



Figure 3 to Paragraph (b)(2)

WARNING: INGESTION HAZARD • DEATH or serious injury can occur • A swallowed button cell or coin battery can cause internal Chemical Burns in as little as 2 hours • KEEP new and used batteries OUT OF REACH OF CHILDREN • Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body • For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-800-438-8665].

(3) The following safety-related statements must be addressed on the principal display panel or secondary display panel:

(i) Keep in original package until ready to use.

(ii) Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash.

(4) For button cell or coin battery packaging included separately with a consumer product, only paragraphs (b)(1) and (2) of this section apply.

[88 FR 65303, Sept. 21, 2023]

PART 1270—SAFETY STANDARD FOR ADULT PORTABLE BED RAILS

Sec.

1270.1 Scope, application, and effective date.

1270.2 Requirements for adult portable bed rails.

1270.3 Prohibited stockpiling.

APPENDIX A TO PART 1270—FINDINGS UNDER THE CONSUMER PRODUCT SAFETY ACT

AUTHORITY: 15 U.S.C. 2056, 15 U.S.C. 2058, and 5 U.S.C. 553.

SOURCE: 88 FR 46979, July 21, 2023, unless otherwise noted.

§ 1270.1 Scope, application, and effective date.

This part establishes a consumer product safety standard for adult portable bed rails manufactured after August 21, 2023.

§ 1270.2 Requirements for adult portable bed rails.

(a) Except as provided in paragraph (b) of this section, each adult portable bed rail must comply with all applicable provisions of ASTM F3186-17, *Standard Specification for Adult Portable Bed Rails and Related Products*, approved on August 1, 2017. The Director of the Federal Register approves this incorporation by reference in accordance with 5

U.S.C. 552(a) and 1 CFR part 51. This incorporation by reference (IBR) material is available for inspection at the U.S. Consumer Product Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email cpsc-os@cpsc.gov. For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. A read-only copy of the standard is available for viewing on the ASTM website at <https://www.astm.org/READINGLIBRARY/>. You may obtain a copy from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959; telephone (610) 832-9585; www.astm.org.

(b) Comply with the ASTM F3186-17 standard with the following changes:

(1) In addition to complying with the definitions in section 3.1 of ASTM F3186-17, comply with the following definitions:

(i) *Entrapment zone*. An area, gap, or opening that can potentially capture or restrain a person's body part. Hazardous openings may not always be visible prior to testing.

(ii) *Initial assembly*. The first assembly of the product components after purchase, and prior to installing on the bed.

(iii) *Initial installation*. The first installation of the product onto a bed or mattress.

(iv) *Installation component*. Component(s) of the bed rail that is/are specifically designed to attach the bed and typically located under the mattress when in the manufacturer's recommended use position.

(2) Instead of complying with section 6.1.3 of ASTM F3186–17, comply with the following:

(i) Permanently attached retention system components shall not be able to be removed without the use of a tool after initial assembly.

(ii) [Reserved]

(3) In addition to complying with section 6.2.1 of ASTM F3186–17, comply with the following:

(i) The test personnel shall choose a mattress and product setting configuration that results in the most severe condition per test requirement (see paragraph (b)(8)(i) of this section).

(ii) [Reserved]

(4) Instead of complying with section 6.3.3 of ASTM F3186–17, comply with the following:

(i) *Zone 3*. When tested in accordance with section 8.4.5 of ASTM F3186–17, the horizontal centerline on the face of the 4.7 in (120 mm) end of the test probe (see paragraph (b)(9)(i) of this section) shall be above the highest point of the uncompressed mattress.

(ii) [Reserved]

(5) Instead of complying with section 6.4.1 of ASTM F3186–17, comply with the following:

(i) Holes or slots that extend entirely through a wall section of any rigid material less than 0.375 in (9.53 mm) thick and admit a 0.210 in (5.33 mm) diameter rod shall also admit a 0.375 in (9.53 mm) diameter rod. Holes or slots that are between 0.210 in (5.33 mm) and 0.375 in (9.53 mm) and have a wall thickness less than 0.375 in (9.53 mm) but are limited in depth to 0.375 in (9.53 mm) maximum by another rigid surface shall be permissible (see Opening Example in Figure 2 of ASTM F3186–17).

(ii) [Reserved]

(6) Instead of complying with section 6.5.1 of ASTM F3186–17, comply with the following:

(i) Any structural components and retention system components of a product covered by this specification that require consumer assembly or adjustment, or components that may be removed by the consumer without the use of a tool, shall not be able to be misassembled when evaluated to (see paragraph (b)(7)(i) of this section).

(ii) [Reserved]

(7) Instead of complying with section 6.5.2 of ASTM F3186–17, comply with the following:

(i) *Determining misassembled product*. A product covered by this specification shall be considered misassembled if it appears to be functional under any condition and it does not meet the requirements of sections 6.1 through 6.4 of ASTM F3186–17.

(ii) [Reserved]

(8) In addition to complying with section 7.1 of ASTM F3186–17, comply with the following:

(i) Mattress thickness ranges used for testing shall be up to 1.5 in. (38 mm) larger or smaller than the range specified by the manufacturer. Test personnel shall choose a mattress and product setting configuration that provide the most severe condition for each test requirement in the standard.

NOTE 1 TO PARAGRAPH (B)(8)(I): The technology and consumer preferences for bedding are highly variable and continuously changing. Therefore, they cannot be reasonably accounted for within this standard. Test facilities and personnel should consider current bedding trends and all types of mattresses that may foreseeably be used with the product when making a test mattress selection.

(ii) [Reserved]

(9) Instead of complying with section 7.2 of ASTM F3186–17, comply with the following:

(i) *Entrapment test probe*. The test probe used for the entrapment tests shall be as described in the Food and Drug Administration (FDA) Guidance Document, “Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment,” which can be found at: www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment.

The test probe can be independently manufactured per the dimensional constraints in the guidance document or purchased from Bionix, 5154 Enterprise Blvd., Toledo, OH 43612, 800-551-7096, www.bionix.com. Videos illustrating use of the test probe are available at: www.youtube.com/c/BionixLLC/search.

(ii) [Reserved]

(10) Substitute the following text as the content of Note 1 in section 8.4 of ASTM F3186–17:

(i) The tests described in this section are similar to those described in the referenced FDA Guidance Document.

(ii) [Reserved]

(11) Instead of complying with section 8.4.3.4 of ASTM F3186-17, comply with the following:

(i) If the test probe does not pull through freely, attach the force gauge and exert a 22.5 lbf (100 N) pulling force to the 2.4 in (60 mm) cylindrical end of the entrapment test probe in the direction most likely to lead to failure of the requirement. If the 4.7 in (120 mm) end of the cone does not enter any of the openings, this space passes the test. If the 4.7 in (120 mm) end of the test probe cone does enter any of the openings, this space fails the test.

(ii) [Reserved]

(12) Instead of complying with section 8.4.4.3 of ASTM F3186-17, comply with the following:

(i) Insert the 2.4 in (60 mm) end of the cone into the opening at the angle most likely to allow it to pass through. Insert the cone into the opening until it is in full contact with the product. The mattress shall only be compressed by the weight of the cone.

(ii) [Reserved]

(13) Instead of complying with section 8.4.4.4 of ASTM F3186-17, comply with the following:

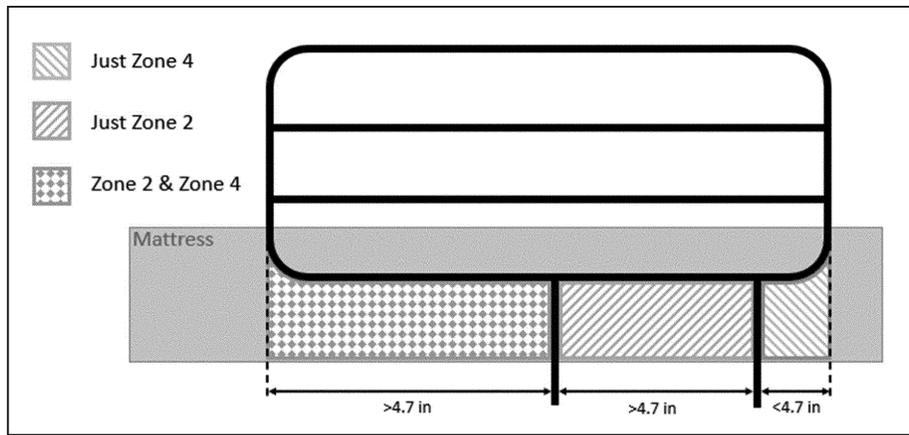
(i) If the test probe does not pull through freely use the force gauge to exert a 22.5 lbf (100 N) pulling force to the 2.4 in (60 mm) cylindrical end of the cone in the direction most likely to lead to failure of the requirement.

(ii) [Reserved]

(14) In addition to complying with section 8.4.4 of ASTM F3186-17, comply with the following:

(i) If a horizontal section of the rail greater than 4.7 in exists along the bottom of the rail, that section must also meet the Zone 2 requirements regardless of the number or location of the supports. Repeat testing described in section 8.4.4.3 of ASTM F3186-17 (see paragraph (b)(12)(i) of this section) and section 8.4.4.4 of ASTM F3186-17 (see paragraph (b)(13)(i) of this section) for all applicable entrapment zones. Figure 1 to this paragraph (b)(14)(i) shows a general example of areas subject to Zone 2 requirements.

Figure 1 to paragraph (b)(14)(i)—General Example of Areas Subject to Zone 2 Requirements



(ii) [Reserved]

(15) Instead of complying with section 8.4.5.4 of ASTM F3186-17, comply with the following:

(i) Turn the cone until the line on the face of the 4.7 in (120 mm) end is horizontal and let the cone sink into the space by its own weight.

§ 1270.2

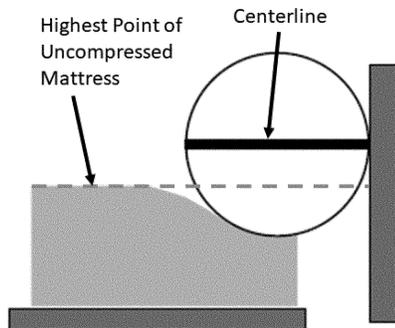
16 CFR Ch. II (1–1–25 Edition)

(A) If the line on the face of the 4.7 in (120 mm) end of the cone is above the highest point of the uncompressed mattress, as shown in Figure 2 to this paragraph (b)(15)(i), the space passes the test.

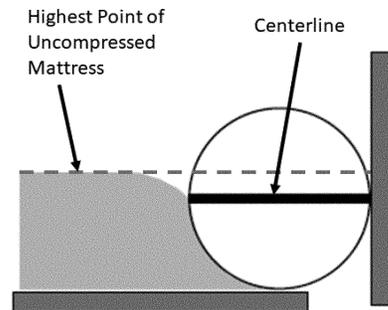
(B) If the line on the face of the 4.7 in (120 mm) end of the cone is at or below

the highest point of the uncompressed mattress, as shown in Figure 2 to this paragraph (b)(15)(i), the space fails the test.

Figure 2 to paragraph (b)(15)(i)—Zone 3 Test: (a) Pass, (b) Fail



a: Zone 3 Pass Criteria
(Centerline **above** highest point of uncompressed mattress)



b: Zone 3 Fail Criteria
(Centerline **below** highest point of uncompressed mattress)

(ii) [Reserved]

(16) In addition to complying with section 8.6.3 of ASTM F3186–17, use the following definition:

(i) The “free end” is defined as the location on the retention system that is designed to produce a counter force; it may be a single distinct point or a location on a loop.

(ii) [Reserved]

(17) Instead of complying with section 9.1.1.3 of ASTM F3186–17, comply with the following:

(i) That the product is to be used only with the type and size of mattress and bed, including the range of thickness of mattresses, specified by the

manufacturer of the product. If beds with head or footboards are allowed, the distance between the head or footboard and the placement of the product shall be indicated to be >12.5 in (318 mm).

(ii) [Reserved]

(18) Instead of complying with section 9.2.5 of ASTM F3186–17, comply with the following:

(i) Each product’s retail package and instructions shall include the warning statements in Figure 3 to this paragraph (b)(18)(i).

Figure 3 to paragraph (b)(18)(i)—Warning Statements for Product Retail Package and Instruction

▲WARNING

ENTRAPMENT, STRANGULATION, SUFFOCATION AND FALL HAZARDS

Gaps in and around this product can entrap and kill. People with Alzheimer’s disease or dementia, or those who are sedated, confused, or frail are at increased risk of entrapment and strangulation. People attempting to climb over this product are at increased risk of injury or death from falls. Always make sure this product is properly secured to bed. If product can move away from bed or mattress, it can lead to entrapment and death.

- (ii) [Reserved]
- (19) Instead of complying with section 9.2.7 of ASTM F3186-17, comply with the following:
 - (i) At least one installation component of the product must be labeled

with the entrapment warning in Figure 4 to this paragraph (b)(19)(i).
 Figure 4 to paragraph (b)(19)(i)—Entrapment Warning

▲WARNING – ENTRAPMENT HAZARD

NEVER use product without properly securing it to bed. Incorrect installation can allow product to move away from mattress, bed frame and/or head or foot boards, which can lead to entrapment and death.

- (ii) [Reserved]
- (20) Instead of complying with section 11.1.1.3 of ASTM F3186-17, comply with the following:
 - (i) In addition to contacting the manufacturer directly, consumers can report problems to the CPSC at its website SaferProducts.gov or call 1-800-638-2772.
 - (ii) [Reserved]

§ 1270.3 Prohibited stockpiling.

- (a) *Prohibited acts.* Manufacturers and importers of adult portable bed rails (APBRs) shall not manufacture or import APBRs that do not comply with the requirements of this part between July 21, 2023, and August 21, 2023, at a rate that is greater than 105 percent of the rate at which they manufactured or imported APBRs during the base period for the manufacturer or importer.
- (b) *Base period.* The base period for APBRs is the calendar month with the median manufacturing or import volume within the last 13 months immediately preceding July 21, 2023.

APPENDIX A TO PART 1270—FINDINGS UNDER THE CONSUMER PRODUCT SAFETY ACT

The Consumer Product Safety Act requires that the Commission, in order to issue a standard, make the following findings and include them in the rule. 15 U.S.C. 2058(f)(3). Because of this, the facts and determinations in these findings apply as of the date the rule was issued, July 21, 2023.

A. Degree and Nature of the Risk of Injury. Between January 2003 and December 2021, there were 332 incident reports concerning adult portable bed rails (APBRs) in the Consumer Product Safety Risk Management System (CPSRMS). Of these, 310 were reports

of fatalities, and 22 were nonfatal. Rail entrapment is the most prevalent hazard pattern among the incidents. There were 284 fatal incidents related to rail entrapment, accounting for more than 90 percent of all fatal incidents, and 2 nonfatal incidents. Falls were the second most common hazard pattern in the incident data, accounting for 25 incidents (8 percent of all incidents). There were 23 fatalities from falls.

B. Number of Consumer Products Subject to the Rule. An estimated 12 firms supply 65 distinct APBR models. In 2021, the number of APBRs sold was approximately 180,000 units.

C. Need of the Public for the Products and Probable Effect on Utility, Cost, and Availability of the Product.

(1) APBRs are installed or used alongside a bed by consumers to: reduce the risk of falling from the bed; assist the consumer in repositioning in the bed; or assist the consumer in transitioning into or out of the bed. Because the rule is a performance standard that allows for the sale of compliant of APBRs, it is not expected to have any impact on the utility of the product.

(2) The cost of compliance to address entrapment hazards includes the costs manufacturers incur to redesign existing models and produce new designs to comply with the mandatory standard, the cost of producing the redesigned APBR, dead weight loss. To redesign existing and new models, manufacturers would likely incur expenditures in design labor, design production, design validation, and compliance testing. CPSC estimates these costs to be \$42,239 per model in the first year. Manufacturers would also incur costs to produce the redesigned APBRs, however, these costs likely closely match existing production costs and therefore incremental cost is expected to be negligible. Dead weight loss refers to the lost producer and consumer surplus from reduced quantities of APBRs sold and consumed due to rule-induced price increases. Producer

surplus represents the foregone profit opportunities, meaning the amount that price exceeds marginal cost for those units no longer produced. Consumer surplus represents the foregone utility from consumption, meaning the amount that willingness to pay exceeds price for units no longer consumed. In the first year, producer manufacturing costs are expected to increase by \$5.40 per APBR, of which \$4.00 per APBR is expected to be passed on to the consumer in the form of higher prices. The resultant decrease in the number of APBRs sold and consumed is expected to generate a dead weight loss of less than \$70,000 per year nationwide, so the rule is not expected to have any significant impact on the availability of APBRs.

D. Any Means to Achieve the Objective of the Rule, While Minimizing Adverse Effects on Competition and Manufacturing. (1) The rule reduces entrapment and other hazards on APBRs while minimizing the effect on competition and manufacturing. Because the rule is based on an existing voluntary standard, and because of CPSC's outreach efforts, APBR manufacturers are generally aware of the requirements. Manufacturers can transfer some, or all, of the increased production cost to consumers through price increases. At the margins, some producers may exit the market because their increased marginal costs now exceed the increase in market price. Likewise, a very small fraction of consumers may be excluded from the market if the increased market price exceeds their personal price threshold for purchasing an APBR.

(2) The Commission considered alternatives to the rule to minimize impacts on competition and manufacturing including: take no regulatory action; continue to conduct recalls of APBRs instead of promulgating a rule; conduct an educational campaign instead of promulgating a rule; ban APBRs from the market; require enhanced safety warnings without other requirements; and implement the rule with a longer effective date. The Commission determines that none of these alternatives would adequately reduce the risk of deaths and injuries associated with APBR entrapment and other hazards presented by APBRs.

E. The rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk of injury. Incident data show 284 fatal incidents related to rail entrapment between January 2003 and December 2021. The incident data show that these incidents continue to occur and are likely to increase because APBR manufacturers do not comply with the voluntary standard and the market for APBRs is forecast to grow. The rule establishes performance requirements to address the risk of entrapments associated with APBRs. Given the fatal and serious injuries associated with entrapments on APBRs, the Commission finds that the

rule and its effective date are necessary to address the unreasonable risk of injury associated with APBRs.

F. Public Interest. The rule addresses an unreasonable risk of entrapments and other hazards associated with APBRs. Adherence to the requirements of the rule would reduce deaths and injuries from APBR entrapment incidents; thus, the rule is in the public interest.

G. Voluntary Standards. If a voluntary standard addressing the risk of injury has been adopted and implemented, then the Commission must find that the voluntary standard is not likely to eliminate or adequately reduce the risk of injury or substantial compliance with the voluntary standard is unlikely.

(1) The Commission determines that, absent modification, the voluntary standard is not likely to eliminate or adequately reduce the risk of injury of entrapments on APBRs. The Commission also determines that ASTM F3186-17, with the modifications described in §1270.2, is likely to adequately reduce the risk of injury associated with APBRs. Entrapment is the most prevalent hazard pattern among the deaths and injuries associated with APBRs. The entrapment test methods specified in the voluntary standard require products to be tested to assess the potential for entrapment in four different zones. The four entrapment zones required to be tested each address specific types of entrapment as follows: head-first entry into fully bounded openings within the structure of the bed rail; head-first entry under the rail into any opening between the mattress and the bed rail; entry of the head into a gap between the inside surface along the length of the bed rail and the compressed mattress; and neck-first entrapment between the ends of the bed rail and the compressed mattress. Most of the reported entrapment fatalities involved one of the four zones listed. In 214 out of 284 fatal incidents, the entrapment location was identified and all but six of these cases occurred in one of the four zones of entrapment tested in ASTM F3186-17.

(2) The Commission determines that modifications to the voluntary standard are needed to improve safety. Such modifications include: providing additional definitions for product assembly and installation to ensure their consistent and differentiated use throughout the standard; adding requirements for manufacturers to take into account the range of mattress thicknesses to ensure safe use of the product and provide testers with additional guidance for selecting the mattress thickness during the test setup; addressing inconsistencies with stated dimensions to ensure consistent dimensional tolerances; and providing additional clarity for Zone 1 and 2 test setup and methods, additional guidance for identifying potential

Consumer Product Safety Commission

§ 1272.1

Zone 2 openings, and updated requirements for Zone 3 testing consistency.

(3) The Commission determines that substantial compliance with the voluntary standard is unlikely. CPSC conducted two rounds of market compliance testing to ASTM F3186-17: the first round in 2018 and 2019, the second round in 2021. In both rounds, no APBRs met all requirements of ASTM F3186-17. All products failed at least one critical mechanical requirement, such as retention strap performance, structural integrity, and entrapment. All products failed the labeling, warning, and instructional requirements.

H. Reasonable Relationship of Benefits to Costs. (1) The benefits expected from the rule bear a reasonable relationship to its cost. The rule reduces the entrapment hazard and other hazards associated with APBRs, and thereby reduces the societal costs of the resulting injuries and deaths. The rule is expected to address the 92 percent of deaths caused by entrapment, resulting in potential societal benefits of \$298.11 million. Benefits additionally were assessed under three scenarios derived from this expected efficacy, estimating benefits at: 75 percent, 50 percent, and 25 percent of their potential value. Under these three scenarios, the estimated quantifiable annualized benefits of the rule are approximately \$200.24 million, \$133.49 million, and \$66.75 million, respectively. The costs associated with the rule's requirements to prevent the hazards associated with APBRs are expected to be approximately \$2.01 million per year. On a per product basis, the estimated benefits of the rule are approximately \$331.78, \$221.19, and \$110.59 per APBR when assessed at 75 percent, 50 percent, and 25 percent of their potential value, respectively, and the costs are approximately \$3.34 per APBR. All these amounts are in 2021 dollars using a discount rate of 3 percent.

(2) The requirements of the rule, with modifications, are expected to address 92 percent of deaths caused by entrapment. Even under the most conservative assumption that only 25 percent of the potential benefits are achieved, every \$1 in costs for the market to adopt the rule equates to approximately \$33.15 in benefits to society. The estimated annualized net benefits of the rule are approximately \$198.23 million, \$131.48 million, and \$64.74 million, at when benefits are assessed at 75 percent, 50 percent, and 25 percent of their potential value, respectively.

I. Least-Burdensome Requirement that Would Adequately Reduce the Risk of Injury. The Commission considered six alternatives to the rule including: take no regulatory action; continue to conduct recalls of APBRs instead of promulgating a rule; conduct an educational campaign without a rule; ban APBRs from the market entirely; require enhanced safety warnings without other re-

quirements; and implement the rule with a longer effective date. Although most of these alternatives may be a less burdensome alternative to the rule, the Commission determines that none of the alternatives would adequately reduce the risk of deaths and injuries associated with APBRs that is addressed by the rule while still preserving the product's utility to consumers.

PART 1272—MARKING OF TOY, LOOK-ALIKE, AND IMITATION FIREARMS

Sec.

- 1272.1 Applicability.
- 1272.2 Prohibitions.
- 1272.3 Approved markings.
- 1272.4 Waiver.
- 1272.5 Preemption.

AUTHORITY: 15 U.S.C. 5001.

SOURCE: 88 FR 30228, May 11, 2023, unless otherwise noted.

§ 1272.1 Applicability.

This part applies to toy, look-alike, and imitation firearms ("devices") having the appearance, shape, and/or configuration of a firearm and produced or manufactured and entered into commerce on or after May 5, 1989, including devices modelled on real firearms manufactured, designed, and produced since 1898. This part does not apply to:

(a) Non-firing collector replica antique firearms, which look authentic and may be a scale model but are not intended as toys modelled on real firearms designed, manufactured, and produced prior to 1898;

(b) Traditional B-B, paint-ball, or pellet-firing air guns that expel a projectile through the force of compressed air, compressed gas or mechanical spring action, or any combination thereof, as described in ASTM F589-85, Standard Consumer Safety Specification for Non-Powder Guns, ASTM F589-85, Standard Consumer Safety Specification for Non-Powder Guns, approved June 28, 1985, is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Consumer Product Safety Commission (CPSC) and at the