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

February 24, 2006

Re: [Docket No. 2005N-0510]

Dear Task Force Members,

Our drug supply is under increasing threat from counterfeit and diverted product. Additionally, the continued and growing incidence of counterfeit drug products entering the supply chain highlights our vulnerability to terrorist attack through this channel. We should endeavor to address these threats immediately using technology that is available today.

Since the FDA issued its report on Combatting Counterfeit Drugs in February of 2004, significant effort and focus has been placed on the development of RFID technology as a potential means of securing the supply chain. Although this technology holds much promise for improving supply chain efficiencies, and the visibility of materials moving through the supply chain, much work and many years will pass before this technology will be ready for widespread use. There remain significant economical, political, and technological challenges to overcome before RFID technology can be effectively used to track products at the unit and even case levels. The original timelines for RFID implementation envisioned in the 2004 report were optimistic, and although much progress has been made over the past two years the RFID technology is still only just only marginally closer to widespread use than it was in 2004.

Therefore, we urge the FDA to reconsider the strong and sole focus that has been placed on RFID technology for product tracking and to place priority on the use of technology that is available today and that can be implemented immediately. Barcode technology is readily available, economic, and will allow mass serialization of product at the unit level. Mass serialization will also open up the opportunity for authentication at the point of dispensing or even at the consumer level.

The adoption of barcode technology into widespread use took many decades and the same will be true for RFID technology. It is logical to conclude that the introduction of RFID technology will occur in a phased manner over time, and that a variety of "hybrid" systems will be implemented that utilize combinations of barcodes and RFID tags. Additionally, as RFID technology comes into broader use, the continued use of serialized barcodes will be necessary as a source of back data for RFID tags that are damaged or unreadable.

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The introduction of mass serialization using barcode technology could be implemented starting immediately and would provide the opportunity to build out a data management infrastructure that is applicable for data from barcodes but also forward compatible for data originating from RFID tags. A variety of barcode symbologies are available and could be used. The two dimensional datamatrix symbology provides advantages in data capacity per area and error correction and is already being implemented with increasing frequency by the pharmaceutical industry. Development of parent child relationships during the manufacturing, labeling, and data capture process, will enable unit level information to be captured through single scans of case and pallet labels. This approach will avoid the need to unpack and scan every item in a box as it moves through the supply chain.

Initially a “book end” strategy could be employed whereby each manufacturer would be responsible for mass serializing their products and establishing a corresponding database of valid serial numbers. This would then open the possibility for verification to occur at the point of dispensing. As each serial number dispensed is registered in the database, an early warning system would be created whereby multiple hits to the system would flag further investigation. Although many details would obviously need to be developed, we believe that a significant impact in the security of the supply chain could be made relatively quickly if mass serialization and monitoring was implemented. We would envision a phased approach progressing along the following type of timeline:

### **Phase I – Now through the next several years**

- Mass serialize product with barcode technology
- Establish a forward compatible data management infrastructure
- Utilize a “bookend” approach that initially involves only the manufacturer and the point of dispensing (e.g. pharmacist, hospital, etc.).

### **Phase II – Two to Five years out**

- Add the “pages” between the bookends
- Involve 3rd party distributors to achieve full traceability through the supply chain
- Incorporate “parent child” information onto the various packaging tiers to simplify data capture through the supply chain whereby single scans of pallet or case labels would also capture complete item level information.

### **Phase III - Five years +**

- Phase in RFID toward the unit level as the technology matures and the various barriers to use are overcome

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- Build out RFID infrastructure for widespread use

Through all phases listed above various hybrid combinations of barcode and RFID tags can be employed as specific situations permit.

We encourage the FDA to provide leadership in facilitating the use of existing technology for mass serialization of pharmaceutical products. This will have a near term positive impact on the security of the supply chain and will provide the basis from which further improvements can develop. In addition, we believe that the FDA can work with Congress and other agencies such as the Department of Justice to effect legislation that would increase the severity of the penalties and punishment to criminals convicted of counterfeiting pharmaceutical products. Countries that have imposed severe penalties for possession of illegal drugs have dramatically reduced the problem. We should do the same for counterfeit drugs. The risk/reward equation in the USA still encourages criminals to turn to drug counterfeiting as a means of realizing great financial gain with relatively low risk.

Sincerely yours,  
James H Rittenburg  
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Vice President  
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