

# Poison Prevention Packaging Act

Prescription Drugs and Physician Samples

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# Prescription Drugs

- If regulated under the PPPA, Rx drugs must be dispensed in CR unless
  - patient requests non-CR packaging when they fill the prescription, or
  - physician requests non-CR packaging in the prescription
- Bulk packages of PPPA - regulated prescription drugs shipped to pharmacies that will be repacked by the pharmacist do not have to be CR

# Drugs included in 16 CFR § 1700.14(a)

- acetaminophen
- aspirin
- controlled drugs
- dibucaine
- diphenhydramine
- ibuprofen
- iron-containing drugs and dietary supplements
- ketoprofen
- lidocaine
- loperamide
- methyl salicylate
- minoxidil
- mouthwash
- naproxen
- oral prescription drugs
- OTC switched drugs

# Oral Rx Drug Regulation

- 16 C.F.R. §1700.14(a)(10)
- Special packaging is required for any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drug

# Oral Rx Drug Regulation

(continued)

- Specific exceptions are listed in the regulation
- Example of exceptions
  - Sublingual dosage forms of nitroglycerin
  - Hormone replacement therapy products that rely solely upon the activity of one or more progestogen or estrogen substances

# Common Questions Regarding “Oral Administration”

- Are topical drugs that are applied to the inside of the mouth considered drugs intended for oral administration?
- Are drugs delivered via inhalers that are placed in the mouth considered drugs intended for oral administration?
- No. These drugs would not require special packaging under the oral Rx drug rule, but might require special packaging under another PPPA rule.

# Non-Oral Drug Regulations

- Other drugs listed at 16 C.F.R. §1700.14(a) also require special packaging
- Example include:
  - Lidocaine
  - Dibucaine
  - Minoxidil

# Clinical Trial Drugs

- Oral drugs for human use when they are dispensed during a clinical trial (investigational drugs) for use in the household (outpatient) are regulated under the oral prescription drug regulation because they are dispensed by or at the order of a licensed practitioner.

# Clinical Trial Drugs (continued)

- Non-oral or other drugs dispensed for human use during clinical trials on an outpatient basis for use in the household must also be dispensed in special packaging if they are subject to one or more of the other regulations issued under the PPPA.
  - See 16 CFR § 1700.14.
- Drugs dispensed for a clinical trial for use in hospitals or similar institutions are not required to be in special packaging.

# Clinical Trial Statement

- Issue of unit dose clinical trial drug packaging.
- The staff issued a statement which is posted on the CPSC web site at:
  - <http://www.cpsc.gov/BUSINFO/trials.pdf>
- The statement permits manufacturers of drugs dispensed in unit packaging for household use in clinical trials to use certain alternatives to strict compliance with the requirements of the PPPA.

# Clinical Trial Statement (continued)

- Non-CR packaging may be used if the amount of drug dispensed into the household will not cause serious injury or illness to a young child.
  - If you take advantage of this option, you must maintain data that demonstrate that the amount dispensed into the household, if ingested, would not be expected to cause serious injury to children.
  - This data must be made available to CPSC staff upon request.

# Clinical Trial Statement (continued)

- Oral clinical trial drugs with sufficient toxicity to cause serious injury or illness to a young child (“toxic”) or drugs subject to other PPPA regulations must be packaged with a CR feature.
  - The unit packages can be made with any of the features described in ASTM D-3475, provided that the packaging has at least one recognizable CR feature.

# Clinical Trial Drugs (continued)

- All drugs used in Phase II, III, or IV clinical trials initiated after November 23, 2000 must be packaged in accordance with the guidelines above.

# Physician Samples

- Oral prescription drugs require special packaging. 16 CFR § 1700.14(a)(10)
- Section 4 of the PPPA grants physicians the authority to order non-CR packaging for their patients in the written prescription.

# Physician Samples (continued)

- The Commission's policy is to not require manufacturers of regulated prescription drug samples to provide the samples in special packaging.
  - 49 FR 8008 (March 5, 1984)
- The decision to provide special packaging is up to the physician on a case by case basis.

# Physician Samples (continued)

- 49 FR 8008 Assumptions
  - Many of the samples probably complied
  - Unit packaging with small numbers of dosages
  - Low toxicity

# Physician Samples (continued)

- Factors for Drug Manufacturers to Consider
  - Toxicity of the drug
  - Number of dosages per sample
    - “starter kits”
  - Use of samples by physicians
  - Vouchers

# Physician Samples (continued)

- Section 4(b) does not apply to regulated over-the-counter (OTC) drugs because they are not dispensed by the order of a licensed practitioner.
- Samples of regulated OTC drugs must be packaged in special packaging.

**Questions?**