

CPSA 6 (b)(1) Cleared

No. of Products Identified

Presented by

Date

Comments

LOG OF MEETING

SUBJECT: PPPA Protocol Revisions

DATE OF MEETING: June 27, 1994

PLACE: CPSC Headquarters, Bethesda, MD. Room 518.

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

COMMISSION REPRESENTATIVE: See attached list

NON-COMMISSION REPRESENTATIVE: See attached list.

SUMMARY OF MEETING:

Representatives from Perritt Laboratories requested a meeting to discuss their comments on the proposed changes to the PPPA test protocols. (A copy of the comments is attached). Dr. Perritt emphasized the three points from the written comments. The use of the consent forms for child-testing will have the most impact on the ability of their agency to test packages. Consent forms decrease the population of children available to be tested. It will result in increased time and expense to conduct child tests.

Dr. Perritt also requested that the two lowest age groups in the senior test be combined. There are no reported differences between these groups and the 60-64 year old (especially men) are more difficult to locate for testing. Combining the 60-64 with the 65-70 year old groups will make it easier to complete a test. The company also requested that the instructions be clarified so that people can only test two packages per sitting rather than per lifetime as the current instructions imply.

The staff assured Dr. Perritt that all the comments were being considered. The staff appreciated receiving data to document many of the comments. The staff estimates that a briefing package for the final rule will be presented to the Commission in December 1994.

Perritt Laboratories

6/27/94

10:30 a.m.

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Alex Perritt	Perritt Labs	609-443-4848
Michael Bogumill	CPSC/CERM	301-504-0400 x1368
NICK WILBUR	CPSC/HSPS	301-504-0477 Ex 1262
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CP 44-1-11

PERRITT LABORATORIES

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May 18, 1994

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, MD 20814

SUBJECT: Comments on: Federal Register, Vol. 59, No. 54, March 21, 1994, pages 13264-13275, "16 CFR Part 1700", "Requirements for the Special Packaging of Household Substances; Request for Comment on Additional Data Concerning Proposed Rule"

My name is Dr. Alexander M. Perritt. I am the president and founder of Perritt Laboratories, Incorporated. We are an independent testing laboratory that specializes in testing packaging for child-resistance. We have been evaluating child-resistant packaging for both industry and the government since 1973. During that time we have tested thousands of different packages on hundreds of thousands of panelists.

Highlights of my background with child-resistant packaging dates includes the following:

- 1969 Assisted the committee headed by Dr. Edward Press during the formulation of the child-resistant protocol as it stands today.
- 1972 Supervised an FDA study that evaluated and critiqued the current child-resistant protocol.
- 1973- Founded Perritt Laboratories, Inc., and continue to conduct studies evaluating child-resistant packaging for both industry and government.
- 1973- Member of the American Society for Testing and Materials (ASTM) D10.31 subcommittee on child-resistant packaging, and the secretary of the subcommittee since 1982.
- 1974-76 Served on the CPSC technical advisory committee on poison prevention packaging.
- 1982- Delegate to the International Standards Organization (ISO).
- 1984 Expert witness for the CPSC in a federal compliance case involving child-resistant packaging.



- 1988 Acted as a member of a panel of experts, at the request of CPSC, to critique a number of child-resistant packaging concepts which were developed at three universities.
- 1991 Represented the position of the United States at an ISO meeting in the United Kingdom.
- 1991 Recipient of ASTM's Award of Merit, and made me a Fellow of the Society for my efforts in the area of child-resistant packaging.

Perritt Laboratories, Inc., is the testing agency that conducted the recent testing of the new protocol using senior adults (under a CPSC contract) to generate data to determine if the proposal was practical and feasible. We were the ones whom originally proposed the 5 minute, one minute test for seniors during the December 1990 open meeting with the CPSC in Washington, D.C.

The CPSC has concluded that if difficult-to-use packages were replaced with packages that are easier to use, more people of all ages would purchase and properly use child-resistant packaging, with a reduction in the number of poisonings of children. To accomplish this goal, the test structure for child-resistant packaging has been changed, and all packaging will be required to meet the new, more stringent standard.

I understand and agree with the CPSC that child-resistant packaging should be made more "user-friendly." I also agree with the major changes which you have proposed to the protocol.

Based upon the protocol changes, all packaging will need to be retested (within the one-year allowable time), however, there are three items that would have a significant effect on the speed, cost, and volume of testing which could be carried out.

1. Consent Forms

On page number 13269 of the Federal Register, Vol. 59, No. 54, Monday, March 21, 1994, in section (B) in the second paragraph of the second column, it is states: "Each child's parent or guardian shall read and sign a consent form prior to the child's participation."

The need for consent forms, as this statement infers, will have a great impact on our ability to conduct child testing. The following points should be carefully considered regarding the need for consent forms for child panelists:

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- a) The CPSC tried to require consent forms before, in the late 1970's. However, they decided not to act upon this because of the undesirable comments they received.
- b) No recorded problems that have occurred with any of the child-resistant testing which has been conducted for over 25 years, involving hundreds of thousands of child panelists. It can be concluded that the testing is not a threat.
- c) Studies we perform for the CPSC have required the use of consent forms. We have been able to carry out these contracted studies in a timely fashion, because a portion of the test sites accept the use of consent forms. However, the contract studies we perform for the government represents less than 6% of our studies, so it does not create a major problem for us. Even at schools that require consent forms, we may only be able to test half the children present because we are unable to get forms for all the children in attendance.
- d) Consent forms are not required by the International Standards Organization (ISO), or the European Community (EC) for child-resistant package testing.
- e) In one of the studies we conducted for the CPSC, the methodology for evaluating cigarette lighters was evaluated employing child panelists. Since consent forms were necessary for this CPSC testing, we found that we were only able to conduct four 50 child panel tests a year because of the difficulty in obtaining signed consent forms. Because of this problem, we decided not to do any further testing with lighters and have since turned away up to 12 industrial type cigarette lighter studies.
- f) Only 24.6% of the test sites (approximately 16% of the total child panelist base) we currently visit use some form of consent.

Based on our experience with these sites, it is expected that we will lose approximately 65% of our child test base at non-consent form schools if we are forced to employ consent forms.

- g) When dealing with consent forms, there is a reduction in the number of participating panelists because:
 - * Few parents sign and return forms to schools
 - * Directors of schools do not want to take the time and trouble that is necessary to handle the paper work involved with consent forms.
 - * Summer camps meet on a weekly only basis, and most day care centers will not use consent forms during the summer programs.

Nursery schools are closed during the summer.

The requiring of child consent forms will result in the following:

- * **Need to drastically increase the number of child test sites.**
- * **Travel time to/from the sites will greatly increase.**
- * **The sites will have fewer children to test, because few children will have their signed consent forms.**
- * **Need to hire a person who will be only responsible for coordinating the consent forms (delivered, sent home, signed, completed, returned, and filing).**
- * **Little to no child testing will be done from the end of June to the middle of September.**

There is no question that requiring consent forms for child testing will:

- * **Significantly reduce the data base of child panelists.**
- * **Increase test costs.**
- * **Increase time to complete a test.**
- * **Delay the test schedule for meeting Federal Register requirements**

We propose eliminating all mention of child consent forms from the protocol.

2. Combine 60 to 64 and 65 to 70 year old age groups

The new senior adult panel is grouped into three different age categories: 60 to 64 year olds, 65 to 70 year olds, and 71 to 75 year olds. In order to speed testing, we propose that the two lower age groups be combined.

We have experienced problems in obtaining panelists in the 60 to 64 year old age range. Most people of this age are still working, so they are extremely difficult to find in a group setting.

In a series of correspondence/reports during July and August of 1993 from Dr. Terry L. Kissinger to Suzanne Barone, Ph.D., of the CPSC, Dr. Kissinger states:

"Thus, using a significant level of 0.05, there does not seem to be a difference in the proportions for the 60-64 and 65-70 age groups for any of these CR packages."

"The 60-64 and 65-70 age groups perform quite similarly in CR testing, with

little difference in their sample proportions."

"The results showed that the 60-64 and 65-70 age groups were not significantly different in performance;..."

We propose the combining of the 60 to 64 year old age group with the 65 to 70 year old age group.

3. Adults may only participate in two tests per sitting

Federal Register, Vol. 59, No. 54,
Monday March 21, 1994, Proposed Rules, Page 13271
Test Instructions for Senior Test, third column, No. 15.

Current wording:

"No adult may participate in more than two tests. If a person participates in two tests, the packages tested shall not be the same ASTM type of package."

Proposed wording:

"No adult may participate in more than two tests *per sitting*. If a person participates in two tests, the packages tested shall not be the same ASTM type of package."

Rationale:

1. Strict interpretation of the current wording would mean that an adult may participate in no more than two tests during his/her entire lifetime. If an adult may only participate in two tests once during his/her lifetime, there will be significant effects on the available testing base. It would mean:
 - a) Sites may only be used once every 15 years.
 - it would take 60 year olds 15 years to "age out" of the 60 to 75 year age bracket.
 - b) The available test population would decrease drastically.
 - once an adult participates in two tests, he/she is eliminated from the available test base forever.
 - c) Time to complete a test would increase significantly.
 - thousands of new test sites would be needed for testing.
 - d) Costs to complete a test would increase significantly.

2. The intent of limiting an adults participation to no more that two tests "per

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sitting" is to avoid the effects of fatigue due to continuous testing. Since each adult has had a lifetime of learning how to open child-resistant packaging, subsequent testing at another time is not a concern.

The above three items are of great concern to us, because they can drastically effect our ability to conduct child-resistant package testing. Please consider these items very carefully before any final ruling is made.

Sincerely,

PERRITT LABORATORIES, INC.

A handwritten signature in cursive script that reads "Alexander M. Perritt". The signature is written in dark ink and is positioned below the typed name of the company.

Alexander M. Perritt, Ph.D.
President