

July 14, 2006

*Via Hand Delivery and
Electronically to <http://www.fda.gov/dockets/ecomments>*

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

To Whom It May Concern:

RE: Prescription Drug Marketing Act Pedigree Requirements; Effective Date and Compliance Guide; Request for Comment
[Docket Numbers 1992N-0297 (Formerly 92N-0297), 1988N-0258 (Formerly 88N-0258, 2006D-0226)]

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

The National Association of Chain Drug Stores (NACDS) represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. NACDS members operate more than 35,000 pharmacies, employ 108,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of over \$700 billion. Other members include almost 1,000 suppliers of products and services to the chain drug industry. NACDS international membership has grown to include 90 members from 30 countries.

NACDS believes the drug distribution system in the United States is one of the safest and most secure in the world. We are proud of the systems and initiatives that our members have developed with other industry stakeholders to improve the integrity of the U.S. drug supply chain. There have been a number of initiatives over the past few years by community pharmacy, wholesale distributors and manufacturers, as well as state-level legislation that represent practical and immediate actions that have had immeasurable positive impact on the drug supply chain's integrity. We support these activities and continuing efforts to work with the supply chain stakeholders to enhance the security and safety of the drug distribution system. It is critical to the chain pharmacy industry that consumers have confidence in their pharmacies, pharmacists, and the prescription drugs they dispense. It is equally important that physicians and pharmacists have confidence in the integrity of the drugs they prescribe and dispense. It takes the concerted partnership of all parties in the prescription drug supply chain to maintain the U.S. drug distribution system among the safest and most secure in the world.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

Pursuant to the Notice in the *Federal Register* published June 14, 2006, NACDS is submitting written comments on the Compliance Policy Guide 160.900 entitled "Prescription Drug Marketing Act Pedigree Requirements under 21 CFR Part 203." We appreciate FDA's issuing the Compliance Policy Guide (CPG) to provide industry

stakeholders with the agency's enforcement priorities over the next year and the factors that the agency will use to focus its enforcement. Our comments ask that FDA provide enforcement guidance to address the drug distribution concerns of the chain pharmacy industry. The FDA's guidance will assist chain pharmacies and other stakeholders to maintain an efficient and cost-effective drug distribution supply chain to meet the needs of consumers and other stakeholders in the legitimate drug distribution system as the federal pedigree requirements are implemented.

We appreciate that FDA has not mandated the use of electronic pedigrees and the corresponding investments in technology to meet the requirements before standards are developed, tested, and adopted. The CPG acknowledges that while progress has been made in the implementation of electronic track and trace technology, the technology is not ready for wide adoption at this time. While technology has the potential to provide optimal long-term solutions to reduce the risk of counterfeit drugs entering the drug distribution supply system, the costs for adoption will be high and its successful adoption across the supply chain will require collaboration by all industry stakeholders and partners to achieve a cost-effective, feasible, scalable, reliable and operational system using a national standard. As a result, full adoption of electronic pedigrees will likely require considerable time and monetary costs to implement.

The Prescription Drug Marketing Act and Status of Authorized Distributors of Record

With FDA ending the stay of the pedigree regulations, and Sections 203.3(u) and 203.50 of 21 CFR Part 203 becoming effective on December 1, 2006, there are a number of questions and concerns that the chain pharmacy industry has regarding FDA's enforcement and implementation of the authorized distributor of record and pedigree requirements.

The exemption for authorized distributors of record may result in an unmanageable system where it is difficult to determine if suppliers have the requisite ADR status. We seek guidance from FDA on management, knowledge, and communication of authorized distributor of record (ADR) status. We remain concerned specifically with how the PDMA pedigree exemption for manufacturers and authorized distributors of record (ADR) will function and operate for chain pharmacy warehouses and pharmacies. We are concerned that managing wholesale drug distributor ADR status may add barriers and complexities to chain pharmacy drug purchasing and substantial costs for the chain pharmacy industry and ultimately their patients.

The ADR concept is difficult to manage from the perspective of the pharmacy and chain pharmacy warehouse. For example, a manufacturer may grant ADR status to a wholesale distributor for certain products in their line, as opposed to the whole line. This is

problematic because pharmacies and chain pharmacy warehouses have to constantly manage that ADR status not only by wholesale distributors, but also by individual products, requiring the ADR status to be managed for thousands of individual products. Finally, the ADR status of a wholesale distributor may change at any time without the knowledge of the pharmacy or chain pharmacy warehouse. A manufacturer may choose to revoke ADR status at any point in time and that communication may or may not be transmitted down to the pharmacy or chain pharmacy warehouse. Pharmacies and chain pharmacy warehouses have no way to know if a pedigree should be required from the wholesale distributor because they would not know the wholesale distributor's ADR status.

The PDMA requires each person engaged in the wholesale distribution of a prescription drug, except for the manufacturer of the drug and the ADR for that drug, to provide a pedigree showing the prior distributions of the drug. The PDMA defines authorized distributors of record as a "distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products." (Emphasis added.) While "ongoing relationship" is not defined in the PDMA, it is defined in regulation at 21 CFR § 203.3(u) which provides as follows:

"(u) Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute." (Emphasis added.)

As a result, the regulation leads to the ADR status being subject to an unmanageable number of variables. The ADR status may vary by time, number of shipments, some or all of a manufacturer's product line, and the terms of the agreements between the wholesale distributor and drug manufacturers, to which pharmacies do not have access. We are concerned that this highly variable system will create a complex and uncontrollable system for pharmacies in determining ADR status of wholesalers and the individual products. For example, drug products could have differing pedigree requirements depending on whether they are purchased one day or the next, and which shipment they came from. While the wholesale distributor would possess the knowledge of ADR status through its agreements with drug manufacturers, and know the applicability of the various time, shipment, and other factors, pharmacies would not have access to this information.

Further, as the pedigree requirement rests on whether a wholesale distributor is an authorized or unauthorized distributor, becoming an ADR through an agreement with a

drug manufacturer provides significant advantages. Since pharmacies are generally not granted ADR status by manufacturers, pharmacies and their distribution centers will be placed in disadvantageous positions in the drug distribution chain. This issue becomes paramount in cases of acquisitions where the purchasing entity may be acquiring the existing inventory as well as the business of the seller. We ask that FDA provide enforcement guidance on pedigree requirements for these types of situations, considering that a selling entity may have received their products from an ADR and consequently may not have detailed pedigrees available for each item in inventory at the time of sale.

We also ask FDA for enforcement guidance on the following questions and concerns:

- Should ADR status have industry-wide set requirements and time periods to provide a degree of certainty?
- Should there be industry standards and restrictions on changes to ADR status?
- Is there a preferable means to manage and provide ADR status to the industry stakeholders so that it is readily available and manageable? Should there be one central site for ADR status managed by the FDA
- Is there an option for FDA to redefine the "ongoing relationship" standard so that it is more manageable?
- Should anyone who purchases directly from manufacturers satisfy the ongoing relationship requirement?
- Should wholesale distributors be required to provide notice to any pharmacy or chain pharmacy warehouse if the distributor is not an ADR for any products it distributes to a pharmacy or chain pharmacy warehouse? This would provide a more workable solution for determining ADR status.

The Prescription Drug Marketing Act and Responsibility for Providing Pedigrees

We ask FDA for guidance clarifying that the PDMA places the responsibility on the wholesale distributor to provide a pedigree to pharmacies and chain pharmacy warehouses if one is required, and that pharmacies do not have responsibility to monitor a wholesale distributor's compliance with the PDMA pedigree requirements.

We request guidance from FDA that pharmacies would not be required to provide pedigrees for prescription drugs that pharmacies return to wholesale distributors or manufacturers, or to third party returns processors. These types of transactions routinely occur for prescriptions drugs that are being returned due to mistakes in ordering or shipment, expired drugs, because of a manufacturer recall or other standard returns processes. These drugs would be received by pharmacies and chain pharmacy warehouses without pedigrees. It would be unmanageable for pharmacies or chain pharmacy warehouses to have to create pedigrees to engage in these types of transactions. We ask that the agency recognize such transactions as returns that are allowed under 21

CFR Part 203. In this regard, we point out that the regulation currently recognizes returns by hospitals.

We also ask for guidance from FDA that pedigrees are not required for prescription drugs that are received by pharmacies or chain pharmacy warehouses via drop shipments. Drop shipments to chain pharmacy warehouses or pharmacies should be considered direct shipments from manufacturers, even though the financial ownership of the product flows through a traditional wholesaler before the chain pharmacy warehouse or pharmacy. In other words, we ask that the pedigree follow the possession of the prescription drug, not the financial ownership.

We further ask FDA for guidance on the pedigree requirement status for prescription drugs that are in the supply chain as of December 1, 2006, such as products in the possession of wholesale distributors, pharmacies, and chain pharmacy warehouses. The "grandfathering" of these products would eliminate our concern as to how such products could be pedigreed and otherwise handled in the drug distribution supply chain. With the short time period between now and December 1, 2006, we have concerns as to how this issue will be addressed so as not to add unmanageable costs and uncertainties into the drug distribution system. We believe that having to obtain pedigrees for all drug products in the supply chain as of December 1, 2006 and determining which of these products came from ADRs or unauthorized distributors would present an unworkable and daunting task for pharmacies and other stakeholders in the drug distribution supply chain.

Conclusion

We very much appreciate the opportunity to provide our comments to FDA on the Compliance Policy Guide and to submit our concerns and questions for the agency's consideration. We look forward to continuing our work with FDA and our drug supply chain partners in assuring the safety and integrity of our drug distribution system.

Any questions about these comments should be directed to Diane Darvey at 703-837-4182 or Kevin Nicholson at 703-837-4183. Thank you.

Sincerely,



Mary Ann Wagner, R.Ph.
Senior Vice President
Policy and Pharmacy Regulatory Affairs
cc. Ilisa Bernstein