

NOTICE TO AVDA MEMBERS REGARDING PDMA PEDIGREE REQUIREMENTS  
EFFEFFECTIVE DATE 12/1/06

The Prescription Drug Marketing Act of 1987 (PDMA) established requirements related to the wholesale distribution of prescription drugs. A primary purpose of the PDMA was to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the U.S. drug supply chain.

*The Pedigree Requirements*

Section 503(e)(1)(A) of the Act establishes the pedigree requirement for prescription drugs. A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them. Under the pedigree requirement, each person who is engaged in the wholesale distribution of a prescription drug in interstate commerce, who is not the manufacturer or an authorized distributor of record for that drug, must provide to the person who receives the drug a pedigree for that drug. The PDMA states that an authorized distributor of record is a wholesaler that has an "ongoing relationship" with a manufacturer to distribute that manufacturer's drug. However, the PDMA does not define "ongoing relationship."

*The 1999 Final Rule*

In 1999, Food and Drug Administration (FDA) published final regulations implementing the PDMA (21 CFR Part 203). The regulations were to take effect in December 2000. After publication of the 1999 final rule, the agency received comments objecting to the provisions in §§ 203.3(u) and 203.50. Section 203.3(u) defines "ongoing relationship" to include a written agreement between manufacturer and wholesaler. Section 203.50 specifies the fields of information that must be included in the drug pedigree and states that the information in the pedigree should be traceable back to the first sale by the manufacturer. Based on concerns raised by various stakeholders, the agency delayed the effective date of §§ 203.3(u) and 203.50 several times.

*The Electronic Pedigree*

In February 2004, FDA delayed the effective date of §§ 203.3(u) and 203.50 until December 1, 2006, in part because it was informed by stakeholders in the U.S. drug supply chain that the industry would voluntarily implement electronic track and trace technology by 2007. If widely adopted, this technology could create a de facto electronic pedigree that would document the sale of a drug product from the place of manufacture through the U.S. drug supply chain to the final dispenser. Although progress has been made, it appears that the use of electronic pedigree will not be widely adopted by 2007.

*Effective Date of PDMA Regulations - December 1, 2006*

**As a result, in June 2006, FDA announced that it did not intend to delay the effective date of §§ 203.3(u) and 203.50 beyond December 1, 2006.** As such, the provisions defining an "ongoing relationship" and setting forth certain pedigree requirements are in effect thereafter. This means that all wholesale distributors of human

prescription drugs must comply with the federal requirements by December 1, 2006. No exception is made for veterinary wholesale distributors at this time.

The FDA has also announced that, during the next year, its enforcement of the pedigree regulations will focus on products most susceptible to counterfeiting and diversion. The FDA has issued a Draft Compliance Policy Guide describing this enforcement approach. By providing guidance on the types of drugs that are currently of greatest concern to FDA, the agency intends to give wholesale distributors a better idea on where and how to focus their initial energies to come into complete compliance with the regulations (21 CFR Part 203) for all the prescription drugs they distribute. The draft guidance clarifies how FDA intends to prioritize its pedigree-related enforcement resources in 2007. The FDA may, under appropriate circumstances initiate regulatory action, including criminal prosecution, for pedigree violations that do not meet the factors listed in the guidance.

AVDA submitted comments on the Draft Compliance Policy Guide in early September, asking the FDA to make an exception for veterinary wholesalers similar to the legislation enacted in Florida. AVDA is continuing to communicate with the FDA regarding our concerns and will monitor the final comments on the Compliance Policy Guide. The final guidance will not be issued until December 2006. Nevertheless, AVDA members should continue their preparations in order to be in compliance on December 1, 2006.

In an effort to keep members informed about the impact of the federal pedigree law and other states' pedigree laws, AVDA is recommending that members attend a one-day educational conference on *Federal and State Pedigree Initiatives: Preparing for Implementation* being sponsored by the Healthcare Distribution Management Association (HDMA) on October 23, 2006 in McLean, Virginia. *Additional information including hotel and conference registration information can be found on the HDMA Web site at <http://www.healthcaredistribution.org/education/seminar-2006-10-23-info.asp>*

The fee for non-HDMA members is \$995 and AVDA members are welcome to attend.