(c) *Applicability.* Special packaging standards for drugs listed under paragraph (a) of this section shall be in addition to any packaging requirements of the Federal Food, Drug, and Cosmetic Act or regulations promulgated thereunder or of any official compendia recognized by that act.

(Pub. L. 91–601, secs. 2(4), 3, 5, 85 Stat. 1670–72; 15 U.S.C. 1471(4), 1472, 1474; Pub. L. 92–573, 86 Stat. 1231; 15 U.S.C. 2079(a))

[38 FR 21247, Aug. 7, 1973]

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 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).