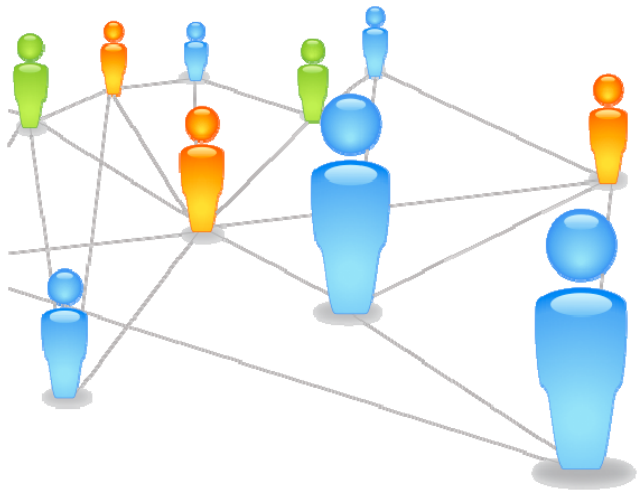


Regulatory Review of the Issues Impacting the Animal Health Industry

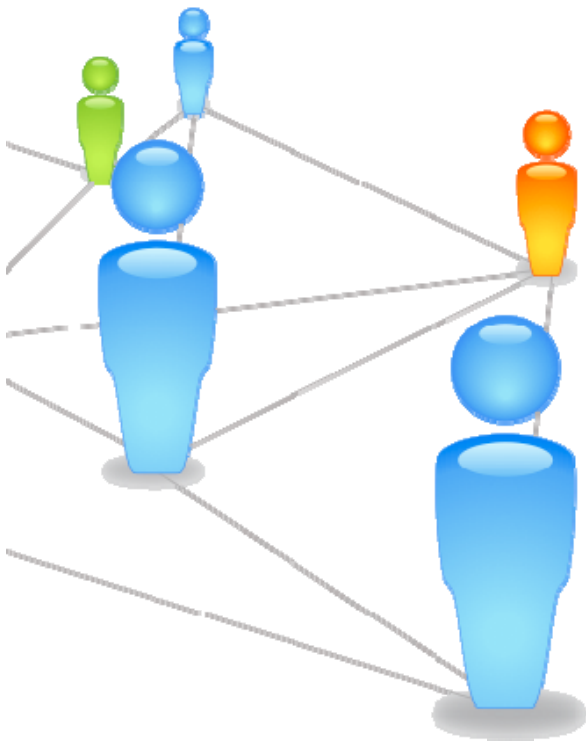


By Ron Buzzeo, Maria Galdos,
Machelle Gray

October 6, 2009

Agenda

- **DEA and FDA Overview**
- **State Licensing Issues**
- **State Disclosure Reporting**
- **Building a Successful Compliance Program**





Section Title

DEA and PDMA REQUIREMENTS

Ronald W. Buzzeo, R.Ph, Chief Compliance Officer



Agenda



- **Developments in Regulatory Controls**
- **Drug Enforcement Administration**
 - List I and II Chemicals
 - Controlled Substances
- **Food and Drug Administration**
 - Wholesale Distribution
 - Physician Samples
- **State Requirements**



Section Title

DEVELOPMENTS IN REGULATORY CONTROLS



Compliance Trends

DEA, US Attorney and State scrutiny is growing in all areas, particularly in Manufacturing, Distribution, R & D, and Pharmacy

- Companies not meeting regulatory requirements for controlled substances, prescription drugs and List I chemicals
- Inconsistent implementation of regulatory (DEA, PDMA and State) requirements
- Lack of understanding of regulatory requirements
- Increase inspections by DEA, States and FDA
- State oversight in licensing, pedigree, gift reporting, counterfeit, outdates and damaged



- Multi-Million dollar fines and penalties being levied
 - 2008 and 2009 – \$58,000,000 in fines and numerous registration actions
 - Several large pending cases
 - Pharmacy
 - Manufacturer
 - Distributor

The Changing Landscape



Drug Enforcement Administration

→ Developments in regulatory controls

- List I Chemicals
- Controlled Substances
 - Suspicious Order Monitoring (SOM)
 - Sept / 06 Letter
 - Feb / 07 Letter
 - Dec / 08 Letter

→ DEA Actions

- Administrative
- Civil
- Criminal



Section Title

PDMA REQUIREMENTS

Prescription Drug Marketing Act



- **21 CFR 203**
 - Distribution of prescription drug samples.
- **21 CFR 205**
 - Wholesale distribution of prescription products

PDMA – Samples – 21 CFR 203



- Mail or Common Carrier
- Sales Reps
- Requirements
 - License validation
 - Sample Request Forms (SRF)
 - Acknowledgement of Delivery (AOD)
 - Storage and handling
 - Standard Operating Procedures (SOPs)
 - Third Party Activities
 - Fulfillment
 - Co-marketing

PDMA Samples



- Requirements (continued)
 - Investigation and Notification
 - 5 day
 - 30 day
 - Tracking
 - Lot number
 - Labeling
 - Not for sale
 - Professional Courtesy package
 - Sample

PDMA – Wholesale Distribution – 21 CFR 205



- Requirements for State licenses
- Requirements for penalties
- Requirements for personnel
- Storage and handling
 - Facilities
 - Security
 - Storage
 - Examination of drugs
 - Returned, damaged, outdates
- Record keeping
- Standard Operating Procedures (SOPs)



Section Title

DEA REQUIREMENTS

Controlled Substances Requirements



→ 21 CFR 1300 to the End

- To prevent the diversion of controlled substances, establish a control system and ensure that a sufficient amount of controlled substances are made available for legitimate medical requirements
 - Controlled Substances
 - Import, export, manufacturing, distribution, dispensing, instruction, research, chemical analysis, narcotic treatment programs
 - List I and II Chemicals
 - Distribution, manufacturing for distribution, import and export

Controlled Substances Requirements



- **Registration**
 - Controlled Substances
 - List I Chemicals
- **Schedules – I, II, III, IV and V**
- **Registration verification**
- **Labeling and packaging**
- **Quotas**
- **Records**
 - Receiving and distribution records
- **Reports**
 - ARCOS – Schedule I, II and III opioids
 - Thefts and significant losses
 - DEA 106
 - Suspicious order monitoring (SOM)
 - Orders of unusual size
 - Orders deviating substantially from a normal pattern
 - Orders of unusual frequency

Controlled Substances Requirements



- Reports (continued)
 - Disposal
 - DEA 41
- Security
 - Schedule I and II
 - Safe, Vault
 - Alarms
 - Personnel
 - Schedule III, IV and V
 - Safe, Vault
 - Alarms
 - Personnel
 - Manufacturing
 - Research
 - Analytical Lab

Controlled Substances Requirements



→ Import / Export

- Schedule I, II and opioids – Permit
- Schedule III, IV and V (non-opioids) – Declaration
- List I and II Chemicals – Declaration



Section Title

STATE LICENSING ISSUES

Machelle Gray, Compliance Director



State Requirements



Guidance from the PDMA

Scope – 21 CFR 205.1

“ . . . Any person, partnership or corporation or business firm engaging in the wholesale distribution of human prescription drugs in interstate commerce.”

State Requirements



→ Provides states the authority to regulate

Purpose – 21 CFR 205.2

“ The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms and conditions for the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs.”



State Requirements

→ Defining the Business – Federal Guidance

■ Definitions – 21 CFR 205.3

(d) Manufacturers

“anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.”

(e) Wholesale distribution

“distribution of prescription drugs to persons other than a consumer or patient, bus does not include:

(1) Intercompany sales

(7) Distribution of drug samples by manufacturer’s. representatives or distributor’s representatives

(g) Wholesale Distributor

“anyone engaged in wholesale distribution of prescription drugs”



What Qualifiers Impact Licensing?

•Activities

- Wholesale Distribution
- Manufacturing
- Dispensing
- Retail Sales

→ Products

- Prescription Drugs
 - Human
 - Vet Labeled
- Controlled Substances
- Medical Devices
- Herbal/Dietary Supplements
- Sampling Permits
- Sales Representatives
 - Disclosure
 - Permits
 - License

→ Customers

- Veterinarians
- Hospitals
- Clinics
- Wholesalers
- Retail
- Patient

State Requirements



→ Types of Registrations

- Manufacturers
- Wholesale Distributors
- Manufacturer's Sampling Permits
- Sales Reps
- Nonresident or Mail Order Pharmacy
- Veterinary Retail Permit



State Registration Requirements

→ Who is affected by the registration requirements?

- Manufacturers
 - NDA and ANDA holders
 - Sponsor Manufacturers
 - Contract Manufacturers
 - Sampling
- Sales Representatives
- Wholesale Distributors
- Brokers
- Third Party Distributors
- Fulfillment Houses
- Contract Sales Organizations
- Vet Only Labeled Distributors
- Dispensers

*** Due Diligence ***

A wholesale distributor of prescription human and veterinary products distributing trade in all 50 states, including DC, would require approximately 51 registrations.

Today's Registration Process

Navigating the Changing Landscape



→ Applications/Renewals

- Detailed Company Information
- Specific personal information for managers/officers/directors
 - Fingerprints/Photos
 - Social Security Numbers
 - Background Checks
 -even family information
- Surety Bonds
- Qualified Certified Designated Representative
 - Testing and Registration
- Detailed Instate Inspection
 - VAWD (Verified Accreditation for Wholesale Distributors)
 - Independent Inspection



What's Next?!!!!!!

- **Continued changes to state requirements for monitoring drug distribution in interstate commerce**
- **Changes in state requirements for drug categories**
 - Veterinary-labeled products
 - OTC
 - Listed Chemicals
 - Dispensing
- **More stringent licensing requirements**
 - Tighter restrictions for licensing
 - More states requiring VAWD certification
 - Increase in licensing fees



Section Title

ENACTED/PENDING ANIMAL HEALTH STATE MARKETING DISCLOSURE LAWS

Maria Galdos, Manager





Agenda

- Overview of Laws
- Pending Legislation

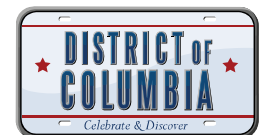


District of Columbia



→ Disclosure

- Report due July 1.
- All expenses associated with advertising, marketing, and direct promotion of prescription drugs.
- With regards to health care professionals, expenses associated with:
 - educational or informational programs, materials, and seminars, and remuneration for same;
 - food, entertainment, gifts valued at more than \$25;
 - trips and travel;
 - product samples, except for samples that will be distributed free of charge to patients; and
 - The aggregate cost of all employees or contractors who directly or indirectly engage in the advertising or promotional activities.



Maine



→ Disclosure

- Report due July 1.
- All expenses associated with advertising, marketing and direct promotion of prescription drugs.
- With regards to health care professionals, expenses associated with:
 - educational or informational programs;
 - food, entertainment, gifts valued at more than \$25 per day and anything provided to health care professional for less than fair market value;
 - trips and travel;
 - Product samples; and
 - Aggregate cost of all employees or contractors of the manufacturer who engage in the advertising or promotional activities to health care professionals in Maine.



Minnesota



→ Disclosure

- Report due May 1.
- payments that exceed \$100 and are given to a particular practitioner -
 - a payment to the sponsor of a medical conference, professional meeting, or other educational program
 - reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference
 - compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project.

→ Prohibition

- items with a total combined retail value, in any calendar year, of over \$50





Other Disclosure States

→ **California**



→ **Massachusetts**



→ **Vermont**



→ **West Virginia**





States that are silent

→ Nevada



Nevada



→ Compliance Program

- Adopt a written marketing code of conduct
 - Companies may develop their own or adopt the PhRMA Code of Interactions with Healthcare Professionals
- Adopt a training program for the marketing code of conduct
- Conduct annual audits to monitor compliance
- Adopt policies and procedures for investigating any deviations
- Identify a compliance officer who is responsible to develop, operate and monitor the code
- Submit to the board annually (June 1) a copy of the above along with a certification that the company has conducted the yearly audit of the marketing code.



Pending Legislation

- Connecticut
- Illinois
- Iowa
- Maine (3 bills)
- Maryland (2 bills)
- Minnesota (3 bills)
- Mississippi
- New Jersey
- New Mexico
- New York (4 bills)
- Ohio
- Oregon (2 bills)
- Texas (2 bills)





Section Title

BUILDING A SUCCESSFUL COMPLIANCE PROGRAM

Ronald W. Buzzeo, RPh, Chief Compliance Officer



Requirements of a Successful Program

- **Compliance Department – Staffing**
 - Chief Compliance Officer, Chief Regulatory Officer etc.
- **Companies Commitment to Compliance**
 - Starts at the top.
 - Weigh risk of non compliance...effect on business & reputation
- **Annual and ongoing Reviews / Audits of your various State and Federal programs**
 - Using internal expertise
 - Using external expertise - Consultants
- **Routine training of staff**
 - New employees, new responsibilities, new or changes to regulatory requirements
 - On going



Requirements of a Successful Program

PDMA Solutions include:

- process design,
- setting significant loss thresholds,
- gap analysis,
- mock FDA audits,
- SOP development,
- third-party audits,
- reconciliation,
- field inventories, and
- sales force and home office training

DEA Solutions, for companies with controlled substances and List I chemicals include:

- DEA registrations,
- suspicious order monitoring,
- risk management program,
- process design,
- gap analysis,
- mock DEA audits, and
- SOP development,

Requirements of a Successful Program



State Solutions include:

- State Licensing Assessments,
- Aggregate Spend Assessment,
- Record keeping,
- Pedigree requirements,
- Training,
- Pre-VAWD audits,
- SOP development, and
- Sales force and home office

Thank you!



→ For more information, contact us at:

- 888-337-3748
- compliance@cegedim.com
- www.cegedimdendrite.com/compliance

- Gary Glotz, Sales Director – Compliance Solutions
 - gary.glotz@cegedim.com
 - 804-230-5003