



December 14, 2006

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

RE: Prescription Drug Marketing Act Pedigree Requirements

Dear Commissioner von Eschenbach:

I write on behalf of the American Veterinary Distributors Association ("AVDA") with respect to the provisions of the Prescription Drug Marketing Act ("PDMA") and the regulations issued by FDA pursuant to its authority under the Act.

AVDA, a not-for-profit corporation, was established in 1976 as the national trade organization for businesses engaged in the distribution of animal health products. Our members distribute animal health supplies to some 55,000 veterinarians practicing in approximately 25,000 animal health clinics throughout the United States. The total annual sales of these supplies is estimated at \$3 billion. Those products include pharmaceuticals, biologicals, white goods, instruments and equipment, and pet foods. In addition, some AVDA member companies also serve the OTC market, made up of farm and feedlot operations, poultry producers, farm stores, etc.

In view of the issuance of the injunction by the U.S. District Court for the Eastern District of New York, AVDA requests the opportunity to discuss and jointly seek Congressional approval for a veterinary wholesaler's exemption from the pedigree requirements found in 21 CFR part 203. We believe this exemption can be granted to this unique class of drug wholesaler, under the terms outlined below, with no resulting negative consequence to the human drug distribution system. We further believe that such an exemption will allow FDA to better focus its enforcement efforts on those drugs sold for human consumption.

AVDA members are distributors who distribute exclusively to animal health entities. A small percentage of these products are human prescription drugs which do not have a corresponding animal health product. Thus, these drugs are not used on humans and are not sold to entities who sell them to humans. The 100 or so human drugs sold to veterinarians are not the types of drugs that are either counterfeited, adulterated or diverted. These drugs include eye ointment, amoxicillin and saline solution.

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Human drugs distributed by veterinary wholesalers do not meet the criteria spelled out in the Compliance Policy Guide. These drugs are not:

- High value drugs in the U.S Market;
- Not found on any list of "prior indicators" of drugs counterfeited or diverted from the stream of commerce;
- New drugs with a reasonable probability of being counterfeited, diverted or adulterated.

AVDA concurs with the risk-based approach undertaken by the FDA and would argue that creating an exemption for veterinary wholesalers will not thwart the FDA's efforts to ensure safe drugs for human patients.

Because AVDA wholesalers do not distribute to those licensed to dispense to humans, we believe that an exception to the Act should be created to exempt veterinary prescription drug wholesalers from the need to pass pedigree as contemplated in the PDMA.

This past spring, the Florida Legislature, based on the argument cited above, recognized the distinction between human drug wholesalers and veterinary drug wholesalers and the need to regulate veterinary wholesalers differently. The Legislature created the Limited Prescription Drug Veterinary Wholesaler License. We would ask that an exemption be enacted in the PDMA modeled on this newly enacted legislation found in Chapter 499, Part I, Florida Statutes.

In order to qualify for this new license, the veterinary wholesaler must meet the following criteria:

- Operate a wholesale business whose clientele are only veterinarians or others in the animal health industry and only offer prescription and veterinary legend drugs to veterinarians or others in the animal health industry;
- Have no more than 30 percent of prescription drug sales consist of prescription drugs approved for humans;
- Not wholesale prescription drugs to any person who is authorized to sell, distribute, purchase, trade, or use these drugs for humans.

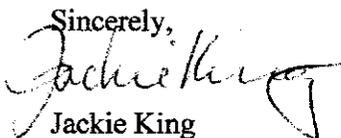
The new permit also mandates that the permit holder must not further distribute any human drug returned by a veterinarian to the wholesaler. Thus, the Florida law creates a closed loop distribution system which ensures that human drugs sold to veterinarians or others in the animal health industry will not be sold to entities who could sell them for

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human use. AVDA believes the PDMA should incorporate the same criteria and resale criteria found in the Florida law.

AVDA very much appreciates this opportunity to provide our comments to the FDA and to submit our concerns for review. Any additional questions or further clarification can be provided by contacting me at 443-640-1040 x105 or by email at jackie@ksgroup.org.

Sincerely,



Jackie King
AVDA, Executive Director

Cc: Ilissa Bernstein, Office of the Commissioner
Jane A. Axelrod, Director, Office of Regulatory Policy