

Poison Prevention Packaging Act

Compliance and Enforcement

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Office of Compliance

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Firms' Responsibilities

- Must package regulated substances in immediate packaging that complies with the special packaging standards of the PPPA
- Over-packages do not comply
- Free samples and trial sizes are included
- Specific criteria special packaging must meet for child-resistance and ease of proper use by adults
 - See 16 CFR §§ 1700.15 and 1700.20

Special Packaging Tests

- The test for child-resistance is specified at 16 CFR § 1700.20(a)(2)
 - Requires 80%+ effectiveness
 - 50-200 children are tested
- The test for senior adult use effectiveness is specified at 16 CFR § 1700.20(a)(3)
 - Requires 90%+ effectiveness
 - 100 adults are tested

Other Requirements

- Packaging must continue to effectively function for the life of the product
- The substance packaged must not interfere with the proper functioning of the package
- Special packaging cannot be re-used if the regulation prohibits re-use
- Restricted flow (in addition to CR/SF) might be required by the regulation

PPPA Regulations

- Regulations do not prescribe package types
- Each regulation specifies the requirements the packaging of each regulated substance must meet under 16 C.F.R. § 1700.15
 - (a) General requirements
 - (b) Effectiveness specifications
 - (c) Reuse of special packaging
 - (d) Restricted flow

PPPA Regulations (continued)

- For example, the furniture polish regulation at 16 C.F.R. § 1700.14(a)(2) specifies that certain furniture polishes must be packaged “in accordance with the provisions of § 1700.15(a), (b), and (d).”
- This means that the package of regulated furniture polish must meet the general requirements at (a), must meet the CR/SF performance requirements at (b), and must restrict the flow of the furniture polish (d). 6

PPPA Regulations (continued)

- Scope of Coverage Issues
 - Use
 - human vs. veterinary
 - Administration
 - oral vs. topical
 - Form
 - liquid vs. powder
 - Conditions
 - %, amount, emulsion, prepackaged

PPPA Regulations (continued)

- To date, the Commission has issued 31 special packaging regulations covering a variety of hazardous substances, drugs, cosmetics, and dietary supplements
 - See 16 CFR § 1700.14(a)

Substances Requiring Special Packaging

- 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 Requiring Special Packaging (continued)

- furniture polish
- methyl salicylate
- sodium/potassium hydroxide
- turpentine
- kindling/illuminating preparations
- methanol
- sulfuric acid
- ethylene glycol
- solvents for paint/surface-coating material
- glue removers containing acetonitrile
- elemental fluoride
- methacrylic acid
- hydrocarbons

Sample Packages / Test Data

- Manufacturers of PPPA-regulated substances are requested to submit sample packages for each type of special packaging used for the substances
 - See 16 C.F.R. § 1700.14(b)
- Labeling for each size package, including labeling for non-complying packages, is also requested
- You are also encouraged to submit your test data for the packages

Section 4 of the PPPA

- 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

Section 4 of the PPPA (continued)

- Manufacturers may supply a non-Rx substance in a single non-complying size package
- Non-complying packaging cannot be used for liquid drain cleaners containing 10%+ sodium and/or potassium hydroxide
 - See 16 C.F.R. § 1500.17(a)(4)

Section 4 of the PPPA (continued)

- Must label non-complying package per 16 C.F.R. § 1700.5
- “This Package for Households Without Young Children” (16 C.F.R. § 1700.5(a))
- Alternate language “Package Not Child-Resistant (16 C.F.R. § 1700.5(b)) is acceptable regardless of size of package
- Regulation contains type size and conspicuousness requirements
- Must appear within the borderline of a square or rectangle

Section 4 of the PPPA (continued)

- Must also supply substance in popular size complying packaging (for non-Rx)
- Make sure your use of a single non-complying package is consistent with the intent of Section 4

Section 4 of the PPPA - Rx

- Patient can request non-CR packaging when they fill the prescription
- Physician can request non-CR packaging in the script

Legal Considerations

- Violations
- Penalties & Enforcement Action
- Reporting Requirements

Violations

- Household substances packaged in violation of the PPPA are misbranded under the FHSA or FD&CA
- Introducing or delivering for introduction into interstate commerce of a misbranded hazardous substance is a prohibited act under the FHSA
- Introducing or delivering for introduction into interstate commerce of a misbranded food, drug or cosmetic is a prohibited act under the FD&CA

FHSA - Penalties and Enforcement Action

- Seizure
- Injunction
- Penalties
 - Not more than \$5,000 for individuals and \$10,000 for organizations and/or imprisonment (90 days maximum)

FHSA - Penalties and Enforcement Action (continued)

- For offenses committed with intent to defraud or mislead, or for second and subsequent offenses, the penalty shall be imprisonment (1 year maximum), and/or
 - Organizations
 - Not more than \$200,000 if offense does not result in death
 - Not more than \$500,000 if offense results in death
 - Individuals
 - Not more than \$100,000 if offense does not result in death
 - Not more than \$250,000 if offense results in death

FD&CA - Penalties and Enforcement Action

- Seizure
- Injunction
- Penalties

Individuals

- Not more than 1 year imprisonment and/or
 1. Not more than \$100,000 if offense does not result in death
 2. Not more than \$250,000 if offense results in death

FD&CA – Penalties (continued)

Organizations

1. Not more than \$200,000 if offense does not result in death
2. Not more than \$500,000 if offense results in death

CPSA - Reporting Requirements

- The Consumer Product Safety Act requires that every manufacturer, distributor and retailer of a consumer product distributed in commerce who obtains information which reasonably supports the conclusion that such product:
 - 1) contains a defect that could create a **substantial product hazard**, or

CPSA – Reporting Requirements

2) creates an unreasonable risk of serious injury or death

shall **immediately** inform the Commission of such defect or unreasonable risk.

(Sec. 15(b))

“Defect”

- See 16 C.F.R. § 1115.4
- A fault, flaw, or irregularity that causes weakness, failure or inadequacy in form or function
- May be the result of a manufacturing or production error
- The design of and/or materials used in a product may also result in a defect

“Defect” (continued)

- May also occur in a product’s contents, construction, finish, packaging, warnings, and/or instructions
- If a product fails to comply with an applicable rule issued under the PPPA, the staff would generally consider such product defective
- For example, a product requiring special packaging that does not meet child resistant standards set forth in the PPPA, would likely be viewed as containing a defect

“Substantial Product Hazard”

- A product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public

“Unreasonable Risk of Serious Injury or Death”

- See 16 C.F.R. § 1115.6
- Information indicating that a product presents an unreasonable risk of serious injury or death can include :
 - reports from experts
 - test reports
 - lawsuits and other claims
 - quality control data
 - reports of injury
 - and other relevant information

When to Report

- Obligation to report arises upon receipt of first information of potential hazard presented by a product defect or when firm obtains information that reasonably supports the conclusion that a product violates a standard under the PPPA and the violation could result in serious injury or death
- Such information includes (but is not limited to) complaints, injury reports, quality control, testing reports and engineering data
- “Immediately” means within 24 hours

CPSA - Civil Penalties

Failure to timely report

- \$8,000 per violation (separate violation for each product) up to \$1.825 million for any related series of violations.

Helpful Links

- CPSC web site
 - www.cpsc.gov
- Summary of the PPPA
 - www.cpsc.gov/businfo/regsumpppa.pdf
- The PPPA and its regulations
 - www.cpsc.gov/businfo/pppa.html

PPPA Contact at CPSC Headquarters' Office of Compliance

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