Prescription Drug Marketing Act (PDMA): Understanding the Regulations

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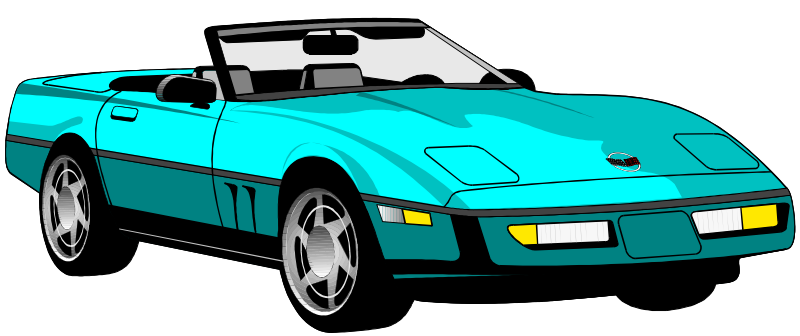
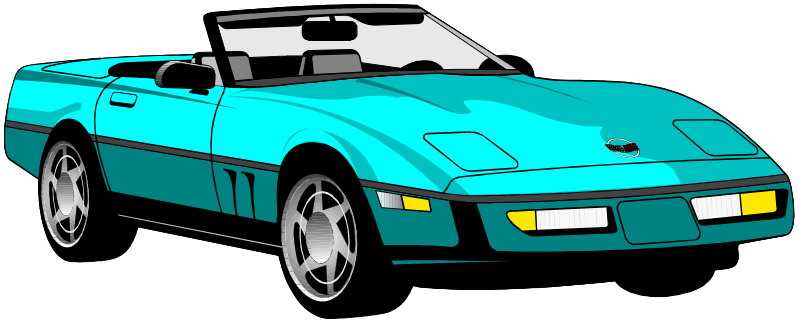
Agenda - PDMA

- Introduction
- Purpose
- Scope
- Key Definitions
- General Provisions
- Review and Summary

Introduction - PDMA

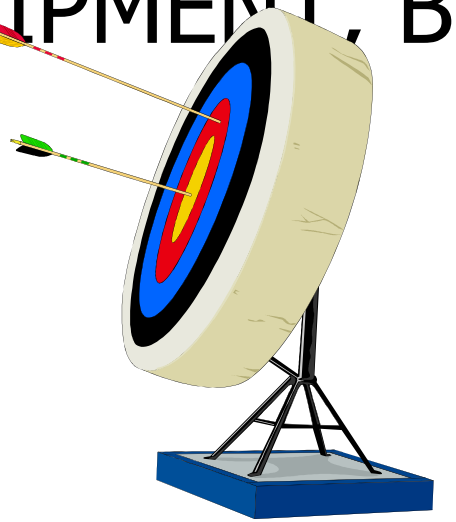
HIS & HERS





Introduction - PDMA

CAMP SUSSEX HAD ARCHERY EQUIPMENT, BUT NEEDED CEREAL



What did the “Boss” do?

PDMA Regulations

- Title 21 of the Code of Federal Regulations contains regulations related to food and drugs.
- The U.S. Food and Drug Administration (FDA) is responsible to enforce the different parts of Title 21 such as:
  - 21 CFR Parts 210 & 211 Good Manufacturing Practices
  - 21 CFR Part 11 Electronic Records and Electronic Signatures
  - **21 CFR Part 203 Prescription Drug Marketing**
  - **21 CFR Part 205 Guidelines for State Licensing of Wholesale Prescription Drug Distributors**

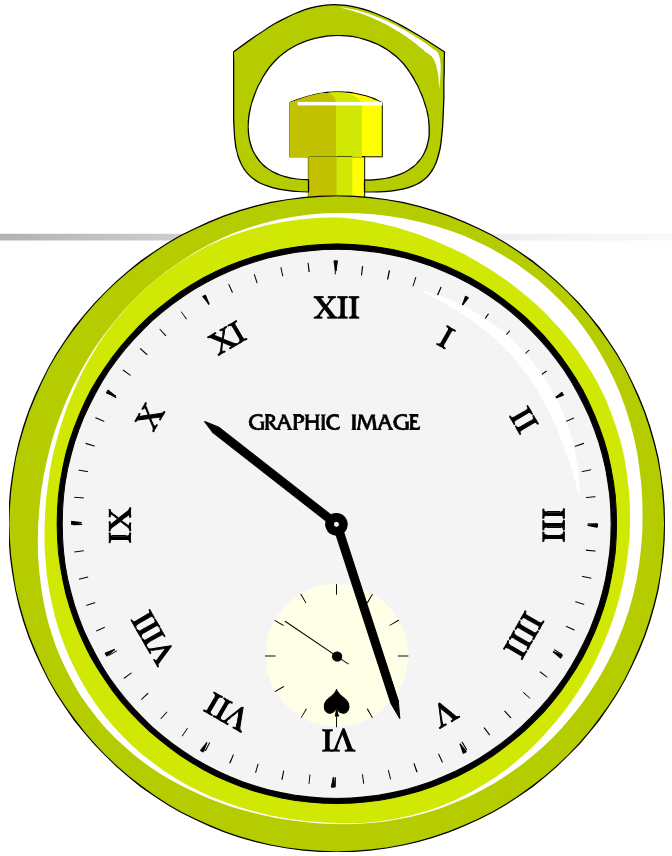
Purpose of PDMA

- Protect the public health
- Protect the public against drug diversion
- Establish procedures, requirements, and minimum standards for the distribution of prescription drugs and prescription drug samples.

Scope of PDMA

- Reimportation of prescription drugs
- Wholesale distribution of prescription drugs
- The sale, purchase, or trade of prescription drugs purchased by hospitals or donated to charitable organizations
- ***Distribution of prescription drug samples***

Timeout # 1



Question: Are samples of Eucerin Cream, Crest Toothpaste, and Neutrogena sunscreen subject to the requirements of PDMA?

Key Definitions of PDMA

- **Drug Sample** - a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug
- **Electronic Record** - any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.
- **Electronic Signature -** any computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

PDMA – General Provisions

- **Reimportation of Insulin** - prohibited except by its original manufacturer
- **Sales Restrictions** - No person may sell trade, purchase or trade any prescription drug from hospitals, and charitable organizations.
- **Returns by a hospital or charitable organization** - may be resold under certain conditions such as providing documentation of credit issued and proper storage.

Requesting Samples

Distribution by mail or by rep requires a <u>written request</u> containing:

- Name, address, professional title and signature of practitioner making the request
- Practitioner's State license number or for controlled substances, the practitioner’s Drug Enforcement Administration number
- Name, strength, and quantity of sample requested
- Name of manufacturer and distributor if applicable
- Date

Receiving Samples

Distribution by mail or by rep also requires a written receipt designated by the manufacturer or distributor acknowledging delivery and containing:

- Name, address, professional title and signature of practitioner or designee
- Name, strength, quantity of samples
- Date

Other Requirements of PDMA

- Performing annual inventory and reconciliation of representatives' samples including a written report
- Storage and handling requirements - to maintain stability, integrity, and effectiveness
- Establish, maintain and adhere to written policies and procedures describing distribution methods, reconciliation of requests and receipts, conducting the annual inventory, implementing security and audit program, storage by representatives, monitoring theft or loss.

Timeout # 2

Question: Are PDMA regulations more stringent than Controlled Substance regulations?

PDMA Records

- Maintain all requests, receipts, forms, and records for no less than 3 years
- Produce requests, forms, and records within 2 business days of a request by a regulatory or law enforcement official.
- May be maintained on paper, or by photographic image
- Scanned records are considered electronic records and must meet the requirements of 21 CFR Part 11.
- Responsibility remains with the manufacturer or distributor if a third party is used.

Thefts and Losses

Manufacturers or distributors who know of falsification of records or know of a significant loss or known theft of drug samples must:

- Notify FDA within 5 working days
- Immediately initiate an investigation
- Provide FDA with a complete written report not later than 30 days after the initial notification

Labeling Requirements

Drug Samples must be labeled with:

- Lot or control number
  - Sample distribution records must be maintained and contain the sample lot numbers to permit the complete tracking of drug samples.
- A label that clearly denotes its status as a drug sample.
  - For example, “sample”, “not for sale”, “professional courtesy package”

Electronic Records

Electronic records, electronic signatures, and handwritten signatures executed to electronic records may be used in lieu of paper records provided that:

- The requirements of 21 CFR Part 11 are met

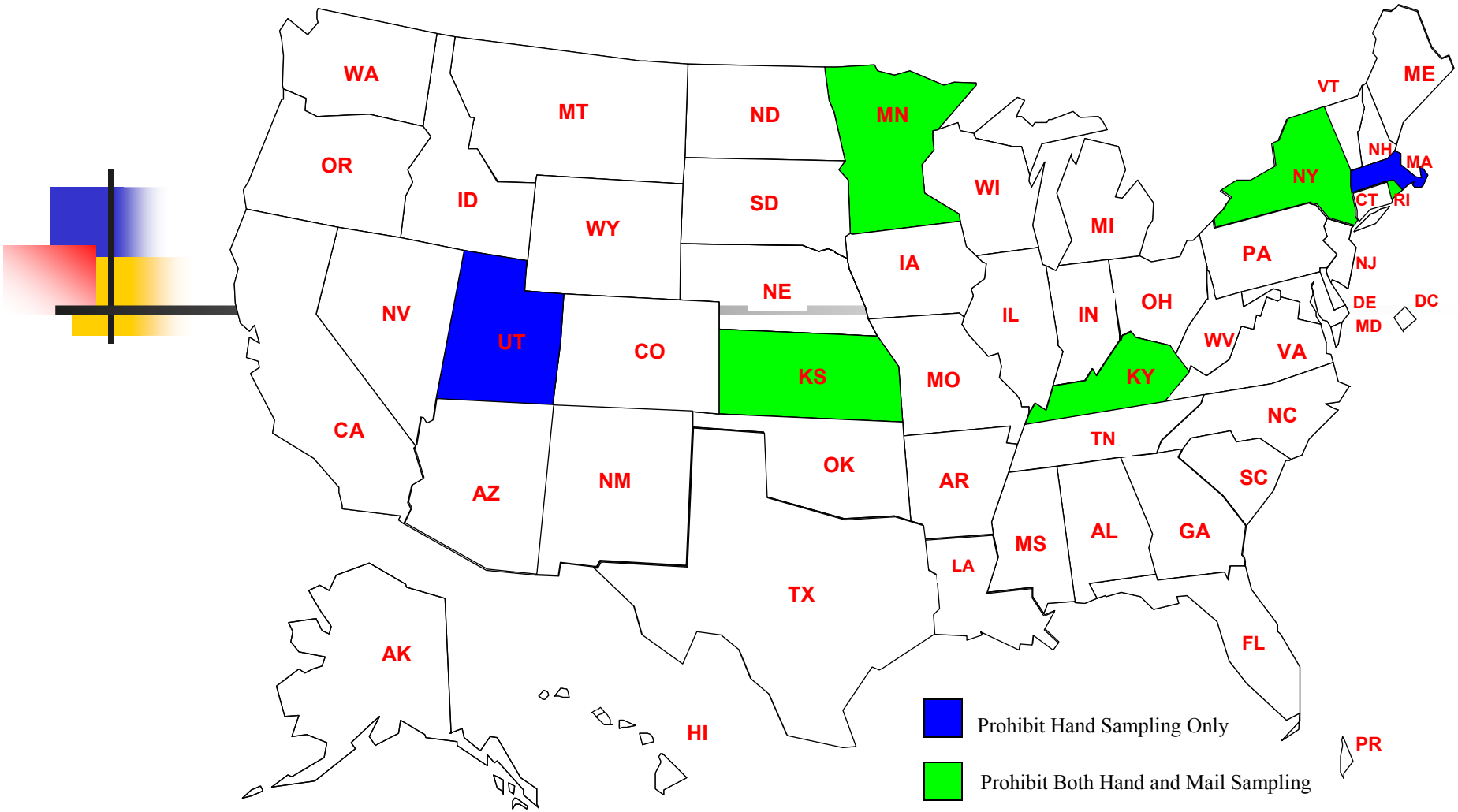
Combinations of paper records and electronic records, electronic records and handwritten signatures executed on paper, or paper records and electronic signatures or handwritten signatures executed to electronic records may be used provided that:

- The requirements for 21 CFR Part 11 are met.
- Secure link exists between paper based and electronic components
- The records and signature are trustworthy and reliable and the signer cannot repudiate the signed records as not genuine.

Other Considerations

- States may impose additional restrictions on distribution of prescription drug samples.
  - State Licensing – required in 48/50 states
  - Types of prescribers – e.g. Mid-Level Practitioners, such as Physician Assistants, Licensed Nurse Practitioners
  - No sampling of Controlled Substances – e.g. NY
  - No hand sampling of Controlled Substances – e.g. UT, MA

State Controlled Substance Sampling Prohibitions



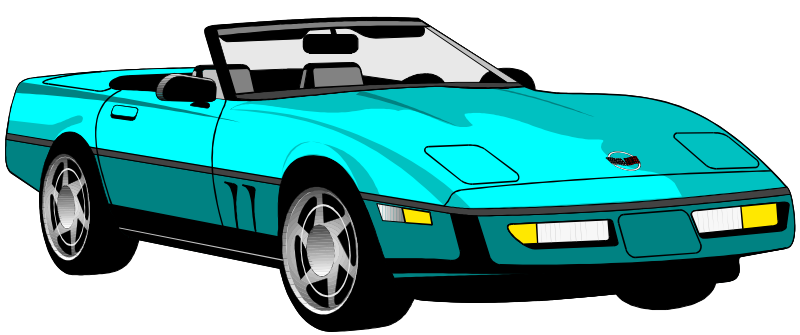
Why use a third party Distributor instead of reps?

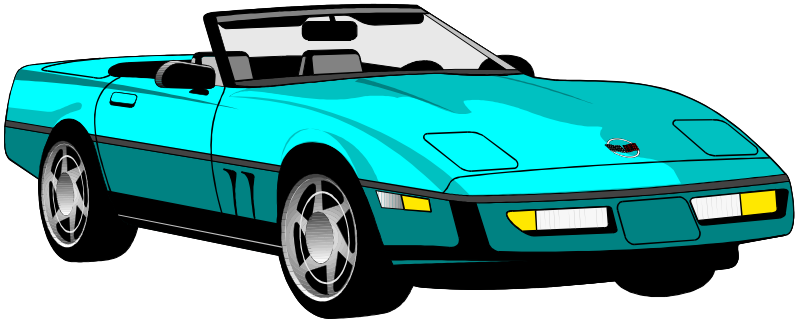
CRITERIA	IMPACT
State Licensing	Expensive, burdensome
Random & For Cause Audits	Not required for distributors
Annual Inventory & Reconciliation	Not required for distributors
Storage	GMP warehousing
Turnover & closeouts	Consumes resources

Rewards

- PDMA rewards a person who provides information leading to the institution of a criminal proceeding against, and conviction of a person for the sale, purchase, or trade of drug samples of one-half the criminal fine imposed and collected , but not more than $125,000
- The procedure for making application for a reward is specified in the regulations.

His & Hers





Summary

- The Prescription Drug Marketing Act addresses reimportation, wholesale distribution of prescription drug products, and wholesale distribution of prescription drug samples.
- PDMA documents specific procedural and documentation requirements for distribution of drug samples.
- Infractions of PDMA may result in substantial penalties.

Quiz

1. Title 21 of the Code of Federal Regulations contains regulations related to:
   - Animal feeds
   - Transport of hazardous goods
   - Food and drugs

2. The PDMA addresses all of the following except:
   - Reimportation of Insulin and Insulin products
   - Wholesale distribution of prescription drugs
   - Distribution of blood and blood components intended for transfusion
   - Wholesale distribution of prescription drug samples

3. Which of the following is not defined as an electronic record by PDMA?
   - A faxed document
   - A sound (Wave) file
   - A MS Word document

Quiz

4. Distribution of drug samples requires:
   - A signed request
   - A signed receipt
   - A reconciliation of requests and receipts
   - All of the above

5. Manufactures and Distributors using third parties to process data may delegate the responsibility of maintaining records to that third party. (True or False)

6. A drug sample must be labeled with all of the following except:
   - The lot number
   - The date of manufacturer
   - Wording that clearly denotes its status as a drug sample

Quiz

7. PDMA records must be maintained for at least _____ years.

8. PDMA records must be made available within _____ business days of a request.

9. Electronic records may not be used in place of paper records under any circumstances (True or False)

10. Rewards for information leading to the conviction of a person selling, purchasing or trading drug samples may be as high as:

- $10,000
- $50,000
- $125,000
- One-half the value of the samples in question

Questions?

Thank you!