Poison Prevention Packaging Act

Overview of the Act and Implementing Regulations

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Purpose of PPPA

To protect children from serious personal injury or serious illness resulting from handling, using or ingesting hazardous household substances.

15 U.S.C. § 1472(a)(1)

Commission's Authority

- Issue regulations requiring special packaging for household substances

- **15 U.S.C. § 1472(a)**

Special Packaging

- Child-resistant
  - significantly difficult for children <5 to open or obtain a toxic or harmful amount of the substance within a reasonable time
- Adult (Senior) Friendly
  - not difficult for normal adults to use properly

15 U.S.C. § 1471(4)

Household Substance

- Customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household, and which are
  - hazardous substances as defined by the Federal Hazardous Substances Act (FHSA);
  - foods, drugs, or cosmetics as defined by the Food, Drug and Cosmetic Act (FD&CA); or

Household Substance (continued)

- substances intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.

15 U.S.C. § 1471(2)

Package

- The child-resistance requirements apply to the immediate container or wrapping.

15 U.S.C. § 1471(3)

PPA Section 4

- The Act contains provisions to ensure that elderly or handicapped individuals unable to use special packaging can obtain regular packaging
- Section 4 allows for limited use of non-complying packaging to achieve this

15 U.S.C. § 1473

PPPA Section 4 (continued)

- Manufacturer may supply non-prescription substance in a single non-complying size package unless prohibited by regulation
- Physician can specify non-CR packaging in prescription
- Patient can request non-CR packaging when filling prescription

15 U.S.C. § 1473

PPPA Rulemaking

Commission findings:

- special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances.

- special packaging is technically feasible, practicable, and appropriate for those substances.

15 U.S.C. § 1472(a)

PPPA Rulemaking (Continued)

The Commission must consider:

- Reasonableness of the standard
- Available scientific, medical, and engineering data
- Manufacturing practices of affected industry
- Nature and use of the substance

15 U.S.C. § 1472(b)

PPPA Rulemaking (Continued)

- Cannot prescribe specific packaging designs, product content, package quantity, or (with one exception) labeling

15 U.S.C. § 1472(d)

PPPA Rulemaking (Continued)

- Can prohibit packaging that is "unnecessarily attractive" to children

15 U.S.C. § 1472(d)

Effective Date

- Not sooner than 180 days unless Commission finds it is in the public interest.
- Not later than 1 year
- Applies to products packaged on or after effective date

15 U.S.C. § 1471n

PPPA Regulations

- Specific criteria for child-resistance and ease of proper use by adults
- Packaging must function effectively for life of product
- Substance packaged must not interfere with the proper functioning of the package

16 CFR Part 1700

Substances at 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

Substances at 16 CFR § 1700.14(a) (continued)

- Ethylene glycol
- Fluoride
- Furniture polish
- Glue removers containing acetonitrile
- Hydrocarbons
- Kindling and/or illuminating preparations
- Methacrylic acid
- Methyl alcohol
- Permanent wave neutralizer containing sodium or potassium bromate
- Sodium and Potassium hydroxide
- Solvents for paint or other coating material
- Sulfuric acid
- Turpentine

Products not subject to the PPPA requirements

- Not customarily used in/around the household
- Specifically exempted at 16 CFR § 1700.14(a)
- Bulk packages of drugs sold to pharmacies that will be repackaged by pharmacist before being dispensed
- Bulk chemicals sold to industry
- Containers of 5 gallons or more (unless otherwise indicated in a regulation)

PPPA Rulemaking Example

Methacrylic Acid

Hazard Identification

Childhood injuries from artificial nail primer cosmetic products

Woolf A., and Shaw J. Arch Pediatr Adolesc Med. 1998 Jan;152(1):41-6

Multidisciplinary Team

- Toxicologist
- Laboratory Chemist
- Packaging Engineer
- Human Factors Specialist
- Epidemiologist
- Economist
- Compliance Officer

Information for Commission

- A briefing package addressing the findings and presenting a staff recommendation was developed for the Commission's consideration

- November 23, 1998

Proposed Rule

- Commission votes to commence rulemaking
- Notice of Proposed Rulemaking (NPR) published in the Federal Register
  - 63 FR 71800 (December 30, 1998)
  - Copies of NPR sent to interested parties

Proposed Rule

- Liquid household products containing more than 5% methacrylic acid in a single package

- Pen-like markers exempt if there is no free liquid in the device and methacrylic acid emerges only from tip of device

Public Comment

- 75-day comment period (NAFTA)
  - Ended March 15, 1999
  - 5 comments received

- Staff addressed comments and sent additional information to Commission.
  - May 21, 1999

Final Rule

- Commission votes to issue a final rule
- No changes from the proposed rule language
- Final Rule published in the Federal Register
  - **64 FR 32799**

Effective Date

- Rule became effective 1 year after publication

  - June 19, 2000

Compliance

- Conformance monitoring

- Recall of acrylic nail primer product (72,000 bottles)

http://www.cpsc.gov/CPSCPUB/PREREL/prhtml04/04066.html

Questions?