



November 2006

Dear Doctor,

Effective December 1, 2006, the FDA will implement federal pedigree requirements for human prescription drugs. **Federal pedigree requirements do not concern veterinary drugs or non-prescription products.** According to the FDA, federal pedigree requirements for human drugs were established as part of the Prescription Drug Marketing Act (PDMA), which “was enacted to ensure that prescription drug products purchased by consumers would be safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs were being sold to the American public.”

What is a human drug pedigree? The FDA explains...

“...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.”

What does this mean for your practice?

Human Rx drugs will continue to be available from MWI Veterinary Supply (as permitted in the FDA’s Compliance Policy Guide Sec. 608.100 Human-Labeled Drugs Distributed and Used in Animal Medicine (CPG 7125.35)). As well, MWI’s service on human Rx drugs will be determined by whether MWI is an “Authorized Distributor of Record” (i.e. ADR) for each human Rx drug as indicated in the table below. A written agreement between the drug manufacturer and a wholesale drug distributor is required to establish a wholesale drug distributor as an Authorized Distributor of Record.

	Authorized Distributor of Record (ADR) Status	
	MWI is an ADR for a given human Rx drug	MWI is not an ADR for a given human Rx drug
Products	Currently, MWI is an ADR for most of the popular human Rx drugs used in veterinary practices.	MWI will continue to offer these products to veterinarians while we pursue ADR status. As a non-ADR wholesaler for these drugs, we will be required to provide pedigree.
Note on MWI invoice	"MWI is an Authorized Distributor of Record for this drug."	"Pedigree information for this drug is available at www.mwivet.com ".
Pedigree	Wholesale drug distributors with ADR status for a given drug are not required to provide pedigree.	If you need to confirm or view pedigree information, simply go to www.mwivet.com and provide your account and invoice numbers. MWI's regulatory affairs department can also help you access pedigree information.
Availability	MWI will offer these human Rx drugs from all or most local warehouses with normal delivery.	MWI will offer these products from a single, central US warehouse via UPS Ground service and may therefore require a few extra days to arrive. Customers may also choose to pay for expedited service. Because of increased transit times, we encourage you to review your inventory levels on human Rx products.
Returns	Human Rx products are non-returnable	Human Rx products are non-returnable.

Selected FAQ's from the FDA's Nov 2006 Guidance for Industry: Prescription Drug Marketing Act (PDMA) Requirements: (please refer to the complete guidance document here: http://www.fda.gov/cder/regulatory/PDMA/PDMA_qa.pdf)

Do pharmacies have to verify the accuracy and authenticity of the pedigree? If so, how should they do this?

No. Pharmacies do not have this express responsibility under the PDMA, but they are encouraged to perform due diligence in verifying the accuracy of the information and integrity of the source of the drug product.

What are the recordkeeping requirements for pedigree recipients?

*Pursuant to 21 CFR § 203.50(b), the pedigree is subject to the record retention requirements in 21 CFR § 203.60, and must be retained by all wholesale distributors involved in the distribution of the drug product, whether ADR or non-ADR, for 3 years. **If the pharmacy receiving the pedigree will not itself engage in further distribution of the product to persons other than a consumer or patient, then the pharmacy is not required to maintain that pedigree under 21 CFR § 203.60.*** However, consistent with the spirit of the PDMA, FDA encourages pharmacies and other end users to retain the pedigree for 3 years. As a result, if there is any question about the source or history of the product, it can be traced back through the drug supply chain.*

Does PDMA apply to veterinary prescription drugs?

No. PDMA applies only to prescription drugs intended for use by man. However, FDA is aware that many human prescription drugs are sold to veterinarians. Given that the human drugs are subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act, the pedigree requirements apply to them under section 503(e). Accordingly, wholesale distributors who are not ADRs must provide a pedigree prior to wholesale distribution of human prescription drugs to veterinarians.

If there are two products on a shelf in a pharmacy, with the same lot number, but one was purchased from an ADR and the other was not, how would the pharmacy know which product came from the ADR and which product came from the non-ADR?

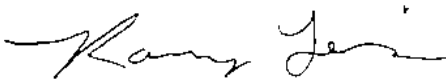
Inventory control is a business process. FDA expects firms to be able to identify and differentiate drug products that have been obtained from different sources and maintain appropriate records in compliance with PDMA.

* Emphasis added

For more information: <http://www.fda.gov/cder/regulatory/PDMA/default.htm#relevantguidances>

MWI appreciates your business and looks forward to continuing as your complete veterinary supplier.

Sincerely,



Randy Lewis
Manager of Compliance and Regulatory Affairs
MWI Veterinary Supply