to the attention of the person identified in paragraph (m)(2) of this AD. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus’s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) Required for Compliance (RC): If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(m) Related Information


(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email airworthiness.A330-A340@airbus.com; Internet http://www.airbus.com. You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on November 22, 2017.

Jeffrey E. Dunen,
Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2017–25747 Filed 11–29–17; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Chapter II

[Docket No. CPSC–2017–0044]

Clothing Storage Unit Tip Overs; Request for Comments and Information

AGENCY: Consumer Product Safety Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission is contemplating developing a rule to address the risk of injury and death associated with clothing storage unit furniture tipping over. This advance notice of proposed rulemaking initiates a rulemaking proceeding under the Consumer Product Safety Act. We invite comments concerning the risk of injury associated with clothing storage units tipping over, the alternatives discussed in this notice, and other possible alternatives for addressing the risk. We also invite interested parties to submit existing voluntary standards or a statement of intent to modify or develop a voluntary standard that addresses the risk of injury described in this notice.

DATES: Submit comments by January 29, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2017–0044, electronically or in writing (hard copy), using the methods described below. The Commission encourages you to submit comments electronically, by using the Federal eRulemaking Portal.

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments provided on the Web site. The Commission does not accept comments submitted by electronic mail (Email), except through www.regulations.gov.

Written Submissions: Submit written comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions must include the agency name and docket number for this rulemaking proceeding. The Commission may post all comments, without change, including any personal identifiers, contact information, or other personal information provided, to: http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted by mail, hand delivery, or courier.

Docket: For access to the docket to read background documents or comments, go to: http://www.regulations.gov, and insert the docket number, CPSC–2017–0044, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Michael Taylor, Project Manager, Directorate for Laboratory Sciences, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987–2338; email: MTaylor@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Consumer Product Safety Commission (Commission or CPSC) is aware of numerous injuries and deaths resulting from furniture tip overs. To address this risk, Commission staff reviewed incident data for furniture tip overs and determined that clothing storage units (CSUs), consisting of chests, bureaus, and dressers, were the primary furniture category involved in fatal and injury incidents. There were 195 deaths related to CSU tip overs between 2000 and 2016, which were reported to CPSC. An estimated 65,200 injuries related to CSU tip overs were treated in U.S. hospital emergency departments between 2006 and 2016. These incident reports indicate that the vast majority of fatal and injury incidents resulting from CSUs tipping over involve children. Eighty-six percent of the reported fatalities involved children under 18 years old, most of which were under 6 years old. Seventy-three percent of the emergency department-treated injuries involved children under 18 years old, most of which were also under 6 years old.

To address the hazard associated with CSU tip overs, the Commission has taken several steps. In June 2015, the Commission launched the Anchor It! campaign. This educational campaign includes print and broadcast public service announcements, information distribution at targeted venues, such as childcare centers, and an informational Web site (www.AnchorIt.gov) explaining the nature of the risk and safety tips for avoiding furniture and television tip overs. In addition, CPSC staff prepared a briefing package in September 2016, which were also under 6 years old.
II. Relevant Statutory Provisions

To address the risk of injury associated with CSUs tipping over, the Commission is considering developing a mandatory safety standard. The rulemaking falls under the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051–2089). Under section 7 of the CPSA, the Commission may issue a consumer product safety standard if the requirements of the standard are “reasonably necessary to prevent or reduce an unreasonable risk of injury associated with [a] product.” Id. 2056(a). The safety standard may consist of performance requirements or requirements for warnings and instructions. Id. However, if there is a voluntary standard that would adequately reduce the risk of injury the Commission seeks to address, and there is likely to be substantial compliance with that standard, then the Commission must rely on the voluntary standard, instead of issuing a mandatory standard. Id. 2056(b)(1). To issue a mandatory standard under section 7, the Commission must follow the procedural and substantive requirements in section 9 of the CPSA. Id. 2056(a).

Under section 9 of the CPSA, the Commission may begin rulemaking by issuing an advance notice of proposed rulemaking (ANPR). Id. 2058(a). The ANPR must identify the product and the nature of the risk of injury associated with it; summarize the regulatory alternatives the Commission is considering; and include information about any relevant existing standards, and why the Commission preliminarily believes those standards would not adequately reduce the risk of injury associated with the product. The ANPR also must invite comments concerning the risk of injury and regulatory alternatives and invite the public to submit existing standards or a statement of intent to modify or develop a voluntary standard to address the risk of injury. Id. 2058(a).

After publishing an ANPR, the Commission may proceed with rulemaking by reviewing the comments received in response to the ANPR, and publishing a notice of proposed rulemaking (NPR). An NPR must include the text of the proposed rule, alternatives the Commission is considering, a preliminary regulatory analysis describing the costs and benefits of the proposed rule and the alternatives, and an assessment of any submitted standards. Id. 2058(c). The Commission would then review comments on the NPR and decide whether to issue a final rule, along with a final regulatory analysis.

III. The Product and Market

CSUs are freestanding furniture intended for storing clothing. CSUs are typically bedroom furniture, but may be used elsewhere. CSUs are available in a variety of designs (e.g., vertical or horizontal dressers), sizes (e.g., weights and heights), and materials (e.g., wood, plastic, leather). CSUs usually have a flat surface on top and commonly include doors, or drawers for consumers to store clothing or other items. Examples of CSUs include chests of drawers, bureaus, dressers, armoires, wardrobes, portable closets, and clothing storage lockers. CSUs do not include products that are permanently attached or built into a structure or products that are not typically intended to store clothing, such as bookcases, shelves, cabinets, entertainment furniture, office furniture, or jewelry armoires. Additional factors may be relevant for the Commission to define CSUs in a mandatory standard, such as the height of products and design features. The Commission seeks comments about the appropriate parameters of a definition for CSUs.

CSUs are available through various distribution channels. The retail price of CSUs varies, with the least expensive products retailing for less than $100, and the most expensive selling for several thousand dollars. Less expensive CSUs are usually mass produced, while more expensive products are often handmade. The lifespans of CSUs vary as well. Consumers may use less expensive CSUs for only a few years, while more expensive products may last for generations.

The Commission has not been able to determine the share of CSUs in the overall furniture market because of a lack of information about sales of specific furniture product types or models. However, according to U.S. Census Bureau information, there are approximately 22,600 U.S. firms that manufacture, import, distribute, or retail household furniture, of which CSUs are a subset. Some manufacturers are large and use mass-production techniques; others are smaller and manufacture products individually or for custom orders. The Commission also has been unable to identify information about the number of CSUs that are in use in U.S. households. The Commission requests information about the CSU market, CSU sales, and the number of CSUs in U.S. households.

IV. Risk of Injury

Commission staff reviewed fatal and nonfatal incidents involving CSU tip overs to determine the age of people involved in these incidents, the types of CSUs and other items involved, the hazard patterns (hazard patterns include activities, behaviors, circumstances, or factors that are associated with incidents) involved, and the types of injuries and deaths that result from these incidents. As the fatal and nonfatal incidents discussed below indicate, the vast majority of CSU tip-over incidents involve children. For that reason, the Commission largely focused its analysis on incidents involving children.

A. Fatal Incidents

To identify fatal incidents that involved CSU tip overs, Commission staff reviewed CPSC’s Death Certificates database, In-Depth Investigations database, Injury and Potential Injury Incidents database, and the National Electronic Injury Surveillance System (NEISS) database. Staff identified 195 fatalities related to CSU tip overs that occurred between January 1, 2000 and December 31, 2016 that were reported to CPSC. Of those fatalities, 22 (11 percent) involved seniors age 60 years and older; 6 (3 percent) involved adults between 18 and 59 years old; and 167 (86 percent) involved children under 18.
years old, of which the oldest child was 8 years old. Of the 167 fatal incidents involving children, 159 (95 percent) were under 6 years old and 142 (85 percent) were under 4 years old. Table 1 provides the number of child fatalities in age categories, broken out by 6-month increments.

**TABLE 1—FATAL INCIDENTS INVOLVING CHILDREN UNDER 18 YEARS OLD, BY AGE, BETWEEN JANUARY 1, 2000 AND DECEMBER 31, 2016**

<table>
<thead>
<tr>
<th>Age</th>
<th>Total fatalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to less than 0.5 years</td>
<td>1</td>
</tr>
<tr>
<td>0.5 to less than 1 year</td>
<td>5</td>
</tr>
<tr>
<td>1 to less than 1.5 years</td>
<td>21</td>
</tr>
<tr>
<td>1.5 to less than 2 years</td>
<td>24</td>
</tr>
<tr>
<td>2 to less than 2.5 years</td>
<td>31</td>
</tr>
<tr>
<td>2.5 to less than 3 years</td>
<td>23</td>
</tr>
<tr>
<td>3 to less than 3.5 years</td>
<td>25</td>
</tr>
<tr>
<td>3.5 to less than 4 years</td>
<td>8</td>
</tr>
<tr>
<td>4 to less than 4.5 years</td>
<td>7</td>
</tr>
<tr>
<td>4.5 to less than 5 years</td>
<td>4</td>
</tr>
<tr>
<td>5 to less than 5.5 years</td>
<td>5</td>
</tr>
<tr>
<td>5.5 to less than 6 years</td>
<td>1</td>
</tr>
<tr>
<td>6 to less than 6.5 years</td>
<td>3</td>
</tr>
<tr>
<td>6.5 to less than 7 years</td>
<td>1</td>
</tr>
<tr>
<td>7 to less than 7.5 years</td>
<td>0</td>
</tr>
<tr>
<td>7.5 to less than 8 years</td>
<td>1</td>
</tr>
<tr>
<td>8 to less than 8.5 years</td>
<td>3</td>
</tr>
<tr>
<td>8.5 to less than 9 years</td>
<td>0</td>
</tr>
<tr>
<td>Greater than 9 years</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>167</td>
</tr>
</tbody>
</table>

Children in a sample of 89 of these incidents ranged in weight from 18 to 66 pounds.

Of the 195 total fatal incidents involving all ages, nearly all involved a chest, bureau, or dresser; some of these involved a television falling with the chest, bureau, or dresser. Of the 167 fatal incidents involving children, 164 (98 percent) involved a chest, bureau, or dresser, 2 (1 percent) involved a wardrobe, and 1 (less than 1 percent) involved an armoire. Of the 167 child fatalities, 89 (53 percent) involved a television falling in addition to the CSU.

**B. Nonfatal Incidents**

To identify nonfatal incidents that involved CSU tip overs, Commission staff reviewed the NEISS database. The NEISS database contains reports of injuries treated in emergency departments of U.S. hospitals selected as a probability sample of all U.S. hospitals with emergency departments. Using the surveillance information in this database, CPSC can estimate the number of injuries, nationwide, that are associated with specific consumer products. An estimated 65,200 injuries related to CSU tip overs were treated in U.S. hospital emergency departments between January 1, 2006 and December 31, 2016. Of these, 47,700 estimated injuries (73 percent) were to children under 18 years old. Of the injuries involving children, 94 percent involved children under 9 years old and 83 percent involved children under 6 years old. Table 2 provides the estimated number of child injuries treated in hospital emergency departments, by age.

**TABLE 2—ESTIMATED INJURIES TREATED IN HOSPITAL EMERGENCY DEPARTMENTS INVOLVING CHILDREN UNDER 18 YEARS OLD, BY AGE, BETWEEN JANUARY 1, 2006 AND DECEMBER 31, 2016**

<table>
<thead>
<tr>
<th>Age</th>
<th>Estimated injuries</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to less than 0.5 years</td>
<td>1,800</td>
</tr>
<tr>
<td>0.5 to less than 1 year</td>
<td>13,000</td>
</tr>
<tr>
<td>1 to less than 1.5 years</td>
<td>5,800</td>
</tr>
<tr>
<td>1.5 to less than 2 years</td>
<td>2,800</td>
</tr>
<tr>
<td>2 to less than 2.5 years</td>
<td>1,700</td>
</tr>
<tr>
<td>2.5 to less than 3 years</td>
<td>1,200</td>
</tr>
<tr>
<td>3 to less than 3.5 years</td>
<td>800</td>
</tr>
<tr>
<td>3.5 to less than 4 years</td>
<td>400</td>
</tr>
<tr>
<td>4 to less than 4.5 years</td>
<td>200</td>
</tr>
<tr>
<td>4.5 to less than 5 years</td>
<td>100</td>
</tr>
<tr>
<td>5 to less than 5.5 years</td>
<td>50</td>
</tr>
<tr>
<td>5.5 to less than 6 years</td>
<td>20</td>
</tr>
<tr>
<td>6 to less than 6.5 years</td>
<td>10</td>
</tr>
<tr>
<td>6.5 to less than 7 years</td>
<td>5</td>
</tr>
<tr>
<td>7 to less than 7.5 years</td>
<td>2</td>
</tr>
<tr>
<td>7.5 to less than 8 years</td>
<td>1</td>
</tr>
<tr>
<td>8 to less than 8.5 years</td>
<td>1</td>
</tr>
<tr>
<td>8.5 to less than 9 years</td>
<td>0</td>
</tr>
<tr>
<td>Greater than 9 years</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>47,700</td>
</tr>
</tbody>
</table>

Of the estimated 47,700 incidents involving children, 99 percent involved a chest, bureau, or dresser; the remainder involved armoires, a portable closet, a wardrobe, and a product that was either an armoire or a dresser. In about 30 percent of injuries involving children, a television fell with the CSU.

**C. Severity and Consequences of Injuries**

The types of injuries that can result from CSUs tipping over can range from scratches, cuts, bruises, joint injuries, and bone fractures to potentially fatal injuries, such as skull fractures, closed-head injuries, internal organ injuries, collapsed lungs, spinal injuries, or mechanical asphyxia (which is a form of suffocation that results from a mechanical force [such as furniture] preventing muscle movement necessary for breathing). The severity of injuries depends on various factors, such as the body part hit or trapped by the CSU, the weight and nature of the stationary forces involved (i.e., the CSU and the floor), the magnitude and duration of the force the CSU applies, the duration of oxygen deprivation from mechanical asphyxia, and the ability to call for help or self-rescue. Blunt head trauma can result in death or severe injuries, and oxygen deprivation can lead to permanent brain damage, organ and tissue injury, or death.

Children are particularly vulnerable to the risk of injury and death associated with CSU tip overs because of their physical and cognitive abilities, the circumstances often involved in CSU tip overs, and their susceptibility to severe injury. Children generally are not strong enough to move heavy furniture when trapped underneath, do not react quickly enough to avoid falling furniture, and lack cognitive awareness of hazards. In addition, many incidents occur when a child is left unattended, reducing the likelihood that a caregiver could quickly rescue the child. Children, in particular, can suffer long-term harm from head injuries, which can affect their motor and emotional development, speech, cognitive ability, and overall quality of life.

Commission staff reviewed fatal incidents and NEISS incidents involving children to identify the types of fatal and nonfatal injuries associated with CSU tip overs. Of the 167 fatal incidents involving children and CSU tip overs that occurred between 2000 and 2016, 71 (43 percent) were the result of head injuries, skull fractures, and brain hemorrhage from blunt head trauma (including crushing injuries and deep scalp hemorrhage). The remaining 96 fatal incidents (57 percent) were the result of chest compression from a child being pinned under a CSU. In 13 of the 167 fatal incidents involving children, the child died despite receiving medical care.

CSU tip-over injuries to children that are treated in hospital emergency departments ranged in severity, including contusions, abrasions, lacerations, fractures, and internal injuries. Of the estimated 47,700 emergency department-treated injuries to children that were associated with CSUs between January 1, 2006 and December 31, 2016, an estimated 17,700 injuries (37 percent) involved contusions or abrasions; an estimated 12,500 injuries (26 percent) involved internal injuries (including closed head injuries); an estimated 8,700 injuries (14 percent) involved lacerations; and an estimated 4,500 injuries (9 percent)
involved fractures. Injuries to children that were reported through NEISS impacted numerous body parts, but the most common was the head (42 percent), followed by the face (15 percent), and trunk (10 percent). Four percent of NEISS injuries involving children and CSU tip overs required hospitalization, whereas 92 percent were treated and released, and 1 percent were observed.

When a television was involved in a CSU tip over, children’s injuries were more likely to require hospitalization and involve internal injuries and head injuries than when no television was involved. When a television was involved in a CSU tip over that resulted in injury to a child, 7 percent of injuries required hospitalization (compared with 3 percent when only a CSU was involved); 36 percent of injuries were internal injuries (compared with 22 percent when only a CSU was involved); and 58 percent were head injuries (compared with 36 percent when only a CSU was involved).

D. Hazard Patterns

CPSC staff analyzed fatal and nonfatal incident reports to identify factors that are associated with CSU tip-over incidents. This analysis revealed that certain user interactions (such as opening multiple drawers) and surroundings (such as specific flooring) were associated with CSU tip overs. To assess relevant incidents in detail, staff reviewed 369 nonfatal incidents involving CSU tip overs that occurred between January 1, 2005 and December 31, 2015, and were reported to CPSC. 3 This data set is useful to identify hazard patterns, but it cannot be used to draw statistical conclusions because it does not include the most recent incident reports, and many of the reports do not include detailed information about circumstances surrounding the incidents. 4

1. Televisions

As the incident data discussed above indicates, in some incidents, televisions tipped over with a CSU, often resulting in more serious injuries. Of the 167 child fatalities between 2000 and 2016, 89 (53 percent) involved a television falling in addition to the CSU. Of the estimated emergency department-
freestanding storage furniture, including cupboards, cabinets, and bookshelves that are fully assembled and ready for use, but excludes wall-mounted and built-in products. AS/NZS 4935 applies to domestic freestanding chests, drawers, and wardrobes over 19.7 inches in height, as well as bookshelves and bookcases more than 23.6 inches. EN–14749 applies to all kitchen, bathroom, and domestic storage units with movable and non-moveable parts.

ASTM International approved ASTM F2057–17 on October 1, 2017, and published it in October 2017. 5 The scope of ASTM F2057–17 specifies that the standard is intended to cover “children up to and including age five.” ASTM F2057–17 includes requirements for stability, labeling, and tip over restraint devices (TRDs).

To assess the stability of a CSU, ASTM F2057–17 requires that the unit withstand two performance tests—one when the unit is loaded, and one when the unit is unloaded. For the loaded test, the CSU must not tip over when each drawer (or door) is open, one at a time, and weighted with 50 pounds. For the unloaded test, the CSU must not tip over when all of the drawers (or doors) are open at the same time. For both stability tests, testing is on a “hard, level, flat surface” and drawers must be open to the outstop (a feature that limits the outward movement of a drawer) or, when there is no outstop, to ⅔ of the operational sliding length, and doors must be open 90 degrees. The standard specifies that if part of the CSU fails, that part should be repaired or replaced and the test repeated.

ASTM F2057–17 also requires a permanent label on CSUs, in a “conspicuous location when in use,” and includes an example label showing warning content and formatting. The standard also includes a test for assessing label permanence.

ASTM F2057–17 requires that TRDs be provided with all products that fall within the scope of the standard and that they comply with ASTM F3096–14. TRDs are supplementary devices that help prevent tip overs. One example of a TRD is a strap that users attach to the back of a CSU and the wall, to stabilize the CSU. ASTM F3096–14 requires TRDs to be tested for strength by affixing one end of the assembled restraint to a fixed structure and applying a 50-pound weight to the opposite end. ASTM F3096–14 also requires instructional literature that includes illustrations of installation methods, step-by-step instructions, and a list of parts with pictures.

The three international standards—ISO 7171, AS/NZS 4935, and EN 14749—address many of the same key performance requirements as the voluntary ASTM standards. Table 3 compares the key elements in each of the standards.

### Table 3—Key Performance Requirements in Voluntary and International Standards Addressing Storage Unit Furniture Tip Overs

<table>
<thead>
<tr>
<th>Test mass</th>
<th>Minimum furniture height</th>
<th>Element breakage</th>
<th>Element extension</th>
<th>TRDs</th>
<th>Warning labels</th>
<th>Load and force test</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASTM F2057–17</td>
<td>50 lbs</td>
<td>Repair, if possible</td>
<td>Outstop or 2/3</td>
<td>Required</td>
<td>Required</td>
<td>None.</td>
</tr>
<tr>
<td>ISO 7171</td>
<td>Not specified</td>
<td>Not specified</td>
<td>Not mentioned</td>
<td>Required</td>
<td>Required</td>
<td>None.</td>
</tr>
<tr>
<td>AS/NZS 4935</td>
<td>29 kg (63.88 lbs)</td>
<td>505 mm (19.7 in)</td>
<td>Strongly rec-</td>
<td>Required</td>
<td>Required</td>
<td>None.</td>
</tr>
<tr>
<td>EN 14749</td>
<td>75 N (16.8 lbs)</td>
<td>Not specified</td>
<td>Not mentioned</td>
<td>None.</td>
<td>Not mentioned</td>
<td>Yes.</td>
</tr>
</tbody>
</table>

ISO 7171 testing requirements address only stability. ASTM F2057–17 and AS/NZS 4935 include requirements for both stability testing and warnings. EN 14749 includes stability requirements, as well as strength and durability requirements. The stability test requirements in ASTM F2057–17 and AS/NZS 4935 are similar in that both require one empty drawer to be open for loaded testing. In contrast, EN 14749 requires that all drawers in a row (not column) be open simultaneously, but specifies a lower force than ASTM F2057–17 and AS/NZS 4935. EN 14749 also includes two further stability tests to assess a vertical force and a loaded test with force applied. ASTM F2057–17 is the only standard that requires TRDs.

### B. Assessment of Existing Standards

Commission staff assessed the requirements in each of the existing standards and determined that the two ASTM standards are the most effective existing standards. Nevertheless, Commission staff preliminarily believes that the existing standards do not adequately reduce the risk of CSU tip overs. Staff believes that the two ASTM standards are more effective than the international requirements primarily for two reasons. First, although it may appear that EN 14749 is the most stringent standard because it requires additional stability tests, the additional tests are not as severe as applying a larger force to the front edge of an empty unit, as ASTM F2057–17 and AS/NZS 4935 require. Second, ASTM F2057–17 is the only standard that requires TRDs. The Commission’s Division of Mechanical Engineering staff believes that TRDs are an important component to effectively prevent CSU tip overs. For these reasons, Commission staff believes that the ASTM standards are the most stringent existing standards, and therefore, focused on these standards when assessing the effectiveness of existing standards that address CSU tip overs. However, as discussed below, there are several provisions in the ASTM standards that staff preliminarily believes do not adequately address the risk of CSU tip overs.

#### 1. Scope

The scope of ASTM F2057–17, which limits the height of CSUs and age of children it addresses, may not adequately reduce the risk of injury associated with CSU tip overs. First, the scope of the standard is limited to addressing CSUs that are more than 30 inches in height. However, there have been incidents involving CSUs that are 30 inches tall or less. These products may present a hazard particularly to children because low-height CSUs may be intended for children and these

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5 Although ASTM F2057–17 was published shortly before this ANPR and staff’s accompanying briefing package, Commission staff was able to review and assess the standard based on the previous version, ASTM F2057–14, which was largely the same as ASTM F2057–17. The only changes in ASTM F2057–17 were to non-substantive provisions (introduction, caveats, and principles on standardization) and warning label requirements. The changes to warning label requirements were the addition of performance requirements for label permanence and the addition of a pictogram in the warning label. Staff considered these changes in their review and assessment.

6 ISO 7171 does not include pass/fail criteria for loaded stability testing. Instead, it directs testers to continue to increase the force until a portion of the product “just lifts away from the floor.”
products can weigh as much as 100 pounds.

Second, the scope of ASTM F2057–17 states that the target population for injury reduction is “children up to and including age five.” However, as the incident data demonstrate, children as old as 8 years old have been killed and injured by CSU tip overs. In particular, children under age 6 are most commonly involved in incidents. The “age five” specified in the standard appears to include only children up to exactly age five (i.e., 60 months), however, and not children between their fifth and sixth birthdays (based on the 50-pound stability test weight, which represents the weight of children 60 months old). In addition, hazard patterns, such as opening multiple drawers, present a risk of injury to users of any age.

2. Stability

There are also several components of the stability testing provisions in ASTM F2057–17 that staff preliminarily believes are not adequate to reduce the risk of injury associated with CSU tip overs.

First, the standard requires that stability testing occur on a “hard, level, flat surface.” This does not reflect the surfaces on which CSUs may rest in consumers’ homes. For example, floors in a home may not be level, and carpeting is not flat. As the incident reports suggest, when a flooring type was reported, carpeting was more commonly involved in CSU tip-over incidents than other types of flooring. Assessing the impact of alternate surfaces on stability may be necessary to accurately assess the stability of a product. In addition, the standard does not provide a detailed definition of a “hard, level, flat surface.” Relevant details may include a surface flatness tolerance (e.g., ±0.1”) over a certain area or a specific type of flooring surface (e.g., Type IV vinyl tile).

Second, the requirement that testing occur with drawers open to the outstop or, if there is no outstop, to ½ of the operational sliding length, is unclear and creates testing inconsistencies. For example, staff has tested CSUs with outstops that are significantly less than ½ of the operational sliding length, the location of the outstop can impact proper placement of the test weight on the drawer, the standard does not address CSUs with multiple outstops, and the standard does not specify a minimum operational sliding length, which would facilitate testing.

Third, the stability test procedure may not reflect conditions during actual consumer use. This test requires that all drawers are empty and open simultaneously. However, when contents were reported in CSU tip-over incidents, CSUs generally contained clothing.

Fourth, staff has several concerns with the loaded stability test procedure. The 50-pound test weight is not consistent with the age and weight of victims. The majority of reported CSU tip-over incidents involved children under 6 years old. As such, the test weight in the standard does not reflect the weight of children involved in the majority of incidents, which is approximately 60 pounds (for the 95th percentile weight of children just under six years old, according to Centers for Disease Control growth charts). In addition, the test weight tolerances may impact the repeatability of testing. ASTM F2057–17 allows a tolerance of ±1 pound for each of the two 25-pound test weights, which means the total weight can range from 48 to 52 pounds, plus the weight of the fastening hardware and strap. Such a wide tolerance may produce variation in test outcomes, which could result in the same CSU passing and failing during multiple tests.

Fifth, the standard’s allowance for the replacement or repair of a failed component may be problematic. For example, this provision does not include a testability requirement, does not account for a failure that cannot be repaired or replaced, and does not account for design-to-fail features that prevent tip overs.

Sixth, during CPSC testing, staff identified several additional issues related to the specificity and clarity of the test procedures in ASTM F2057–17. For example, the standard does not address how to apply test weights to drawers with center components (e.g., handles), does not include a timeframe in which to apply and maintain the test weight, and does not address how to place weights in shallow drawers to avoid contact with the drawer bottom.

3. Labeling

Commission staff has concerns with the location and content requirements for warning labels in ASTM F2057–17.7 With respect to location, the standard specifies that a label must be in a “conspicuous location when in use” but does not provide further details. For a warning label to be effective, it must be in a location where users will see it. For example, users are not likely to notice or read a label in a lower drawer because it is outside their line-of-sight and they would have to crouch to read it. In contrast, if a label is in a drawer at eye level, an adult, parent, or caregiver is more likely to notice and read the label. For this reason, the label placement provision in the standard may not be adequate for the label to be effective.

Staff also has concerns with the hazard communication statements ASTM F2057–17 requires on a label. First, the label does not allow for customization of hazard avoidance statements for different unit designs. Second, the warning messages may not reflect the hazard patterns demonstrated in the incident data. Third, the warning language may not be easy to understand, may not motivate consumers to comply, and contradicts typical CSU uses. For example, the warning label states that consumers should not open multiple drawers simultaneously, but this contradicts common consumer use. Another example is the warning label statement that users should not place a television on a CSU, unless it is specifically designed to accommodate a television. The CSU manufacturer, not the consumer, is in the best position to determine whether a CSU is designed to accommodate a television.

4. TRDs

Commission staff believes that the TRD requirements in ASTM F3096–14 do not adequately assess the strength of TRDs under conditions in which they are commonly used. Staff believes the following provisions are inadequate. First, the test method in ASTM F3096–14 only addresses TRD designs that have a linear connection to the means of attachment (strap-style TRDs). This test does not account for varied or innovative TRD designs. Second, the test does not examine the strength of all of the components of a TRD (e.g., brackets, fastener). Third, the test does not simulate the types of materials to which consumers are likely to secure TRDs. Fourth, the standard does not include explicit criteria for determining whether a TRD passes or fails the test.

VI. Regulatory Alternatives the Commission Is Considering

The Commission is considering several alternatives to address the risk of death and injury associated with CSU tip overs.

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7 Staff also expressed concerns with the label placement provision in ASTM F2057–17 in the 2016 briefing package (U.S. Consumer Product Safety Commission, Staff Briefing Package on Furniture Tipover (September 30, 2016)). However, those concerns have been resolved with the label permanence requirements added to ASTM F2057–17.
A. Mandatory Standard

The Commission could issue a mandatory standard addressing the hazard associated with CSU tip overs. A mandatory standard could include performance requirements, warning and instructional requirements, or both. However, warning and instructional requirements alone may not be adequate to address the risk because they rely on consumers noticing, reading, and following the warning. The Commission may consider the following factors in developing performance and warning requirements:

1. Scope and Definition of CSUs

In developing a mandatory standard, the Commission would need to consider the appropriate scope for the standard, including the types of products the standard would cover, the hazard scenarios it would address, and whether to focus on a particular target population for injury reduction. For example, CPSC would need to consider whether to limit the scope of a standard to the CSU tip-over hazard posed to children under 6 years old. Such a scope may be appropriate because the large majority of CSU tip over injuries and deaths involve children under 6 years old. However, it may also be appropriate not to limit the scope of the standard because some injuries and fatalities have involved older children and adults, and some demonstrated hazard patterns (e.g., opening multiple drawers) involve a risk of injury to all ages.

Similarly, CPSC also must consider how to define CSUs that are subject to a mandatory rule. Defining CSUs by certain characteristics may be appropriate. Such characteristics could include product height or weight, product types, or product features, reflecting the characteristics of products involved in incidents.

2. Stability

The Commission believes that it may be appropriate to consider performance requirements and test methods that simulate actual use, including weighting a CSU to represent common use, dynamic testing to represent a child climbing (exerting a downward force), and testing that reflects actual floor surfaces in homes. In developing a mandatory standard, the Commission would consider ways to address the hazard patterns demonstrated in the incident data, such as:

- A child under 6 years old (weighing approximately 60 pounds) standing on a lower drawer to reach into an upper drawer;
- A consumer (of any age) fully opening multiple drawers simultaneously that contain items typically stored in a CSU; and
- A CSU on a soft surface that simulates average carpet.

3. Labeling

Clear and explicit requirements regarding the content and placement of warning labels may assist in reducing the risk of injury associated with CSU tip overs. This may include identifying a conspicuous location on CSUs for a warning label; allowing for customization of hazard-avoidance statements, based on unit designs; comparing warning messages with incident data to make sure that the known hazardous situations are addressed; and including warning content that is easy to understand and consistent with the way consumers typically use CSUs.

4. TRDs

TRDs are an important feature for reducing the risk of CSU tip overs. To assess the effectiveness of TRDs at preventing tip overs, performance requirements and test methods that assess the strength of the entire TRD system and reflect the circumstances under which TRDs are likely to be used (including the materials to which consumers are likely to attach them and the forces to which they are likely to be subjected) would be useful.

B. Rely on Voluntary Standards

The Commission could rely on the voluntary ASTM standards—ASTM F2057–17 and ASTM F3096–14—that address CSU tip overs. If the Commission determines that the voluntary standards adequately reduce the risk of injury associated with CSU tip overs, and it finds that there is substantial industry compliance with the standards, then the Commission must rely on the voluntary standards, instead of issuing a mandatory standard. 15 U.S.C. 2058(b)(2).

However, as discussed above, the Commission preliminarily believes that the ASTM standards do not adequately reduce the risk of injury associated with CSU tip overs. The Commission is assessing the level of compliance with the voluntary standards.

C. No Regulatory Action

The Commission could rely on methods other than mandatory or voluntary standards to address the risk of injuries associated with CSU tip overs. This may include relying on product recalls or promoting the ongoing Anchor It! educational campaign. These alternatives may not be as effective at reducing the risk of injury as a mandatory standard. Recalls only apply to an individual manufacturer and product and do not extend to similar products. Recalls also can only address products that are already on the market, and cannot prevent unsafe products from entering the market. As for educational campaigns, staff does not have information regarding the effectiveness of the Commission’s education campaign to date.

VII. Request for Comments and Information

The Commission requests comments on all aspects of this ANPR, but specifically requests comments regarding:

- Data about the risk of injury associated with CSU tip overs;
- studies, tests, or surveys analyzing furniture tip-over injuries, including the severity and costs associated with injuries;
- the alternatives the Commission is considering, as well as additional alternatives for addressing the risk of injury;
- the appropriate scope of a mandatory standard and definition of CSUs, including the type of products it should address (e.g., other furniture; televisions; all CSUs; CSUs with certain features or over a certain height, such as 30 inches) and the ages it should address (e.g., children under 6 years old, all children, or all ages);
- the effectiveness of the stability, warning, and TRD requirements being considered;
- studies, tests, or surveys analyzing the use of aftermarket products that address tip-over hazards (e.g., wall straps, anchors) and their effectiveness at reducing tip overs;
- information or studies about how characteristics of the flooring surface under a CSU may impact the stability of the CSU and the effectiveness of a stability standard;
- a suitable definition for a soft surface that could serve as a surrogate for “average” or typical carpet;
- the effectiveness of voluntary or international standards at reducing the risk of injury associated with CSU tip overs;
- compliance with ASTM F2057–17 and ASTM F3096–14;
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2017–N–6529]

The Food and Drug Administration’s Approach To Evaluating Nicotine Replacement Therapies; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public hearing on FDA’s approach to evaluating the safety and efficacy of nicotine replacement therapy (NRT) products, including how they should be used and labeled.

DATES: The public hearing will be held on Friday, January 26, 2018, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation. Persons seeking to attend or to present at the public hearing must register by Tuesday, January 2, 2018. Section II provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until Thursday, February 15, 2018.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room A, Silver Spring, MD 20993–0002. Entrance for public hearing participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 15, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of February 15, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2017–N–6529 for “FDA’s Approach to Evaluating Nicotine Replacement Therapies”; Public Hearing; Request for Comments. Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit only one copy total. One copy will include the information you claim to be confidential.