



September 1, 2006

Docket Officer  
Division of Dockets Management  
HFA – 305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857

**Re: Prescription Drug Marketing Act Pedigree Requirements; Effective Date and Compliance Policy Guide; Docket Nos. 1992N-0297, 1988N-0258 and 2006D-0226 ( 71 Fed. Reg. 34249, June 14, 2006)**

Dear Docket Officer:

The American Veterinary Distributors Association (AVDA) appreciates this opportunity to provide public comments on the Draft Compliance Policy Guide 160.900, Prescription Drug Marketing Act (PDMA) – Pedigree Requirements under 21 CFR part 203 (draft CPG), described in the June 14, 2006 Federal Register.

AVDA was established in 1976 as the national trade organization for businesses engaged in the distribution of animal health products. AVDA is comprised of the nation's leading animal health veterinary wholesaler-distributors and manufacturers. AVDA has 22 distributor member companies and 47 manufacturer member companies.

AVDA is seeking an 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.

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 human drugs are never used on 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.

Human drugs distributed by veterinary wholesalers do not meet the criteria spelled out in the Draft 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.

Page Two  
AVDA Letter to FDA  
September 1, 2006

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

Because our wholesalers do not distribute to those licensed to dispense to humans, AVDA believes that an exception to the Compliance Policy Guide should be created to exempt veterinary prescription drug wholesalers from the guidance and 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 FDA to model the exemption 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:

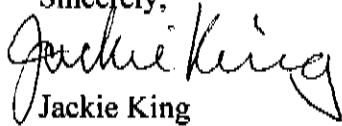
- Must be in the business of wholesaling prescription and veterinary legend drugs to veterinarians on a full-time basis;
- Must have no more than 30 percent of prescription drug sales may be prescription drugs approved for humans;
- Must not be permitted, licensed, or otherwise authorized in any state to wholesale prescription drugs to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or 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. AVDA believes the FDA should incorporate the same criteria and resale criteria found in the Florida law.

Page Three  
AVDA Letter to FDA  
September 1, 2006

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](mailto:jackie@ksgroup.org).

Sincerely,

A handwritten signature in cursive script that reads "Jackie King". The signature is written in black ink and is positioned above the printed name.

Jackie King  
AVDA, Executive Director

Enclosures

Cc: Poppy Kendall,  
Special Assistant to the Assistant Commissioner for Policy

**ATTACHMENT**

**AVDA MEMBER LIST**

AVDA is committed to the success of its members by providing information, education, advocacy, and business tools to strengthen the vital link between suppliers, distributors and veterinarians in the animal health industry.

The primary market for veterinary supplies consists of some 55,000 veterinarians practicing in approximately 25,000 animal health clinics throughout the United States. The total annual sales of these supplies are estimated at \$3 billion. Those products include pharmaceuticals, biologics, white goods, instruments and equipment, and pet foods.

<b>Distributor Members</b>
Bradley Caldwell, Inc.
Butler Animal Health Supply, LLC
Columbus Serum Company
Henry Schein Animal Health
HSB Veterinary Supply
IVESCO
Merritt Veterinary Supplies, Inc.
Micro Beef Technologies, Ltd
Midwest Veterinary Supply
Miller Veterinary Supply Co., Inc.
MWI Veterinary Supply
Nelson Laboratories
Northwest Vet Supply, Inc.
PCI Animal Health/Prescription Containers, Inc.
Penn Veterinary Supply, Inc.
Red-X Medical
RS Veterinary Supply
TW Medical Veterinary Supply
Vet Brands International Inc.
Vet Pharm Inc.
Walco International
Webster Veterinary Supply

<b>Manufacturing Members</b>
3M - Animal Health Division
ABAXIS
Abbott Laboratories
Addison Biological Laboratory, Inc.
AgriLabs
Bayer
Boehringer Ingelheim Vetmedica, Inc.
Butler Sales Associates, Inc.
Colorado Serum Co.
Dechra Veterinary Products
Delmarva 2000 Ltd.

<b>Manufacturer Members continued</b>
Dermapet, Inc.
Elanco Animal Health
Focus Technology Group
Fort Dodge Animal Health
Heska Corporation
IDEXX Laboratories, Inc.
Intervet, Inc.
IVX Animal Health, Inc.
Johnson & Johnson Consumer Products
Jorgensen Laboratories, Inc.
MAI/Genesis
Merial
Miltex, Inc.
Multivet International Inc.
Neogen Corporation
Nestle Purina PetCare
Norbrook, Inc.
Novartis Animal Health U.S., Inc.
Pfizer Animal Health
Phoenix Pharmaceutical, Inc.
PractiVet
PRN Pharmacal, Inc.
Royal Canin USA, Inc.
Schering-Plough Animal Health
Summit Hill Laboratories
Synbiotics Corporation
Thornell Corp.
Tyco Healthcare - Kendall
Vedco, Inc.
Veterinary Products Laboratories (VPL)
Vet-Kem
Vetoquinol USA, Inc.
Virbac Animal Health
VSSI, Inc.
Welch Allyn, Inc.