



**New U.S. Regulation of E-liquid Containers Under the
Child Nicotine Poisoning Prevention Act of 2015 (the "Act")**

- **Who's Covered and What's Covered?:** The Act gives the Consumer Product Safety Commission (CPSC) jurisdiction over anyone selling a "liquid nicotine container" in or into the U.S. and controls the packaging of such containers under the Poison Prevention Packaging Act (PPPA).
 - A "liquid nicotine container" includes containers holding e-liquids and is defined as a "package" from which nicotine (in any concentration) in a solution is accessible by a consumer through normal and foreseeable use.
 - The definition does NOT include "sealed, prefilled, and disposable" containers that are inserted directly into an e-cigarette and where the e-liquid is inaccessible to the consumer.
 - Hence, the Act *includes* e-liquid nicotine containing bottles sold for open systems, but *excludes* closed system products and non-nicotine products.
- **Child Resistant Packaging Standards and Testing:** The purpose of PPPA regulations is to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting regulated substances.
 - Under the Act, any e-liquids offered for sale in the United States will have to comply with the CPSC's standards for child resistant packaging, which are already defined in existing regulations under the PPPA. The PPPA **packaging standards** can be found at 16 CFR 1700.15 and here are some key standards:
 - Children shown how to open the package must be unsuccessful 80% of the time (§1700.15(b)(1)).
 - Seniors-adults must be able to open the package at least 90% of the time (§1700.15(b)(2)).
 - The Act also requires you to conduct **testing** and to certify your compliance with PPPA standards. Detailed PPPA **testing procedures** can be found at 16 CFR 1700.20.
 - To review the CPSC's "Guide to Child Resistant and Senior-Friendly Packages," [click here](#).
 - For the CPSC's list of firms that conduct tests on child resistant packaging under the PPPA, [click here](#).
- **New Regulations Will Preempt State/Local Laws:** While the Act is silent on the issue, it is well established that CPSC regulation will preempt state and local requirements applicable to the same product.
 - The PPPA, at 15 USC 1476, specifically preempts state and local standards on child resistant packaging that are not identical to the CPSC standard. This means that only state regulations or laws addressing child resistant packaging would be preempted; state regulation of e-liquids in other areas would not be impacted.
- **No Impact on HHS Regulation:** The Act specifically states that it will have NO impact on FDA's authority to regulate these products under the Tobacco Control Act, nor would it have any impact on FDA's authority related to its deeming regulation. *However*, the Act will require FDA to consult with and take into account the expertise of the CPSC if the FDA wants to adopt any packaging requirements for e-liquids.
- **Get Prepared!** The child resistant packaging requirements of the Act go into effect the week of July 25, 2016.

VTA offers this information for informational guidance only; not legal advice.

You must consult an attorney to make sure you comply with the Act.

If you are interested in learning more, please email us at guidance@vaportechnology.org

EDITORIAL NOTE: FOR FEDERAL REGISTER citations affecting §1700.14, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 1700.15 Poison prevention packaging standards.

To protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, the Commission has determined that packaging designed and constructed to meet the following standards shall be regarded as “special packaging” within the meaning of section 2(4) of the act. Specific application of these standards to substances requiring special packaging is in accordance with §1700.14.

(a) *General requirements.* The special packaging must continue to function with the effectiveness specifications set forth in paragraph (b) of this section when in actual contact with the substance contained therein. This requirement may be satisfied by appropriate scientific evaluation of the compatibility of the substance with the special packaging to determine that the chemical and physical characteristics of the substance will not compromise or interfere with the proper functioning of the special packaging. The special packaging must also continue to function with the effectiveness specifications set forth in paragraph (b) of this section for the number of openings and closings customary for its size and contents. This requirement may be satisfied by appropriate technical evaluation based on physical wear and stress factors, force required for activation, and other such relevant factors which establish that, for the duration of normal use, the effectiveness specifications of the packaging would not be expected to lessen.

(b) *Effectiveness specifications.* Special packaging, tested by the method described in §1700.20, shall meet the following specifications:

(1) Child-resistant effectiveness of not less than 85 percent without a demonstration and not less than 80 percent after a demonstration of the proper means of opening such special packaging. In the case of unit packaging, child-resistant effectiveness of not less than 80 percent.

(2) *Ease of adult opening*—(i) *Senior-adult test.* Except for products specified in paragraph (b)(2)(ii) of this section, special packaging shall have a senior adult use effectiveness (SAUE) of not less than 90% for the senior-adult panel test of §1700.20(a)(3).

(ii) *Younger-adult test*—(A) *When applicable.* Products that must be in aerosol form and products that require metal containers, under the criteria specified below, shall have an effectiveness of not less than 90% for the younger-adult test of §1700.20(a)(4). The senior-adult panel test of §1700.20(a)(3) does not apply to these products. For the purposes of this paragraph, metal containers are those that have both a metal package and a recloseable metal closure, and aerosol products are self-contained pressurized products.

(B) *Determination of need for metal or aerosol container*—(1) *Criteria.* A product will be deemed to require metal containers or aerosol form only if:

(i) No other packaging type would comply with other state or Federal regulations,

(ii) No other packaging can reasonably be used for the product’s intended application,

(iii) No other packaging or closure material would be compatible with the substance,

(iv) No other suitable packaging type would provide adequate shelf-life for the product’s intended use, or

(v) Any other reason clearly demonstrates that such packaging is required.

(2) *Presumption.* In the absence of convincing evidence to the contrary, a product shall be presumed not to require a metal container if the product, or another product of identical composition, has previously been marketed in packaging using either a nonmetal package or a nonmetal closure.

(3) *Justification.* A manufacturer or packager of a product that is in a metal container or aerosol form that the manufacturer or packager contends is not required to comply with the SAUE requirements of §1700.20(a)(3) shall provide, if requested by the Commission’s staff, a written explanation of why the product must have a metal container or be an aerosol. Manufacturers and packagers who wish to do so

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voluntarily may submit to the Commission's Office of Compliance a rationale for why their product must be in metal containers or be an aerosol. In such cases, the staff will reply to the manufacturer or packager, if requested, stating the staff's views on the adequacy of the rationale.

(c) *Reuse of special packaging.* Special packaging for substances subject to the provisions of this paragraph shall not be reused.

(d) *Restricted flow.* Special packaging subject to the provisions of this paragraph shall be special packaging from which the flow of liquid is so restricted that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is taken or squeezed once or when the container is otherwise activated once.

(Secs. 2(4), 3, 5, 84 Stat. 1670-72; 15 U.S.C. 1471(4), 1472, 1474)

[38 FR 21247, Aug. 7, 1973, as amended at 60 FR 37734, July 21, 1995]

§ 1700.20 Testing procedure for special packaging.

(a) *Test protocols*—(1) *General requirements*—(i) *Requirements for packaging.* As specified in §1700.15(b), special packaging is required to meet the child test requirements and the applicable adult test requirements of this §1700.20.

(ii) *Condition of packages to be tested*—(A) *Tamper-resistant feature.* Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design. Where a package is supplied to the consumer in an outer package that is not part of the package's child-resistant design, one of the following situations applies:

(1) In the child test, the package is removed from the outer package, and the outer package is not given to the child.

(2) In both the adult tests, if the outer package bears instructions for how to open or properly resecure the package, the package shall be given to the test subject in the outer package. The time required to remove the package from the outer package is not counted in the times allowed for attempting to open and, if appropriate, reclose the package.

(3) In both the adult tests, if the outer package does not bear any instructions relevant to the test, the package will be removed from the outer package, and the outer package will not be given to the test subject.

(B) *Reclosable packages—adult tests.* In both the adult tests, reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to beginning the test to allow the materials (e.g., the closure liner) to "take a set." If assembled by the testing agency, torque-dependent closures shall be secured at the same on-torque as applied on the packaging line. Application torques must be recorded in the test report. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

(2) *Child test*—(i) *Test subjects*—(A) *Selection criteria.* Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in table 1. No more than 20% of the children in each group shall be tested at or obtained from any given site. Each group of children shall be randomly selected as to age, subject to the limitations set forth below. Thirty percent of the children in each group shall be of age 42-44 months, 40% of the children in each group shall be of age 45-48 months, and 30% of the children in each group shall be of age 49-51 months. The children's ages in months shall be calculated as follows:

(1) Arrange the birth date and test date by the numerical designations for month, day, and year (e.g., test date: 8/3/1990; birth date: 6/23/1986).

(2) Subtract the month, day, and year numbers for the birth date from the respective numbers for the test date. This may result in negative numbers for the months or days. (e.g.,

$$\begin{array}{r} 8 / 03 / 1990 \\ -6 / 23 / 1986 \\ \hline 2 -20 \quad 4 \end{array}$$

(3) Multiply the difference in years by 12 to obtain the number of months in the difference in years, and add this

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voluntarily may submit to the Commission's Office of Compliance a rationale for why their product must be in metal containers or be an aerosol. In such cases, the staff will reply to the manufacturer or packager, if requested, stating the staff's views on the adequacy of the rationale.

(c) *Reuse of special packaging.* Special packaging for substances subject to the provisions of this paragraph shall not be reused.

(d) *Restricted flow.* Special packaging subject to the provisions of this paragraph shall be special packaging from which the flow of liquid is so restricted that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is taken or squeezed once or when the container is otherwise activated once.

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(1) In the child test, the package is removed from the outer package, and the outer package is not given to the child.

(2) In both the adult tests, if the outer package bears instructions for how to open or properly resecure the package, the package shall be given to the test subject in the outer package. The time required to remove the package from the outer package is not counted in the times allowed for attempting to open and, if appropriate, reclose the package.

(3) In both the adult tests, if the outer package does not bear any instructions relevant to the test, the package will be removed from the outer package, and the outer package will not be given to the test subject.

(B) *Reclosable packages—adult tests.* In both the adult tests, reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to beginning the test to allow the materials (e.g., the closure liner) to "take a set." If assembled by the testing agency, torque-dependent closures shall be secured at the same on-torque as applied on the packaging line. Application torques must be recorded in the test report. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

(2) *Child test*—(i) *Test subjects*—(A) *Selection criteria.* Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in table 1. No more than 20% of the children in each group shall be tested at or obtained from any given site. Each group of children shall be randomly selected as to age, subject to the limitations set forth below. Thirty percent of the children in each group shall be of age 42-44 months, 40% of the children in each group shall be of age 45-48 months, and 30% of the children in each group shall be of age 49-51 months. The children's ages in months shall be calculated as follows:

(1) Arrange the birth date and test date by the numerical designations for month, day, and year (e.g., test date: 8/3/1990; birth date: 6/23/1986).

(2) Subtract the month, day, and year numbers for the birth date from the respective numbers for the test date. This may result in negative numbers for the months or days. (e.g.,

$$\begin{array}{r} 8 / 03 / 1990 \\ -6 / 23 / 1986 \\ \hline 2 -20 \quad 4 \end{array}$$

(3) Multiply the difference in years by 12 to obtain the number of months in the difference in years, and add this

value to the number of months that was obtained when the birth date was subtracted from the test date (i.e., $4 \times 12 = 48$; $48 + 2 = 50$). This figure either will remain the same or be adjusted up or down by 1 month, depending on the number of days obtained in the subtraction of the birth date from the test date.

(4) If the number of days obtained by subtracting the days in the birth date from the days in the test date is +16 or more, 1 month is added to the number of months obtained above. If the number of days is -16 or less, subtract 1 month. If the number of days is between -15 and +15 inclusive, no change is made in the number of months. Thus, for the example given above, the number of days is -20, and the number of months is therefore $50 - 1 = 49$ months.

(B) *Gender distribution.* The difference between the number of boys and the number of girls in each age range shall not exceed 10% of the number of children in that range. The children selected should have no obvious or overt physical or mental handicap. A parent or guardian of each child shall read and sign a consent form prior to the child's participation. (The Commission staff will not disregard the results of tests performed by other parties simply because informed consent for children is not obtained.)

(ii) *Test failures.* A test failure shall be any child who opens the special packaging or gains access to its contents. In the case of unit packaging, however, a test failure shall be 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 individual units, whichever number is lower, during the full 10 minutes of testing. The number of units that a child opens or gains access to is interpreted as the individual units from which the product has been or can be removed in whole or in part. The determination of the amount of a substance that may produce serious personal injury or serious illness shall be based on a 25-pound (11.4 kg) child. Manufacturers or packagers intending to use unit packaging for a substance requiring special packaging are requested to submit such toxicological data to the Commission's Office of Compliance.

(iii) *Sequential test.* The sequential test is initially conducted using 50 children, and, depending on the results, the criteria in table 1 determine whether the package is either child-resistant or not child-resistant or whether further testing is required. Further testing is required if the results are inconclusive and involves the use of one or more additional groups of 50 children each, up to a maximum of 200 children. No individual shall administer the test to more than 30% of the children tested in each group. Table 1 gives the acceptance (pass), continue testing, and rejection (fail) criteria to be used for the first 5 minutes and the full 10 minutes of the children's test. If the test continues past the initial 50-child panel, the package openings shown in table 1 are cumulative.

TABLE 1—NUMBER OF OPENINGS: ACCEPTANCE (PASS), CONTINUE TESTING, AND REJECTION (FAIL) CRITERIA FOR THE FIRST 5 MINUTES AND THE FULL 10 MINUTES OF THE CHILDREN'S PROTOCOL TEST

Test panel	Cumulative number of children	Package openings					
		First 5 minutes			Full 10 minutes		
		Pass	Continue	Fail	Pass	Continue	Fail
1	50	0-3	4-10	11+	0-5	6-14	15+
2	100	4-10	11-18	19+	6-15	16-24	25+
3	150	11-18	19-25	26+	16-25	26-34	35+
4	200	19-30	31+	26-40	41+

(iv) *Test procedures.* The children shall be divided into groups of two. The testing shall be done in a location that

is familiar to the children, for example, their customary nursery school or regular kindergarten. No child shall test

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more than two special packages. When more than one special package is being tested, each package shall be of a different ASTM type and they shall be presented to the paired children in random order. This order shall be recorded. The children shall be tested by the procedure incorporated in the following test instructions:

STANDARDIZED CHILD TEST INSTRUCTIONS

1. Reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to the opening described in instruction number 3 to allow the materials (e.g., the closure liner) to "take a set." Application torques must be recorded in the test report.
2. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.
3. Reclosable packages shall be opened and properly resecured one time (or more if appropriate), by the testing agency or other adult prior to testing. The opening and resecuring shall not be done in the presence of the children. (In the adult-resecuring test, the tester must not open and resecure the package prior to the test.) If multiple openings/resecurings are to be used, each of four (4) testers shall open and properly resecure one fourth of the packages once and then shall open and properly resecure each package a second, third, fourth, through tenth (or other specified number) time, in the same sequence as the first opening and resecuring. The packages shall not be opened and resecured again prior to testing. The name of each tester and the package numbers that he/she opens and resecurers shall be recorded and reported. It is not necessary for the testers to protocol test the packages that they opened and resecured.
4. The children shall have no overt physical or mental handicaps. No child with a permanent or temporary illness, injury, or handicap that would interfere with his/her effective participation shall be included in the test.
5. The testing shall take place in a well-lighted location that is familiar to the children and that is isolated from all distractions.
6. The tester, or another adult, shall escort a pair of children to the test area. The tester shall seat the two children so that there is no visual barrier between the children and the tester.
7. The tester shall talk to the children to make them feel at ease.
8. The children shall not be given the impression that they are in a race or contest. They are not to be told that the test is a game or that it is fun. They are not to be offered a reward.
9. The tester shall record all data prior to, or after, the test so that full attention can be on the children during the test period.
10. The tester shall use a stopwatch(s) or other timing devices to time the number of seconds it takes the child to open the package and to time the 5-minute test periods.
11. To begin the test, the tester shall hand the children identical packages and say, "PLEASE TRY TO OPEN THIS FOR ME."
12. If a child refuses to participate after the test has started, the tester shall reassure the child and gently encourage the child to try. If the child continues to refuse, the tester shall ask the child to hold the package in his/her lap until the other child is finished. This pair of children shall not be eliminated from the results unless the refusing child disrupts the participation of the other child.
13. Each child shall be given up to 5 minutes to open his/her package. The tester shall watch the children at all times during the test. The tester shall minimize conversation with the children as long as they continue to attempt to open their packages. The tester shall not discourage the children verbally or with facial expressions. If a child gets frustrated or bored and stops trying to open his/her package, the tester shall reassure the child and gently encourage the child to keep trying (e.g., "please try to open the package").
14. The children shall be allowed freedom of movement to work on their packages as long as the tester can watch both children (e.g., they can stand up, get down on the floor, or bang or pry the package).
15. If a child is endangering himself or others at any time, the test shall be stopped and the pair of children eliminated from the final results.
16. The children shall be allowed to talk to each other about opening the packages and shall be allowed to watch each other try to open the packages.
17. A child shall not be allowed to try to open the other child's package.
18. If a child opens his/her package, the tester shall say, "THANK YOU," take the package from the child and put it out of the child's reach. The child shall not be asked to open the package a second time.
19. At the end of the 5-minute period, the tester shall demonstrate how to open the package if either child has not opened his or her package. A separate "demo" package shall be used for the demonstration.
20. Prior to beginning the demonstration, the tester shall ask the children to set their packages aside. The children shall not be allowed to continue to try to open their packages during the demonstration period.
21. The tester shall say, "WATCH ME OPEN MY PACKAGE."

22. Once the tester gets the children's full attention, the tester shall hold the demo package approximately two feet from the children and open the package at a normal speed as if the tester were going to use the contents. There shall be no exaggerated opening movements.

23. The tester shall not discuss or describe how to open the package.

24. To begin the second 5-minute period, the tester shall say, "NOW YOU TRY TO OPEN YOUR PACKAGES."

25. If one or both children have not used their teeth to try to open their packages during the first 5 minutes, the tester shall say immediately before beginning the second 5-minute period, "YOU CAN USE YOUR TEETH IF YOU WANT TO." This is the only statement that the tester shall make about using teeth.

26. The test shall continue for an additional 5 minutes or until both children have opened their packages, whichever comes first.

27. At the end of the test period, the tester shall say, "THANK YOU FOR HELPING." If children were told that they could use their teeth, the tester shall say, "I KNOW I TOLD YOU THAT YOU COULD USE YOUR TEETH TODAY, BUT YOU SHOULD NOT PUT THINGS LIKE THIS IN YOUR MOUTH AGAIN" In addition, the tester shall say, "NEVER OPEN PACKAGES LIKE THIS WHEN YOU ARE BY YOURSELF. THIS KIND OF PACKAGE MIGHT HAVE SOMETHING IN IT THAT WOULD MAKE YOU SICK."

28. The children shall be escorted back to their classroom or other supervised area by the tester or another adult.

29. If the children are to participate in a second test, the tester shall have them stand up and stretch for a short time before beginning the second test. The tester shall take care that the children do not disrupt other tests in progress.

(3) *Senior-adult panel*—(i) *Test subjects*. Use a group of 100 senior adults. Not more than 24% of the senior adults tested shall be obtained from or tested at any one site. Each group of senior adults shall be randomly selected as to age, subject to the limitations set forth below. Twenty-five percent of the participants shall be 50–54 years of age, 25% of participants shall be 55–59 years of age, and 50% of the participants shall be 60–70 years old. Seventy percent of the participants of ages 50–59 and ages 60–70 shall be female (17 or 18 females shall be apportioned to the 50–54 year age group). No individual tester shall administer the test to more than 35% of the senior adults tested. The

adults selected should have no obvious or overt physical or mental disability.

(ii) *Screening procedures*. Participants who are unable to open the packaging being tested in the first 5-minute time period, are given a screening test. The screening tests for this purpose shall use two packages with conventional (not child-resistant (CR) or "special") closures. One closure shall be a plastic snap closure and the other a CT plastic closure. Each closure shall have a diameter of 28 mm±18%, and the CT closures shall have been resecured 72 hours before testing at 10 inch-pounds of torque. The containers for both the snap- and CT-type closures shall be round plastic containers, in sizes of 2 ounce±½ ounce for the CT-type closure and 8 drams±4 drams for the snap-type closure. Persons who cannot open and close both of the screening packages in 1-minute screening tests shall not be counted as participants in the senior-adult panel.

(iii) *SAUE*. The senior adult use effectiveness (SAUE) is the percentage of adults who both opened the package in the first (5-minute) test period and opened and (if appropriate) properly resecured the package in the 1-minute test period.

(iv) *Test procedures*. The senior adults shall be tested individually, rather than in groups of two or more. The senior adults shall receive only such printed instructions on how to open and properly secure the special packaging as will appear on or accompany the package as it is delivered to the consumer. The senior-adult panel is tested according to the procedure incorporated in the following senior-adult panel test instructions:

TEST INSTRUCTIONS FOR SENIOR TEST

The following test instructions are used for all senior tests. If non-reclosable packages are being tested, the commands to close the package are eliminated.

1. No adult with a permanent or temporary illness, injury, or disability that would interfere with his/her effective participation shall be included in the test.

2. Each adult shall read and sign a consent form prior to participating. Any appropriate language from the consent form may be used to recruit potential participants. The form shall include the basic elements of informed consent as defined in 16 CFR 1028.116. Examples of the forms used by the Commission

staff for testing are shown at §1700.20(d). Before beginning the test, the tester shall say, "PLEASE READ AND SIGN THIS CONSENT FORM." If an adult cannot read the consent form for any reason (forgot glasses, illiterate, etc.), he/she shall not participate in the test.

3. Each adult shall participate individually and not in the presence of other participants or onlookers.

4. The tests shall be conducted in well-lighted and distraction-free areas.

5. Records shall be filled in before or after the test, so that the tester's full attention is on the participant during the test period. Recording the test times to open and resecure the package are the only exceptions.

6. To begin the first 5-minute test period, the tester says, "I AM GOING TO ASK YOU TO OPEN AND PROPERLY CLOSE THESE TWO IDENTICAL PACKAGES ACCORDING TO THE INSTRUCTIONS FOUND ON THE CAP." (Specify other instruction locations if appropriate.)

7. The first package is handed to the participant by the tester, who says, "PLEASE OPEN THIS PACKAGE ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.) If the package contains product, the tester shall say, "PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, etc.) INTO THIS CONTAINER." After the participant opens the package, the tester says, "PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate)

8. Participants are allowed up to 5 minutes to read the instructions and open and close the package. The tester uses a stopwatch(s) or other timing device to time the opening and resealing times. The elapsed times in seconds to open the package and to close the package are recorded on the data sheet as two separate times.

9. After 5 minutes, or when the participant has opened and closed the package, whichever comes first, the tester shall take all test materials from the participant. The participant may remove and replace the closure more than once if the participant initiates these actions. If the participant does not open the package and stops trying to open it before the end of the 5-minute period, the tester shall say, "ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?" If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, skip to Instruction 13.

10. To begin the second test period, the tester shall give the participant another, but identical, package and say, "THIS IS AN IDENTICAL PACKAGE. PLEASE OPEN IT ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction loca-

tions if appropriate.) If the package contains product, the tester shall say, "PLEASE EMPTY THE (PILLS, TABLETS, CONTENTS, etc.) INTO THIS CONTAINER." After the participant opens the package, the tester says, "PLEASE CLOSE THE PACKAGE PROPERLY, ACCORDING TO THE INSTRUCTIONS ON THE CAP." (Specify other instruction locations if appropriate.)

11. The participants are allowed up to 1 minute (60 full seconds) to open and close the package. The elapsed times in seconds to open and to close the package are recorded on the data sheet as two separate times. The time that elapses between the opening of the package and the end of the instruction to close the package is not counted as part of the 1-minute test time.

12. After the 1-minute test, or when the participant has opened and finished closing the package, whichever comes first, the tester shall take all the test materials from the participant. The participant shall not be allowed to handle the package again. If the participant does not open the package and stops trying to open it before the end of the 1-minute period, the tester shall say, "ARE YOU FINISHED WITH THAT PACKAGE, OR WOULD YOU LIKE TO TRY AGAIN?" If the participant indicates that he/she is finished or cannot open the package and does not wish to continue trying, this shall be counted as a failure of the 1-minute test.

13. Participants who do not open the package in the first 5-minute test period are asked to open and close two non-child-resistant screening packages. The participants are given a 1-minute test period for each package. The tester shall give the participant a package and say, "PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE." The tester records the time for opening and closing, or 61 seconds, whichever is less, on the data sheet. The tester then gives the participant the second package and says, "PLEASE OPEN AND PROPERLY CLOSE THIS PACKAGE." The time to open and resecure, or 61 seconds, whichever is less, shall be recorded on the data sheet.

14. Participants who cannot open and resecure both of the non-child-resistant screening packages are not counted as part of the 100-seniors panel. Additional participants are selected and tested.

15. 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.

16. If more adults in a sex or age group are tested than are necessary to determine SAUE, the last person(s) tested shall be eliminated from that group.

(4) *Younger-adult panel.* (i) One hundred adults, age 18 to 45 inclusive, with no overt physical or mental handicaps, and 70% of whom are female, shall

comprise the test panel for younger adults. Not more than 35% of adults shall be obtained or tested at any one site. No individual tester shall administer the test to more than 35% of the adults tested. The adults shall be tested individually, rather than in groups of two or more. The adults shall receive only such printed instructions on how to open and properly resecure the special packaging as will appear on the package as it is delivered to the consumer. Five minutes shall be allowed to complete the opening and, if appropriate, the resealing process.

(ii) Records shall be kept of the number of adults unable to open and of the number of the other adults tested who fail to properly resecure the special packaging. The number of adults who successfully open the special packaging and then properly resecure the special packaging (if resealing is appropriate) is the percent of adult-use effectiveness of the special packaging. In the case of unit packaging, the percent of adult-use effectiveness shall be the number of adults who successfully open a single (unit) package.

(b) The standards published as regulations issued for the purpose of designating particular substances as being subject to the requirements for special packaging under the act will stipulate the percent of child-resistant effectiveness and adult-use effectiveness required for each and, where appropriate, will include any other conditions deemed necessary and provided for in the act.

(c) It is recommended that manufacturers of special packaging, or producers of substances subject to regulations issued pursuant to the act, submit to the Commission summaries of data resulting from tests conducted in accordance with this protocol.

(d) *Recommendations.* The following instructions and procedures, while not required, are used by the Commission's staff and are recommended for use where appropriate.

(1) *Report format for child test.*

A. IDENTIFICATION

1. Close-up color photographs(s) clearly identifying the package and showing the opening instructions on the closure.
2. Product name and the number of tablets or capsules in the package.

3. Product manufacturer.
4. Closure model (trade name—e.g., “KLIK & SNAP”).
5. Closure size (e.g., 28 mm).
6. Closure manufacturer.
7. Closure material and color(s) (e.g., white polypropylene).
8. Closure liner material.
9. TAC seal material.
10. Opening instructions (quote exactly, e.g., “WHILE PUSHING, DOWN, TURN RIGHT”). Commas are used to separate words that are on different lines.
11. Symbols, numbers, and letters found inside the closure.
12. Package model.
13. Package material and color.
14. Net contents.
15. Symbols, numbers, and letters on the bottom of the package.
16. Other product identification, e.g., EPA Registration Number.

B. PROCEDURES

1. Describe all procedures for preparing the test packages.
2. Describe the testing procedures.
3. Describe all instructions given to the children.
4. Define an individual package failure.

C. RESULTS

1. Openings in each 5-minute period and total openings for males and for females in each age group.
2. Opening methods (e.g., normal opening, teeth, etc.).
3. Mean opening times and standard deviation for each 5-minute test period.
4. The percentage of packages tested at each site as a percentage of total packages.
5. The percentage of packages tested by each tester as a percentage of total packages.
6. Child-resistant effectiveness for the first 5-minute period and for the total test period.

(2) *Standardized adult-resealing test instructions.* CPSC will use the adult-resealing test where an objective determination (e.g., visual or mechanical) that a package is properly resealed cannot be made. The adult-resealing test is performed as follows:

ADULT-RESEALING PROCEDURE

1. After the adult participant in either the senior-adult test of 16 CFR 1700.20(a)(3) or the younger-adult test of 16 CFR 1700.20(a)(4) has resealed the package, or at the end of the test period (whichever comes first), the tester shall take the package and place it out of reach. The adult participant shall not be allowed to handle the package again.
2. The packages that have been opened and appear to be resealed by adults shall be

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tested by children according to the child-test procedures to determine if the packages have been properly resecured. The packages are given to the children without being opened or resecured again for any purpose.

3. Using the results of the adult tests and the tests of apparently-resecured packaging by children, the adult use effectiveness is calculated as follows:

a. *Adult use effectiveness.*

1. The number of adult opening and resecuring failures, plus the number of packages that were opened by the children during the full 10-minute test that exceeds 20% of the apparently-resecured packages, equals the total number of failures.

2. The total number of packages tested by adults (which is 100) minus the total number of failures equals the percent adult-use effectiveness.

(3) *Report format for adult-resecuring test.*

A. IDENTIFICATION

1. Close-up color photograph(s) clearly identifying the package and showing the top of the closure.

2. Product name and the number of tablets or capsules in the package.

3. Product manufacturer.

4. Closure model (trade name).

5. Closure size (e.g., 28 mm).

6. Closure manufacturer.

7. Closure material and color(s) (e.g., white polypropylene)

8. Closure liner material.

9. Symbols, numbers, and letters found inside the closure.

10. TAC seal material.

11. Opening instructions (Quote exactly, e.g., "WHILE PUSHING, DOWN, TURN RIGHT"). Commas are used to separate words that are on different lines.

12. Package model.

13. Package material and color.

14. Net contents.

15. Symbols, numbers, and letters on the bottom of the package.

16. Other product identification, e.g., EPA Registration Number.

B. PROCEDURES

1. Describe all procedures for preparing the test packages.

2. Describe the testing procedures in detail.

3. Describe all instructions given to participants.

4. Define an individual package failure and the procedures for determining a failure.

C. RESULTS

ADULT TEST

1. Total packages opened and total packages resecured; packages opened by males

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and by females; and packages resecured by males and by females.

2. Mean opening times and standard deviation for total openings, total openings by females, and total openings by males.

3. Mean resecuring times and standard deviation for total resecuring, total resecuring by females and total resecuring by males.

4. The percentage of packages tested at each site as a percentage of total packages.

5. The percentage of packages tested by each tester as a percentage of total packages.

6. Methods of opening (e.g., normal opening, pried closure off, etc.)

CHILD TEST

1. Openings in each 5-minute period, and total openings, for males and females in each age group.

2. Opening methods.

3. Mean opening times and standard deviation for each 5-minute test period.

4. The percentage of packages tested at each site as a percentage of total packages.

5. The percentage of packages tested by each tester as a percentage of total packages.

(4) Consent forms. The Commission uses the following consent forms for senior-adult testing reclosable and unit-dose packaging, respectively.

1. *Reclosable packages.*

[Testing Organization's Letterhead]

CHILD-RESISTANT PACKAGE TESTING

The U.S. Consumer Product Safety Commission is responsible for testing child-resistant packages to make sure they protect young children from medicines and dangerous household products. With the help of people like you, manufacturers are able to improve the packages we use, keeping the contents safe from children but easier for the rest of us to open.

Effective child-resistant packages have prevented thousands of poisonings since the Poison Prevention Act was passed in 1970. The use of child-resistant packages on prescription medicines alone may have saved the lives of over 350 children since 1974.

As part of this program, we are testing a child-resistant package to determine if it can be opened and properly closed by an adult who is between 50 and 70 years of age. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested—we are testing the package, not you.

Description of the Test

1. I will give you a package and ask you to read the instructions and open and properly close the package.

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- 2. I will then give you an identical package, and ask you to open and properly close it.
- 3. I may ask you to open some other types of packages.
- 4. The packages may be empty or they may contain a product.
- 5. I will ask you whether you think the child-resistant package was easy or hard to use.

- 2. I will then give you an identical package, and ask you to open one unit and remove the contents.
- 3. I may ask you to open some other types of packages.
- 4. I will ask you whether you think the child-resistant package was easy or hard to use.

CONSENT FORM FOR CHILD-RESISTANT PACKAGE TESTING

The Consumer Product Safety Commission has been using contractors to test child-resistant packages for many years with no injuries to anyone, although it is possible that a minor injury could happen.

I agree to test a child-resistant package. I understand that I can change my mind at any time. I am between the ages of 50 and 70, inclusive.
Birthdate _____
Signature _____
Date _____
Zip Code _____

Office Use

Site: _____
Sample Number: _____
Test Number: _____
Package Number: _____

2. Unit-dose packages.

[Testing Organization's Letterhead]

UNIT DOSE CHILD-RESISTANT PACKAGE TESTING

The U.S. Consumer Product Safety Commission is responsible for testing child-resistant packages to make sure they protect young children from medicines and dangerous household products. With the help of people like you, manufacturers are able to improve the packages we use, keeping the contents safe from children but easier for the rest of us to open.

Effective child-resistant packages have prevented thousands of poisonings since the Poison Prevention Act was passed in 1970.

The use of child-resistant packages on prescription medicines alone may have saved the lives of over 350 children since 1974.

As part of this program, we are testing a child-resistant package to determine if it can be opened by an adult who is between 50 and 70 years of age. You may or may not be familiar with the packages we are testing. Take your time, and please do not feel that you are being tested—we are testing the package, not you.

Description of the Test

- 1. I will give you a package and ask you to read the instructions, open one unit, and remove the contents.

CONSENT FORM FOR CHILD-RESISTANT PACKAGE TESTING

The Consumer Product Safety Commission has been using contractors to test child-resistant packages for many years with no injuries to anyone, although it is possible that a minor injury could happen.

I agree to test a child-resistant package. I understand that I can change my mind at any time. I am between the ages of 50 and 70, inclusive.
Birthdate _____
Signature _____
Date _____
Zip Code _____

Office Use

Site: _____
Sample Number: _____
Test Number: _____
Package Number: _____

[38 FR 21247, Aug. 7, 1973, as amended at 60 FR 37735, 37738, July 22, 1995]

PART 1701—STATEMENTS OF POLICY AND INTERPRETATION

Sec.

1701.1 Special packaging for substances subject to a standard that are distributed to pharmacies to be dispensed pursuant to an order of a licensed medical practitioner.

1701.3 Applicability of special packaging requirements to hazardous substances in large size containers.

§ 1701.1 Special packaging for substances subject to a standard that are distributed to pharmacies to be dispensed pursuant to an order of a licensed medical practitioner.

(a) In order to assist manufacturers of prescription drugs in discharging their responsibilities under the act concerning such drugs that are distributed to pharmacies, the Consumer Product Safety Commission has codified this statement of its policy concerning which prescription drug packages supplied by manufacturers to pharmacies must comply with the "special" (child-resistant) packaging