Child-Resistant and Senior-Friendly Packaging Regulations and Testing Requirements

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Moderated By: Jay Sirois, CHPA
CPSC AND THE POISON PREVENTION PACKAGING ACT

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These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

The U.S. Consumer Product Safety Commission

Poison Prevention Packaging Act

To protect children from serious personal injury or serious illness resulting from handling, using or ingesting hazardous household substances. The PPPA is enforced by CPSC.

Household Substances

Customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household which are-
Household Substances (cont.)

A. A hazardous substance as defined by the Federal Hazardous Substances Act (FHSA);

B. Foods, Drugs, or Cosmetics as defined by the Federal Food, Drug, and Cosmetics Act (FD&CA); or

C. Substances intended for use as a 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)

What Is a Package?

“The term “package” means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage in or about the household…”

15 U.S.C. § 1471(3)

PPPA Findings

“the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance…”

PPPA Findings

“the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.”

15 U.S.C. § 1472(a)(2)

Special Packaging

“Packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly.”


Special Packaging

“Nothing in this Act shall authorize the Commission to prescribe specific packaging designs, product content, package quantity, or, with the exception of authority granted in section 4(a)(2) of this Act [15 U.S.C. § 1473(a)(2)], labeling.”

15 U.S.C. § 1472(d)
Drugs currently included in 16 CFR § 1700.14

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

Exceptions

• Not Used In/Around the Household
  ➢ Institutional Use
    — Hospitals, Nursing Homes
  ➢ Professional Use

Exceptions (cont.)

• Prescription
  ➢ Bulk Drugs Repackaged by the Pharmacist
  ➢ Requested by Patient or Physician
    — Section 4 allows limited use of non-complying packaging 15 U.S.C. § 1473
  ➢ Exempted (16 CFR § 1702)
    — 16 CFR §1700.14(a)(10)(i)-(xxi)
Exceptions (cont.)

• OTCs - Household Products
  - One size
  - Labeled (16 CFR §1700.5)
    - “This Package For Households Without Young Children”
    - “Package Not Child-Resistant”
  - Other popular sizes are CR
  - Imposed exclusive CR
    - Drain cleaners (16 CFR 1500.17(a)(4))

Questions

Packaging Test Methods

• Child Test - 16 CFR § 1700.20(a)(2)
  - Panels of 50 children (42-51 months)
  - Tester restriction - 30% children
  - Site restriction - 20% children
  - 5 minutes - demo - Teeth - 5 minutes
  - Sequential Pass/Fail Table
    - 16 CFR § 1700.20(a)(2)(iii)
    - 80% after 200 children
SEQUENTIAL TEST

<table>
<thead>
<tr>
<th>Test Panel</th>
<th># Children Tested</th>
<th>Package Openings (Full 10 minutes)</th>
<th>Pass</th>
<th>Continue</th>
<th>Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50</td>
<td>0-5</td>
<td>6-14</td>
<td>15+</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>100</td>
<td>6-15</td>
<td>16-24</td>
<td>25+</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>150</td>
<td>16-25</td>
<td>36-34</td>
<td>35+</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>200</td>
<td>26-40</td>
<td>---</td>
<td>41+</td>
<td></td>
</tr>
</tbody>
</table>

Packaging Test Methods

Senior Test -16 CFR § 1700.20(a)(3)
- 100 adults (50-70 years old)
- Site restriction (24%)
- Tester restriction (35%)
- 5 minute/1 minute test period
- Screening
- 90% effectiveness

Packaging Test Methods

Metal cans/metal closures and aerosols
- Use 100 Adults aged 18-45 years
- One 5 minute time period
- 90% effectiveness
Physician’s Samples
• Oral prescription drugs require special packaging.
  16 CFR § 1700.14(a)(10)
• Section 4(b) of the PPPA grants physicians the authority to order non-CR packaging for their patients in the written prescription.

Physician’s Samples (continued)
• The Commission’s policy is to not require manufacturers of regulated prescription drug samples to provide the samples in special packaging.
  – 49 Fed. Reg. 8008 (March 5, 1984)
• The decision to provide special packaging is up to the physician on a case by case basis.

Physician’s 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.
Consumer Product Safety Improvement Act (CPSIA)

Under Section 102 a general certification requirement has been extended to products subject to any similar rule, standard, ban, or regulation under any Act enforced by the Commission. General conformity certifications do not need to be based on testing done by a third-party laboratory. Certification must be based on a test of the product or a “reasonable testing program.”

Does Required Special Packaging Need Certification?

YES!

- The PPPA requires special packaging for certain substances.
- Special packaging must meet the performance specifications of 16 C.F.R. § 1700.15.
- The importer or the domestic party that packages any substance that requires special packaging must certify that the special packaging meets the performance specifications of 16 C.F.R. § 1700.15.

GENERAL CONFORMITY CERTIFICATION

1. Identification of the product
2. Citation to each CPSC product safety regulation applicable
3. Identification of the U.S. importer or domestic manufacturer
4. Contact information for the individual maintaining records of test results
It would help to note why cc do not need to be based on testing done by a third-party laboratory. The way this is written may leave the impression that this is true for all cc.

ejelder, 9/22/2010
GENERAL CONFORMITY CERTIFICATION (cont.)

5. Date and place where the product was manufactured
6. Date and place where the product was tested for compliance with the regulation(s) cited above
7. Identification of any laboratory on whose testing the certificate depends

For complete instructions and more information see: http://www.cpsc.gov/PageFiles/110321/certiffaq.pdf

Questions

Special Packaging

Richard A. Ward, CPP
www.perritt.com
Who gets poisoned?
- One and two year olds account for 72% of exposures in pharmaceuticals.
- Happens quickly, usually when caregiver has stepped away for short time.

Poison Prevention Packaging Regulations
- Consumer Product Safety Commission (CPSC)
  - Poison Prevention Packaging Act of 1970
    - CFR Title 16, Part 1700

Child Testing
- Panels of 50 children
  - tested sequentially
- 42 to 51 months old
  - tested in pairs
  - divided into three age categories
    - 42 - 44 months
    - 45 - 48 months
    - 49 - 51 months
Child Testing (continued)

- 50% male, 50% female
- Testing performed at nursery schools and day care centers
- 10 minute test period

Child Testing (continued)

- Demo and instructions that may use teeth
- Minimum of 4 testers and 5 sites
- 85% before demo, 80% after demo

Child Panelists

- Pick, scrape, bend, tear, bite, shake
- Even open properly

(video)
Sequential Child Test Performance Standards

<table>
<thead>
<tr>
<th>Test Panel</th>
<th>Cumulative number of children</th>
<th>Package Openings</th>
<th>First 5 Minutes</th>
<th>Full 10 Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pass</td>
<td>Continue</td>
</tr>
<tr>
<td>1...</td>
<td>50</td>
<td></td>
<td>0-5</td>
<td>6-14</td>
</tr>
<tr>
<td>2...</td>
<td>100</td>
<td></td>
<td>4-10</td>
<td>11-18</td>
</tr>
<tr>
<td>3...</td>
<td>150</td>
<td></td>
<td>11-18</td>
<td>19-25</td>
</tr>
<tr>
<td>4...</td>
<td>200</td>
<td></td>
<td>19-25</td>
<td></td>
</tr>
</tbody>
</table>

Unit Packaging - Failures

- “Any child who opens or gains access to the number of individual units that constitute the amount that may produce serious personal injury or serious illness, or a child who opens or gains access to more that 8 individual units, whichever number is lower.”
- Based on a 25 pound child

Senior Adult Use Effectiveness

(Used for Torque-Dependent Threaded Closures)

- 100 senior adults (50 - 70 years old)
- All apparently-closed units from the one-minute opening and closing test are then tested with children.
- All packages that are opened in excess of 20% count against the SAUE (senior adult use effectiveness)
- Performance standard remains at 90% or greater
CRP Testing Provides
- A design tool
- Regulatory compliance
- Legal due diligence
- Quality assurance

Special Packaging Extras
- Immediate packaging only
- OTC samples and trial sizes must comply
- Prescription physician samples need not comply

Special Packaging Extras
- Package must function for the life of the use of the product
- Packaging may not be unnecessarily attractive to children
- Children in test receive tools only when part of the unit of sale.
When is Re-Testing Required?

- Requalification / Equivalency
- Changes that may affect results:
  - materials, component shapes/sizes
  - torque / liner
  - process / equipment
  - product
  - suppliers

Questions

Appendix
ASTM D3475 Classification System

- 13 Types
- 100+ functional sub-groups
- Updated annually

Type I A

Type I B
Type IX B

Type XIII A

Standard Classification of Child-Resistant Packages
D 3475
WWW.ASTM.ORG
Useful Contact Information:

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