflect the consensus and support the adoption of Electronic Pedigrees.

Serialization

While Electronic Pedigree does not require product serialization, mass serialization combined with Electronic Pedigree will provide an even greater level of security against counterfeiting. The FDA must take a leadership role in defining the serialization structure and hierarchy management for the industry. Patient safety, consumer privacy and business efficiency concerns converge in a manner that only the FDA can resolve.

The definition of the serialization structure, management and representation is an extension of the foundation the FDA has already provided with the NDC and barcode rules. Furthermore, only the FDA can lead the industry when security and privacy are at stake.

The serialization structure can be represented in many competing Auto Identification technologies (e.g. many types of Barcode and RFID). The financial and physical benefits of these technologies will continue to vary and stakeholders must converge on the technologies that best meet their evolving needs.

Today, case serialization via RFID and item serialization via Barcodes is technically and financially feasible. The FDA needs to provide guidelines that enable the use of “implied reads” in order to provide a phased migration path for the adoption of RFID. SupplyScape believes that a phased migration path of case serialization via RFID and product serialization via Barcodes will be the shortest and financially beneficial path to a safe and secure supply chain.

By developing guidelines in support of implied reads, the FDA will address key operational efficiency and technology cost concerns without compromising the safety and security of the supply chain. Furthermore, by establishing a migratory path, the FDA will accelerate adoption. As a result industry will be able to rapidly migrate to RFID in a phased manner. SupplyScape believes the optimal phases are: case level RFID serialization, item level barcode serialization and finally item level RFID serialization.

Looking Forward

Since 2003, SupplyScape has been a participant with other industry leaders in developing a safe and secure supply chain. We have worked with all segments of the industry and all levels of the government. The sincere and earnest efforts of all the companies, agencies and individuals have generated tremendous progress. 2006 promises to be a year when all of us reach key milestones with regard to Electronic Pedigree, serialization and RFID. The FDA’s leadership has been invaluable and we believe the FDA can once more show the way for the next set of accomplishments.

SupplyScape would be pleased to provide more detail on these recommendations. SupplyScape may be contacted at 781-305-8085 or www.supplyscape.com.