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December 14, 2006

Andrew C. Von Eschenback, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Von Eschenback:

I am writing today regarding the Prescription Drug Marketing Act Pedigree Requirements, Effective Date and Compliance Guide [Docket Nos. 1992N-0297, 1998N-0258].

I feel compelled, not only as a member of the distribution supply chain, but also as a member of the public to express my concerns with the Prescription Drug Marketing Act ("PDMA") pedigree requirements and to ask the FDA to work with our industry and the Congress to enact amendments to the PDMA to provide greater protection to the public and to assure continuity to the drug supply chain. PDMA was enacted specifically to avoid risks that counterfeit, adulterated, misbranded, sub potent or expired drugs weren't being sold to the American public. Especially given the preliminary injunction adopted by the New York federal district court, it is critical that we all work together to achieve these objectives.

As was noted in a letter to the FDA on October 20, 2006, our industry is committed to assuring the safety of our products in the marketplace. We appreciate that Compliance Policy Guide 160.900 ("CPG") and accompanying Questions and Answer guidance issued by the FDA recognized that ADR's should provide pedigree information to downstream distributors, noting that "to further advance the shared goals of protecting the public health, FDA encourages all parties in the prescription drug supply chain to cooperate fully by providing pedigrees and information to trading partners for each sale, transfer, or trade of prescription drugs."

However, because the FDA is only "encouraging" ADR's to provide pedigrees, rather than "requiring" them to do so, ADR's are either refusing to provide pedigrees to non-ADR distributors or offering to provide pedigrees on uneconomic terms. The FDA's guidance indicates that it recognizes the importance of allowing non-ADR's an appropriate method to distribute products and provide the required pedigree; however, we also recognize that the FDA lacks the legal authority to require ADR's to provide pedigrees to non-ADR distributors.

Without doubt, there is an enhanced risk to public safety when ADR's are exempted from the pedigree requirements. FDA's own criminal enfor4cement agents can attest to this. In a case developed by FDA agents, for example, an employee of H. D. Smith, and ADR, pleaded guilty in 2004 to involvement in a scheme relating to counterfeit Lipitor. And while denying complicity in the scheme, H. D. Smith agreed to pay more than $2 million in civil forfeiture to the federal government.

In addition to these public safety concerns, the anticompetitive effects stemming from the pedigree requirements (as set forth by the final regulations set to take effect on December 1, 2006) will hinder the ability of many small doctors' offices, rural pharmacies, clinics, and hospitals to acquire needed medications. Because Authorized Distributors of Record ("ADR's") are not required to provide pedigree to non-ADR distributors, thousands of non-ADR distributors who supply smaller and rural operations may be forced under the law to cease conducting business, leaving only a few ADR's left to supply the thousands of customers we currently supply.

Our industry has begun working with members of Congress to adopt a change to the PDMA that would put legal force behind the FDA's "encouragement" to ADR's to provide pedigrees. After the adoption of the preliminary injunction, it is even more critical that we work together to revise the PDMA to provide greater protection to the public and to assure continuity to the drug supply chain.

Our industry as you to formally indicate to Congress that you support changes in the PDMA that provide FDA with immediate authority to safeguard the public by requiring all wholesale distributors to provide drug pedigrees on all sales to other suppliers. We, and thousands of other important businesses in the drug supply network, look forward to working with you toward our common goal.

Sincerely,

David B Harms

David B. Harms
Director of Purchasing