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

Re: Docket No. 2005N-0510
Comments on RFID and Other Electronic Pedigree Technologies

Dear Sir or Madam:

UPS Supply Chain Solutions ("UPS SCS") appreciates the opportunity to discuss potential requirements for the use of radio frequency identification ("RFID") or other electronic technology to satisfy prescription drug "pedigree" requirements, and otherwise enhance the integrity of the U.S. pharmaceutical supply chain. We also urge the Food and Drug Administration ("FDA") to fulfill the critical need for a single set of preemptive federal standards governing (i) drug product pedigrees and (ii) distribution facility licensing. The current state-by-state regulatory approach -- involving duplicative, sometimes inconsistent, and continually changing requirements across 50+ regulatory jurisdictions -- is simply unworkable, unnecessarily increases costs, and drains important resources from the common goal of providing U.S. citizens one of the safest, most effective pharmaceutical supplies in the world.

UPS SCS is part of the United Parcel Service family of companies. Our most widely-known affiliate is the UPS parcel delivery service. UPS SCS provides third party logistics services (*e.g.*, warehousing, distribution, and order fulfillment) to a wide variety of pharmaceutical manufacturer and distributor customers. This business requires us to comply with "wholesale drug distributor" requirements of the Prescription Drug Marketing Act ("PDMA") and similar state laws. We are thus directly affected by, and keenly aware of obligations arising under, pedigree and licensing laws across the United States.

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I. Summary of Comments

As discussed in detail below:

1) It is imperative that FDA make effective uniform, nationally-preemptive requirements for (i) drug product pedigrees, (ii) drug distributor licensing, and (iii) other supply chain obligations affecting U.S. commerce. UPS SCS, for example, receives and distributes prescription pharmaceuticals on a nationwide basis. Our experience has painstakingly and painfully revealed that the lack of clear federal standards results in a patchwork of inconsistent, duplicative, and continually shifting state law requirements. Although certainly well- and similarly-intentioned, these state laws impose substantial inefficiencies and impracticable requirements for even the most diligent, committed companies. The inevitable result of this unnecessary inefficiency is higher cost to all, including consumers of pharmaceuticals.

2) In the context of establishing nationally-preemptive pedigree standards, FDA should codify the substantive information and authentication requirements that are necessary for effective distribution control and public health protection. Thereafter, FDA must enable industry to reasonably develop and implement robust, yet feasible and flexible, systems and technologies that can satisfy FDA requirements.

3) At present, RFID remains a technology fragmented in application, and not adequately mature for adoption as a drug pedigree standard. In any event, FDA should not mandate the adoption of RFID or any other specific technology for purposes of drug pedigree information. The agency should instead establish performance standards that allow the adoption and evolution of effective and efficient technologies over time.

II. Nationally Uniform Standards Are Critical For Effective Public Health Protection And The Demands Of Interstate Commerce

UPS SCS currently operates nine prescription drug distribution centers in eight U.S. states. We receive prescription drug products from drug sponsors, contract manufacturers, and distributor customers located in approximately 42 states, and we fill

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orders and ship prescription drug products to all 50 states, the District of Columbia, and Puerto Rico. We are deeply committed to legal compliance. However, in the context of pharmaceutical distribution operations, we and other national companies currently face:

- Federal statutory and regulatory standards, including PDMA and FDA's implementing regulations (key elements of which have been in questionable enforcement status for at least six years);

- Numerous state laws imposing wholesale drug distributor licensing requirements, on both in-state and out-of-state distribution centers. These state laws impose repetitive, sometimes inconsistent standards for facility and personnel qualification. A prime example of the regulatory burden created is multiple, state-specific testing requirements applicable (via out-of-state licensure requirements) to personnel in distribution centers located throughout the United States.

- At least 10 states have adopted, and approximately 20 more are currently considering, state-level pedigree requirements. Some states allow paper records; others are working to mandate electronic recordkeeping with fast-approaching deadlines (e.g., California law would require the implementation of electronic pedigree by January 2007). Yet these states have not fully defined or coordinated their expectations in a manner to accomplish desired goals.

To date, UPS SCS has invested many hours of staff, consultant, and customer resources, and also demanded substantial quantities of regulators' time, to monitor, understand, provide input, and plan for compliance with federal and individual state law requirements. On the issue of electronic pedigree alone, we could spend millions of dollars, and again invest substantial human capital, to identify, procure, and implement an effective technological solution. Yet, today we have no assurance that a solution we adopt for California will be acceptable to Nevada, other states, FDA, or any other regulatory body that currently, or in the future, may require or authorize the use of electronic recordkeeping systems. Certainly, however, we have no reason to believe that the citizens of one jurisdiction warrant different quality or integrity standards for their pharmaceutical supplies.

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By all accounts, the current state law confusion has resulted from an absence of on-point federal regulation. FDA has both the authority and the opportunity to remedy this situation before it worsens. The agency may do this through effective implementation of nationally uniform, preemptive standards under PDMA.

We respectfully request that, rather than further delay the effectiveness of clear, uniform federal standards, FDA make regulation 21 C.F.R. § 203.50 firmly effective and preemptive in the U.S. as of December 1, 2006. The agency should then establish reasonable, phased-in compliance dates tied to realistic timelines for the adoption of electronic pedigree or other relevant recordkeeping requirements.

III. FDA Should Establish Uniform Pedigree Information Fields

Congress and FDA, in consultation with the public, are the appropriate entities to define the information content of a prescription drug pedigree. UPS SCS has found the following data elements most significant to enable pedigree-to-pedigree correspondence through processes of receiving, warehousing, put-away, picking, packing, shipping, quantity adjustments, damage assessment, and other handling:

- National Drug Code ("NDC") number
- Package size
- Number of containers
- Lot number
- Drug type
- Drug strength
- Serialization information (if present)
- Sales invoice number or other unique business transaction identifier (to allow ready cross-reference to other transaction documents)

Mass Serialization. UPS SCS supports the use of mass serialization for prescription drug product tracking. As with other pedigree information components, a single numbering convention should be required for consistency and system compatibility. From a technical perspective, UPS SCS recommends that the EPC Global standard be adopted. UPS SCS believes a product's NDC number should comprise part of any unique identifier, as it is already in widespread use for individual product identification.

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IV. FDA Should Adopt Performance Standards Instead Of Mandating A Specific Technology

Although FDA should properly participate in the development of information content of a pedigree, in order to implement technical parameters (*e.g.*, frequency and data storage/access) for electronic pedigree systems, UPS SCS requests that FDA partner with a recognized standard-setting body that can consider technological options and requirements in broad industry context (*e.g.*, considering tracking systems that are used for non-drug products). Based on their experience and historical effectiveness in such a role, the most appropriate entity for this task would be EPC Global.

Although it is appropriate to have a centralized, coordinated effort for technology standard-setting, UPS SCS does not believe it appropriate to require a centralized database for information to be managed. Instead, information should be managed by individual participants, in accordance with FDA requirements for data management and retention.

V. RFID Technology Is Not Adequately Developed For Current Purposes

UPS and UPS SCS have designed and implemented some of the most sophisticated computerized tracking systems in the world. We fully agree that advanced technology systems are better suited than paper pedigrees to track a prescription drug product's chain of custody from manufacturer to the end consumer.

Following careful scrutiny of RFID options, however, we have concluded that this technology is fragmented, immature, and very costly in its current form. Current obstacles to RFID implementation include:

- In our assessment, RFID technology is realistically 5 to 7 years away from being available at the SKU level.
- There are no consistent standards related to the type and format of data encoded in an RFID tag.
- Tags are sometimes larger than actual product, requiring additional packaging and associated product costs.

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- FDA itself has acknowledged that there is significant development work to be done to establish the compatibility of RFID technology and drug products (*e.g.*, study of thermal and non-thermal frequency effects on various types of drugs, biologics, and various types of packaging materials).

FDA must bear in mind that RFID tags are only one small part of the investment needed to elicit value from an RFID solution: interpretive and tracking technology is required throughout the supply chain in order to add any benefit.

VI. Electronic Pedigree Requirements Should Be Phased-In

FDA would best serve U.S. patients and regulated industry by promptly announcing that regulation 21 C.F.R. § 203.50 will become effective immediately upon expiration of the current stay on December 1, 2006, and will thereafter preempt any state law or regulation that imposes different or additional requirements. Among other benefits, this will clarify applicable requirements (*e.g.*, FDA rule will apply and will preempt any inconsistent California requirement slated to take effect in January 2007).

Compliance dates, however, should then be phased-in to accommodate reasonable adoption and validation of corresponding technologies. Based on UPS SCS' internal review (including interviews of a number of available vendors and discussions with our client base of manufacturers and distributors), we believe at least 2 years would be necessary for the widespread implementation of electronic pedigree systems.

VII. Privacy Issues

Privacy issues related to prescription drugs should be broadly addressed in the context of existing or new privacy laws. To the extent that privacy issues are directly linked to the use of an electronic technology such as RFID tags, EPC Global or another standard-setting body could establish standards for decommissioning (*e.g.*, obligation on dispensing pharmacists to deactivate or remove electronic tags prior to delivering prescription drug products to consumers).

A centralized set of requirements should better support privacy protection than a decentralized state-variable system.

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VII. Wholesale Drug Distributor Licensing Requirements

Finally, and of real importance as the agency works to enhance the pharmaceutical supply chain without unnecessarily raising prices or burdening consumers, UPS SCS asks FDA to pursue up-to-date, nationally-consistent standards for state licensure of wholesale drug distributors. As with pedigree requirements, the current system of state-by-state licensure (including out-of-state licensing requirements) is ineffective and unnecessarily costly due to inconsistencies and duplicative requirements.

We request that FDA revise 21 C.F.R. Part 205 to standardize licensure requirements, including:

- Providing for nationwide uniformity of standards and reciprocity of state licensure.

- Establishing a single, clear set of requirements for facility personnel (*e.g.*, the "designated representative" responsible for compliance issues). This should include: experience level, testing requirements, and options for one person to efficiently and consistently represent more than a single facility throughout the United States.

As is the case with pedigree requirements, if a qualification is important, it should pertain nationally. Otherwise, federal law should preempt any state laws that seek to impose different or additional requirements for drug distributor licensure.

* * *

Thank you for your consideration of these comments. UPS SCS fully supports FDA's and state regulators' efforts to enhance drug supply chain integrity. However, our practical experience leads us to believe only a federal standard will appropriately focus control activities and achieve a workable, effective solution.

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UPS SCS shall be pleased to provide more information if helpful to the agency.

Sincerely,

Fred M. Lamb

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