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LOG OF MEETING

SUBJECT: Child-Resistant Packaging

DATE OF MEETING: October 15, 1997

PLACE: Sands Expo and Convention Center, Las Vegas, Nevada

LOG ENTRY SOURCE: Suzanne Barone, Ph.D., Pharmacologist, HSPS *sz*

COMMISSION REPRESENTATIVE: Suzanne Barone, Ph.D.

NON-COMMISSION REPRESENTATIVE: Attendees of Conference

SUMMARY OF MEETING:

A talk entitled, "Don't Gamble With Your Packages: Make Them Senior-Adult-Use-Effective" was presented at the Solutions97 Packaging and Processing Technology Conference. The Conference was sponsored by the Packaging Machinery Manufacturers Institute and the Food Processing Machinery and Supplies Association. A copy of the Conference Proceeding prepared by Suzanne Barone is attached.



Don't Gamble With Your Packages: Make Them Senior-Adult-Use-Effective
Suzanne Barone, Ph.D.*
U.S. Consumer Product Safety Commission

The U.S. Consumer Product Safety Commission (CPSC) administers the Poison Prevention Packaging Act of 1970 (PPPA), which authorizes special packaging requirements for hazardous household substances. These requirements protect children from serious personal injury or serious illness from handling, using, or ingesting the substances. Twenty-four different substances and product categories, including most human oral prescription drugs, aspirin, methanol, and ethylene glycol, require special packaging (16 CFR § 1700.14).

Special packaging is defined as "packaging that is designed or constructed to be significantly difficult for children under 5 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, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time" (15 USC 1471(2)(4), 16 CFR § 1700.1(b)(4)). Regulations issued under the PPPA establish performance test methods and standards that determine if a package is child-resistant and adult-use-effective (16 CFR § 1700.15 and 16 CFR § 1700.20).

The Commission issued revised test methods in July 1995 (60 FR 37710). The revisions to the child test will make the test results more consistent and the test easier to perform, without adversely affecting the ability of the test to determine child-resistance (Attachment 1). The revised child test protocol allows testing for child-resistance by using sequential groups of 50 children, rather than using a full 200-child panel each time, until a statistically valid determination of whether the package is child-resistant is obtained, or until 200 children are tested (Attachment 2). When tested according to the methods, 80 percent of tested children (41-52 months old) must not be able to access the package.

The revisions to the adult test were issued in order to increase the use of child-resistant packaging by making it easier for adults to open. The revised method tests 100 adults aged 50 to 70, instead of the original 18 to 45 year-old age group (Attachment 3). Packaging must be accessible to 90 percent of the tested adults. Most packaging must comply with these revised standards. The exception to this are products that require either metal containers with metal closures or aerosols. These products must be accessible to 90 percent of adults tested aged 18 to 45 (16 CFR § 1700.15(b)(2)(ii)).

The PPPA requires that the effective date of a regulation establishing a special packaging standard shall not be later than 1 year after the date the regulation is published in the Federal Register. The revised test methods were published in July 1995 (60 FR 37710) with a 1-year effective date. The

Commission recognized that the revised standard may affect as many as three billion packages annually. This requires action on the part of closure manufacturers, as well as packagers of products subject to regulations, manufacturers of bottles and containers, mold manufacturers, and other firms involved in the packaging and distribution of products subject to PPPA regulations. In adopting these protocol revisions, the Commission wanted to (i) minimize any commercial disruption, (ii) allow for a more orderly transition to packaging that complies with the revised requirements, and (iii) help assure that — consistent with the results of CPSC testing on certain currently available packages — any other new packaging designs or modifications provide ease of adult use without sacrificing child resistance. Therefore, the Commission granted companies a blanket exemption from having to comply with the revised adult protocol for 18 months after it goes into effect. The exemption from the senior-adult requirement will apply only to products that comply with the younger-adult requirement.

The Commission believes that the additional 18 months will provide adequate time for affected firms to make any necessary changes to their packages or machinery, and to place timely orders for complying packaging to assure delivery well in advance of the effective date. Packages are required to comply with the new senior-adult requirements as of January 21, 1998.

The Commission also recognized, however, that unique circumstances may arise that require additional time for individual firms to comply. The Commission will therefore also consider requests for additional reasonable enforcement stays after the expiration of the 18-month exemption.

The Commission, through appropriate staff, shall grant a request for an enforcement stay that demonstrates, based upon supporting information and documentation, (i) a good-faith effort to obtain packaging that complies with the revised standards during the period after publication of the final rule in the Federal Register, and (ii) compliance with one of the following criteria:

1. *Delay in Protocol Testing.* Protocol testing likely will not be completed within the time required to enable complying packages to be used by the applicable deadline. Estimated dates upon which testing will be completed and complying products will be produced shall be submitted. (Several protocol testing firms should be contacted to obtain the earliest completion date.) (A list of firms is in Attachment 4.)
2. *Product Testing.* Required FDA testing likely will not be completed within the time required to enable complying packages to be used by the applicable deadline. Estimated dates by which testing will be completed and complying products will be produced shall be submitted.

3. *Equipment.* Necessary manufacturing equipment will likely not be available within the time required to manufacture finished products in compliance with the revised requirements. The estimated date by which equipment will be in use and complying CRP will be produced shall be submitted.
4. *CRP Availability.* Where CRP is claimed to be unavailable, an explanation shall be provided of why currently available, alternative CRP cannot reasonably or practicably be used. An estimated date by which complying CRP will be obtained and produced shall also be submitted.
5. *Redesigned/New CRP: Maintaining Child Resistance.* Where a claim is made that CRP will have to be redesigned or developed, an explanation shall be provided of why commercially available packaging cannot reasonably or practicably be used. The rationale for a temporary enforcement stay under this provision may include, among other reasons, that more time is reasonably needed to develop a CRP that will meet the new adult protocol and not significantly reduce the child resistance of the package. An estimated date by which complying CRP will be obtained and produced shall also be submitted.
6. *Other.* Other substantial reasons demonstrating that additional time is reasonably necessary to comply with the amended protocol. An estimated date by which complying CRP will be obtained and implemented shall be submitted.

The Commission, through appropriate staff, shall issue a decision granting or denying the request for a temporary stay of enforcement within 30 days after receipt of the request and appropriate supporting material. All requests for enforcement stays, including any supporting data or information, for which claims of confidentiality are made, shall be considered confidential and exempt from public disclosure to the extent allowable by law.

For additional information about the protocol test methods please call Suzanne Barone, at (301) 504-0477 ext. 1196. For compliance information call Laura Washburn, at (301) 504-0400 ext. 1452.

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CHILD TEST PROTOCOL

PREVIOUS

200 children

10 age groups

(42-51 months)

50% boys/50% girls

5 min. - demo - 5 min.
Use of teeth

85% after 5 minutes
80% after 10 minutes

NEW

Sequential test
50 children up to 200

3 age groups
(Months)
42-44, 45-48, 49-51
30% 40% 30%
Standardized age
calculation

50% boys/50% girls

5 min. - demo - 5 min.
Use of teeth
Standardized test
instructions

85% after 5 minutes
80% after 10 minutes
For 200 children

Tester - No more than
30% children tested
Site - No more than 20%
of children tested

Attachment 2

SEQUENTIAL CHILD TEST*

| Test Panel | # Children | 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 + |

* From 60 FR 37736

ADULT TEST PROTOCOLS

ADULT

100 adults

18-45 years old
random selection

70% female

5 minute test period

90% adult-use
effectiveness

Tester - No more than
35% adults tested (3)
Site - No more than 35%
of adults tested (3)

Metal cans and aerosols

SENIOR

100 adults

50-70 years old
50-54, 55-59, 60-70
25% 25% 50%

70% female

5 minute/1 minute test
period
Screening tests for
unsuccessful participants
Standardized test
instructions

90% adult-use
effectiveness

Tester - No more than
35% adults tested(3)
Site - No more than 24%
of adults tested (5)

All regulated products
except those in metal
cans and aerosols

Attachment 4

CHILD-RESISTANT PACKAGE TESTING

The Consumer Product Safety Commission (CPSC) is aware that the following firms that have conducted tests or have indicated an interest in conducting tests on child-resistant packaging, following the procedures in 16 CFR 1700.20. (CPSC does not approve, certify, or endorse these firms.)

American Institute for Research
3333 K St. N. W.
Washington, D.C. 20007
(202) 342-5000
Michael Wiklund
Patricia Shettel

Bell Technologies - Testing Division
1133 Rt. 23 South
Wayne, N.J. 07470
(201) 628-1363
Susan Roth

Child Related Research, Inc.
2605 East 3300 South
Salt Lake City, Utah 84109
(801) 467-9440
Michael Buie

Forensic Packaging Concept, Inc.
2624 Moss Lane
Marietta, GA 30067
(770) 818-0091
Jack L. Rosette, Ph.D.

Gene Miller Testing Service
1508 Sunset Ave.
Lancaster, PA 17601
(717) 581-6602
David S. Hipple

Dr. Gerald Greenway
UM-R Package Sealing Labs
217 Engineering Man.
Rolla, MO 65401
(314) 341-6153

Great Lakes Marketing Assoc., Inc.
The Executive Building
3103 Executive Parkway
Toledo, Ohio 43606-1311
(419) 534-4700
Lori Dixon, Ph.D.

Home Arts Guild Research Ctr.
35 E. Wacker Drive
Chicago, Illinois 60601
(312) 726-7406
Roy Roberts

International Research Services
222 Grace Church St.
Port Chester, NY 10573
914-937-6500
Edward Boisits, Ph.D.

Maritz Market Research, Inc.
1297 No. Highway Drive
Fenton, Missouri 63099
(800) 325-3338

Milford Consulting Associates
80 Ocean Avenue
Milford, CT 06460
(203) 876-0948
Gerald O. Cavallo, Ph.D.

New Institutional Research Service
555 Tilton Road
Northfield, NJ 08225
(609) 646-4545

Perritt Laboratories, Inc.
145 So. Main St. (P.O. Box 147)
Hightstown, N.J. 08520-0147
(609) 443-4848
Richard Ward

Product and Market Studies
718 Republic Drive
Rolla, MO 65401
(314) 364-8371

Promatura Group
428 North Lamar
Oxford, MS 38655
(601) 234-0158
Margaret A. Wylde, Ph.D.

SGS U.S. Testing Company Inc.
291 Fairfield Avenue
Fairfield, NJ 07004
(201) 575-5252
Leon, Venech

Shuster Laboratories, Inc.
5 Hayward St.
Quincy, MA 02171
(617) 328-7600
Nancy Dravis

Stephens and Associates
3310 Keller Springs Road
Suite 130
Carrollton, TX 75006
(214) 392-1529

TestPak Inc.
34-36 Troy Road
Wippany, N.J. 07981
(201) 887-4440
Evelyn Malinosky

THX, Inc.
Tenco Laboratories Division
1150 Junction Avenue
Schererville, Indiana 46375

U.S. Research Company
300 Marguardt Drive
Wheeling, Illinois 60090
(847)-520-3600

Walker Information
6963 Hillsdale Court
Indianapolis, IN 46250-2054
(317) 576-5433
Kristina K. Leonard

Youth Research
36 Tamarack Ave.
Suite 107
Danbury, CT 06811
(203) 797-0666
Karen M. Forcade

firmtest.ls2 July 23, 1997