LOG OF MEETING

SUBJECT: PPPA Protocol Revisions

DATE OF MEETING: March 28, 1995

PLACE: Jacob Javits Convention Center, New York City, New York

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

COMMISSION REPRESENTATIVE: Suzanne Barone

NON-COMMISSION REPRESENTATIVE: Attendees of the InterphexUSA Conference.

SUMMARY OF MEETING:

Suzanne Barone, Ph.D. presented a discussion of the Poison Prevention Packaging Act and the proposed revisions to the test procedures at the InterphexUSA Conference. The session was entitled, "Responsible Packaging: Child-Resistant, Senior-Friendly, and Tamper-Evident Packaging and the Consumer. A copy of the material presented is attached.

POISON PREVENTION PACKAGING ACT

Suzanne Barone, Ph.D.

Project Manager for Poison Prevention

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I. Poison Prevention Packaging Act

A. Purpose
B. Ingestions and Deaths
C. Substances
D. Special Packaging

II. Proposed Changes

A. Child Test
B. Adult Test

THE POISON PREVENTION PACKAGING ACT

by

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U.S. Consumer Product Safety Commission[1]

The Consumer Product Safety Commission (CPSC) administers the regulations of the Poison Prevention Packaging Act of 1970 (PPPA). The PPPA authorizes the CPSC to issue special packaging standards for household substances that present a threat of serious personal injury or illness to young children. Special packaging is defined as packaging designed to be significantly more difficult for children under 5 years of age to open in a reasonable time (child-resistant effectiveness), and not difficult for normal adults to use properly (adult-use effectiveness).

The test procedure (16 CFR 1700.20(a)(1)) now used to measure child-resistance involves testing 200 children (approximately 50 percent boys and 50 percent girls) between the ages of 42 and 51 months, equally distributed among 10 specified age groups. The children are tested in pairs and are given 5 minutes to open a package; they are given a single demonstration of how to open the package and are given 5 more minutes to attempt to open the package. The current regulations (16 CFR 1700.15(b)(1)) require a child-resistant effectiveness of not less than 85 percent before the demonstration and not less than 80 percent after the demonstration.

The procedure currently used to measure adult-use effectiveness tests 100 adults between the ages of 18 and 45. Seventy percent of the participants are women. The participants are given 5 minutes to open and properly close (if

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applicable) the package. The current regulations require an adult-use effectiveness of not less than 90 percent.

The Commission proposed changes to the child and adult test procedures. The proposed changes to the test for child-resistance included reducing the number of age groups from 10 to 3 (42-44 months, 45-48 months, and 49-51 months), standardizing the age calculation, instituting site and tester limitations (no tester would test more than 30 percent of children and no more than 20 percent of children would be tested at one site), and allowing the sequential testing of groups of 50 children to determine child-resistance. These changes to the child test were proposed to make it easier to sample children and to standardize the test method.

The Commission proposed to substitute a panel of 60 to 75-year-old participants for the current panel of 18 to 45-year-old participants to measure adult-use effectiveness. A two time period test was proposed. Participants who successfully open the package during an initial 5 minute period would then be given 1 minute to open and properly close an identical package. The proposed 5 minute/1 minute senior test include dividing the 60-75 year old age group into two age groups (60-70, and 71-75) to assure a more uniform spread of subjects throughout the age range. The age groups are allocated as follows: 60 percent ages 60-70, and 40 percent ages 71-75. The test data from the age groups are then weighted so the 71-75 year old group is not more heavily represented. Seniors are tested sequentially in panels of 100, until a statistically reliable pass/fail determination can be made or 400 adults are tested. Test participants are limited to seniors who demonstrate the ability to open and resecure non-child-resistant packaging. The Commission proposed including standardized instructions for the child and the senior tests in the rule.

POISON PREVENTION

The goal is to reduce childhood injuries and deaths associated with exposure to household chemical products.

.e National Center for Health Statistics in Washington, D.C. receives mortality reports from all 50 states. The annual data reports show that the number of deaths involving all household products among children under five years of age declined since 1972. The Consumer Product Safety Commission also examines the number of deaths resulting from the accidental ingestion of aspirin-containing products. The first regulation passed under the Poison Prevention Packaging Act required child-resistant packaging for aspirin. At the time the regulation passed, aspirin products were the most frequently ingested product by young children.

DEATHS OF CHILDREN UNDER AGE 5 INVOLVING HOUSEHOLD PRODUCTS

Deaths Due To All Household Chemicals			Deaths Due To Aspirin Products		
Year	# Deaths	Decline since 1972	Year	# Deaths	Decline since 1972
1972	216	---	1972	46	---
1973	149	31%	1973	26	43%
1974	135	38%	1974	24	48%
1975	114	47%	1975	17	63%
1976	105	51%	1976	25	46%
977	94	56%	1977	11	76%
)78	81	63%	1978	13	72%
_979	78	64%	1979	8	83%
1980	73	66%	1980	12	74%
1981	55	75%	1981	6	87%
1982	67	69%	1982	5	89%
1983	55	75%	1983	7	85%
1984	64	70%	1984	7	85%
1985	56	74%	1985	0	100%
1986	59	73%	1986	2	96%
1987	31	86%	1987	3	93%
1988	42	81%	1988	3	93%
1989	55	75%	1989	2	96%
1990	49	77%	1990	1	98%
1991	62	71%	1991	2	96%
1992	42	81%	1992	0	100%

SUBSTANCES - 16 CFR 1700.14

Aspirin
Furniture Polish
Methyl Salicylate
Controlled Drugs
Sodium and Potassium Hydroxide
Turpentine
Kindling and Illuminating Preparations
Methyl Alcohol
Sulfuric Acid
Oral Prescription Drugs
Ethylene Glycol
Iron-containing Drugs
Iron-containing Dietary Supplements
Paint Solvents
Acetaminophen
Diphenhydramine
Glue Removers with Acetonitrile
Permanent wave neutralizers with sodium or potassium bromate
Ibuprofen
Loperamide
Lidocaine/dibucaine
Ethanol-containing Mouthwash

DEFINITION

SPECIAL PACKAGING OR CHILD-RESISTANT PACKAGING

PACKAGING THAT IS DESIGNED OR CONSTRUCTED TO BE SIGNIFICANTLY DIFFICULT FOR CHILDREN UNDER 5 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.

OR

CHILD-RESISTANT

AND

ADULT-USE EFFECTIVE

CHILD TEST PROTOCOLS

CURRENT	PROPOSED
200 children	*Sequential test* *50 children up to 200*
10 age groups (42-51 months)	*3 age groups* *42-44, 45-48, 49-51* *30% 40% 30%* *Standardized age calculation*
50% boys/50% girls	50% boys/50% girls
5 min. - demo - 5 min. Use of teeth	5 min. - demo - 5 min. Use of teeth *Standardized test instructions*
85% after 5 minutes 80% after 10 minutes	85% after 5 minutes 80% after 10 minutes
	Tester - No more than 30% children tested *Site - No more than 20% of children tested*

ADULT TEST PROTOCOLS

CURRENT	PROPOSED
100 adults	Sequential test 100 adults to 400 adults
18-45 years old random selection	60-75 years old 60-70, 71-75 60% 40% weighted
70% female	70% female
5 minute test period	5 minute/1 minute test period Screening tests for unsuccessful participants Standardized test instructions
90% adult-use effectiveness	Proportions of success 0.900 after 400 adults.
	Tester - No more than 35% adults tested Site - No more than 24% of adults tested.