Poison Prevention Packaging Act

Testing Issues
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Special Packaging Tests – Child Test

- Test specified at 16 CFR § 1700.20(a)(2)
 - Panels of 50 children
 - -42-51 months old
 - 30% from 42 through 44 months old
 - 40% from 45 through 48 months old
 - 30% from 49 through 51 months old
 - 50% boys and 50% girls
 - Tester restriction 30% of the children
 - Site restriction 20% of the children

Special Packaging Test - Child Test (continued)

- 5 minutes Demo 5 minutes
 - Use of teeth
- Sequential Pass/Fail Table
 - see 16 CFR§1700.20(a)(2)(iii)
 - 80% after 200 children

Sequential Test Pass/Fail Table at 16 C.F.R. § 1700.20(a)(2)(iii)

Test Panel	Total Children Tested	Package Openings (10 minutes)		
		Pass	Continue	Fail
1	50	0-5	6-14	15+
2	100	6-15	16-24	25+
3	150	16-25	26-34	35+
4	200	26-40	-	41+

Special Packaging Test Child Test (continued)

- Definition of a test failure
 - Any child who opens the package or gains access to its contents
 - For unit-dose packaging
 - any child who opens or gains access to the number of individual units which constitute the amount that may produce serious personal injury or serious illness, or
 - a child who opens or gains access to more than 8 units,
 - whichever is lower

Special Packaging Tests - Adult Test

- Test specified at 16 CFR § 1700.20(a)(3)
 - 100 adults
 - 50-70 years old
 - 25% from 50 through 54 years old
 25% from 55 through 59 years old
 50% from 60 through 70 years old
 - 70% must be women
 - Tester restriction 35% of the adults
 - Site restriction 24% of the adults

Special Packaging Test - Adult Test (continued)

- Test Procedure
 - Consent form
 - 5 minute/1 minute test periods
 - Screening procedure
 - If adult cannot open package, given 2 non-CR packages to try to open each within 1 minute. If cannot open non-CR packages, results of their test with CR package are not included in test results

Special Packaging Test Adult Test (continued)

- 90% Effectiveness
 - Open package in 5-minute test period and open and properly resecure package in the 1-minute test period
 - Adult-Resecuring Test
 - -16 CFR § 1700.20(d)(2)

Special Packaging Test - Adult Test (continued)

- Metal cans/closures and aerosols tested with adults 18-45 years old
 - 70 percent female
 - Single 5-minute test period
 - 90 percent must open and properly resecure the package

What To Give To Children

- The package configuration that represents the "worst case scenario"
- Packages in the form in which they will enter or be stored in the home
- The tool, if the package will be provided to consumers with a tool

How Many Children?

- The child test is divided into consecutive panels of 50 children
- Once passing results are obtained, there is no need to test additional panels of children
- Obtaining results in the "continue to test" range after testing 50, 100, or 150 children is perfectly acceptable as long as the package passes the test by the time 200 children have been tested

Sequential Test Pass/Fail Table at 16 C.F.R. § 1700.20(a)(2)(iii)

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What To Give To Adults

- Tools required to open the package, regardless of whether the tool is supplied with the product
- Only such printed instructions on how to open and properly resecure the package as will appear on or accompany the package as it is delivered to the consumer

New or Conditioned?

• Special packaging is required to continue to function so that it meets the PPPA effectiveness specifications for the life of the product 16 CFR § 1700.15(a)

New or Conditioned? (continued)

- Test children with packages in their easiestto-open condition, and test adults with packages in their hardest-to-open condition, so the testing represents the "worst-case scenario"
- This can be achieved through conditioning, if necessary

Other Testing Issues

- Multiple openings
 - If a child gains access to or opens the package through any means, that package is counted as a test failure
- Leaking packages

When to Test

It is advisable to test:

- When developing/designing a new package
- Anytime it would be reasonable to expect that the effectiveness of the package has changed

Examples of When to Test/Retest

If you think the effectiveness of the package may be affected due to:

- A change in the package materials
- A change in the manufacturing process
- A different substance in a previously tested package
- When using a previously tested closure on a new or different bottle

Examples of When to Test or Retest (continued)

- When you receive incident reports or complaints
- When you become aware of a manufacturing or materials defect

Who Can Perform Testing?

- There are no provisions in the law or in the regulations that restrict who can perform the testing.
- If a test is conducted in accordance with the regulations, the test should be valid.
- CPSC maintains a list of firms that have informed us that they conduct testing in accordance with the PPPA regulations.
 CPSC does not endorse those firms.

Questions?