(ii) If the results of the BSI are ''unsatisfactory'' using the criteria in Accomplishment Instructions, paragraph 5.B.(6)(g), of CFM SB LEAP–1B–72–00–0222–01A–930A–D, Issue 007, dated May 17, 2019, then you must continue the repetitive inspections required by paragraphs (g)(1)(i)(B) or (g)(1)(ii)(B) of this AD.

(2) [Reserved]

(j) Definition

For the purpose of this AD, ''flight hours (FHs) since new'' are the FHs accumulated on the RDS bearings on new engines delivered from production and on engines that have had the RDS bearing replaced during an engine shop visit.

(k) No Reporting Requirement

The reporting requirement in paragraph 5.A.(6) in CFM SB LEAP–1B–72–00–0222–01A–930A–D, Issue 007, dated May 17, 2019, is not required by this AD.

(l) Credit for Previous Actions

You may take credit for the inspections that are required by paragraph (g)(1) of this AD, if you performed those actions before the effective date of this AD using CFM SB LEAP–1B–72–00–0222–01A–930A–D, Issue 006, dated March 22, 2019, or an earlier revision. You may also take credit for the optional BSI in paragraphs (h)(1) or the optional terminating inspection in paragraph (i)(1) of this AD, if you performed that action before the effective date of this AD using CFM SB LEAP–1B–72–00–0256–01A–930A–D, Issue 002, dated May 6, 2019, or an earlier revision.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (n) of this AD. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(2) 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.

(n) Related Information

For more information about this AD, contact Christopher McGuire, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA, 01803; phone: 781–238–7120; fax: 781–238–7199; email: *chris.mcguire@faa.gov.*

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) CFM Service Bulletin LEAP–1B–72–00–0222–01A–930A–D, Issue 007, dated May 17, 2019.

(ii) [Reserved]

(3) For CFM service information identified in this AD, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH, 45125; phone: 877–432–3272; fax: 877–432–3329; email: *aviation.fleetsupport@ge.com.*

(4) You may view this service information at FAA, Engine & Propeller Standards Branch, 1200 District Avenue, Burlington, MA, 01803. For information on the availability of this material at the FAA, call 781–238–7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on June 14, 2019.

Karen M. Grant,

Acting Manager, Engine & Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2019–13022 Filed 6–17–19; 8:45 am]

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1238

[Docket No. CPSC–2018–0015]

Safety Standard for Stationary Activity Centers

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the United States Consumer Product Safety Commission (CPSC) to adopt safety standards for durable infant or toddler products. To comply with the CPSIA, the Commission is issuing a safety standard for stationary activity centers (SACs). This rule incorporates by reference ASTM F2012–18$^{\varepsilon 1}$, *Standard Consumer Safety Performance Specification for Stationary Activity Centers* (ASTM F2012–18$^{\varepsilon 1}$). This rule also amends the regulations for third party conformity assessment bodies to include the safety standard for SACs in the list of notices of requirements (NORs).

DATES: The rule will become effective on December 18, 2019. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of December 18, 2019.

FOR FURTHER INFORMATION CONTACT: Keysha Walker, Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission; 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504–6820; email: *KWalker@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

Congress enacted the CPSIA (Pub. L. 110–314, 122 Stat. 3016), including the Danny Keysar Child Product Safety Notification Act, on August 14, 2008. Section 104(b) of the CPSIA requires the Commission to: (1) Examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) issue consumer product safety standards for durable infant or toddler products. 15 U.S.C. 2056a(b)(1). Any standard the Commission adopts under this mandate must be ''substantially the same as'' the voluntary standard, or more stringent than the voluntary standard if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. *Id.* Section 104(f)(1) of the CPSIA defines the term ''durable infant or toddler product'' as ''a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years,'' and lists SACs as a durable infant or toddler product. *Id.* 2056a(f).

On June 19, 2018, the Commission issued a notice of proposed rulemaking (NPR), proposing to incorporate by reference the voluntary standard for SACs, ASTM F2012–18$^{\varepsilon 1}$, without modifications. 83 FR 28390. ASTM F2012–18$^{\varepsilon 1}$ is still the current version of the standard.

In this final rule, the Commission incorporates by reference ASTM F2012–18$^{\varepsilon 1}$, with no modifications, as the mandatory safety standard for SACs. CPSC staff consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this standard, largely through the ASTM standard-development process. In addition, this final rule amends the list of NORs in 16 CFR part 1112 to include the standard for SACs. This rule is based on information in CPSC staff's briefing package, ''Staff's Draft Final Rule for Stationary Activity Centers Under the Danny Keysar Child Product Safety Notification Act,'' which is available on CPSC's website.

II. Product Description

ASTM F2012–18$^{\varepsilon 1}$ defines a SAC as ''a freestanding product intended to remain stationary that enables a sitting or standing occupant whose torso is completely surrounded by the product to walk, rock, play, spin or bounce, or all of these, within a limited range of motion.'' ASTM F2012–18$^{\varepsilon 1}$, section 3.1.12. This definition does not include doorway jumpers.

SACs are intended for children who are not yet able to walk, but who are able to hold up their heads unassisted. SACs vary in style and design complexity, but typically consist of a seat that is suspended from a frame by springs or supported from the bottom by a fixed base. ASTM F2012–18$^{\varepsilon 1}$ defines three types of SACs: Closed-base SACs, open-base SACs, and spring-supported SACs. The standard defines each of these terms, as follows:

- A closed-base SAC is ''a stationary activity center that does not allow the occupant's feet to contact the floor when the product is in any manufacturer's recommended use position'' (section 3.1.1.);
- an open-base SAC is ''a stationary activity center that allows the occupant's feet to contact the floor'' (section 3.1.7); and
- a spring-supported SAC is ''a stationary activity center in which the sitting or standing platform is supported from below or suspended from above by springs (or equivalent resilient members)'' (section 3.1.10).

III. Market Description

SACs typically range in price from $40 to $150, with spring-supported SACs typically ranging from $70 to $150. Some manufacturers produce multiple models, and several produce models that are similar in design, but with different accessories. SACs typically accommodate children who weigh less than 25 pounds and have a maximum height of 32 inches.

There were approximately 7.5 million [1] SACs in U.S. households with children under 5 years old in 2013, according to CPSC's 2013 Durable Nursery Product Exposure Survey. However, only about 4.1 million of these SACs were actually in use.[2]

CPSC staff identified 11 domestic firms that currently supply SACs to the U.S. market. These firms primarily specialize in manufacturing children's products. According to the U.S. Small Business Administration's (SBA) standards,[3] 7 of the 11 firms are small businesses. All seven firms manufacture SACs; staff did not identify any small domestic importers of SACs. Of the seven small manufacturers, three produce spring-supported SACs. The Juvenile Products Manufacturers Association (JPMA) certifies the SACs of all seven firms, which indicates that these SACs comply with the ASTM standard and undergo third party testing.

IV. Incident Data and Recalls

CPSC receives data about product-related injuries from several sources. One source is the National Electronic Injury Surveillance System (NEISS), from which CPSC may obtain estimates based on a probability sample, determined by sampling weights from NEISS hospitals projected to national estimates. Other sources include reports from consumers and others through the Consumer Product Safety Risk Management System (which also includes some NEISS data) and reports from retailers and manufacturers through CPSC's Retailer Reporting System—CPSC refers to these sources collectively as Consumer Product Safety Risk Management System data (CPSRMS).

CPSC staff reviewed the NEISS and CPSRMS databases for incidents involving SACs. For the NPR, staff reviewed incident data reported to have occurred between January 1, 2013 and September 30, 2017. For the final rule, staff updated this review to include incident data received from October 1, 2017 through February 20, 2019. This updated review includes additional incident data reported to have occurred between January 1, 2013 and September 30, 2017, as well as new incidents that occurred between October 1, 2017 and February 20, 2019. Because reporting is ongoing, the number of reported incidents may change. For both the NPR and updated data periods, the number of injuries associated with SACs treated in U.S. EDs was insufficient for staff to derive reportable national estimates.[4] For this reason, staff has not provided injury estimates. However, injuries associated with SACs treated in U.S. EDs are included in the total count of reported incidents presented below.

A. Fatalities

CPSC is not aware of any fatalities associated with SACs that occurred between January 1, 2013 and February 20, 2019.

B. Nonfatal Injuries

CPSC is aware of 4,035 nonfatal incidents related to SACs that reportedly occurred between January 1, 2013 and February 20, 2019. CPSC had received reports of 3,488 of these incidents at the time of the NPR; since the NPR, CPSC received 547 additional reports of SAC incidents that reportedly occurred between January 1, 2013 and February 20, 2019. Of the 4,035 total incidents, 359 reportedly resulted in injuries (CPSC had received reports of 304 of these injury incidents at the time of the NPR, and received 55 additional injury reports since the NPR). The remaining 3,676 incidents either did not result in injuries, or did not include sufficient information to determine whether an injury occurred (CPSC had received reports of 3,184 of these incidents at the time of the NPR, and received 492 additional reports since the NPR). Although these reports did not indicate that an injury occurred, many of the incident descriptions indicated the potential for a serious injury.

Of the 304 incidents that had reportedly resulted in injuries at the time of the NPR, 24 of the injured children were treated and released from a U.S. ED. A majority of the injured children suffered a fall, resulting in head injuries, limb fractures, and contusions. A few children treated in U.S. EDs suffered foot, leg, or pelvic bruising, or fractures or swelling while jumping in the product. One child had an allergic reaction to the product's finish or materials, and the limbs of two children became entrapped in the product. Among the remaining 280 injury reports, some identified the type of injury sustained, while others only mentioned an injury, but provided no specifics about the injury. Some of the commonly reported injuries were fractures, head injuries, concussions, teeth injury, abrasions, contusions, and lacerations.

Of the 55 injury incidents reported since the NPR, there were reports of head contusions; arm and leg contusions, abrasions, and lacerations; hand contusions, abrasions, lacerations, and blisters; finger entrapments; mouth lacerations; torso abrasions; a nose contusion; a torso abrasion; a leg fracture; and a skull fracture. Three children suffered allergic reactions to the product finish or material, and one

[1] 95% confidence interval between 6.2 million and 8.8 million.

[2] 95% confidence interval between 3.1 million and 5.2 million.

[3] Under SBA size standards, a SAC manufacturer is ''small'' if it has 500 or fewer employees, and an importer is ''small'' if it has 100 or fewer employees.

[4] According to NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33% or smaller.

child experienced a choking episode. Three children suffered multiple injuries.

The majority of reported incidents and injuries involved children between 6 months old and 11 months old. Of the 4,035 total incidents, 13 percent involved children under 6 months old; 60 percent involved children between 6 and 11 months old; 7 percent involved children between 12 and 17 months old; 1 percent involved children between 18 and 23 months old; and 18 percent did not report the age of the victim.[5] Of the 359 incidents that reportedly resulted in injuries, 20 percent involved children under 6 months old; 60 percent involved children between 6 and 11 months old; 6 percent involved children between 12 and 17 months old; 1 percent involved children between 18 and 23 months old; and 12 percent did not report the age of the victim.[6]

C. Hazard Patterns

The hazards reported in the new incidents are consistent with the hazard patterns staff identified in the incidents presented in the NPR. Table 1 lists the number and percentage of the 4,035 total reported incidents within each hazard pattern.

TABLE 1—REPORTED INCIDENTS BY HAZARD PATTERN

[January 1, 2013 to February 20, 2019]

Hazard	Number of incidents	Percentage of total incidents
Spring Issues	1,756	44
Problems with Toy Accessories	1,166	29
Strap Issues	513	13
Structural Integrity Problems	166	4
Problems with Seats/Seat Pads	136	3
Stability Issues	112	3
Design Issues	59	1
Electrical Problems	38	1
Miscellaneous/Other Problems	31	1
Multiple Problems	32	1
Unspecified/Unknown Problems	26	1
Total	4,035	[7] 101

Spring issues. These incidents involved problems with the springs that attach the seat of the SAC to the frame. A total of 1,756 incident reports CPSC received between January 1, 2013 and February 20, 2019 involved spring issues (CPSC received 1,617 of these reports before the NPR and 139 after the NPR). Thirty of these incidents reportedly resulted in injuries, including 1 injury treated in a U.S. ED (CPSC received 27 of these reports before the NPR and 3 after the NPR).

Problems with toy accessories. These incidents involved problems with the toy accessories attached to SACs, including detached small parts posing a choking hazard, toys striking children in the face, toys pinching or entrapping children's fingers, and laceration hazards caused by sharp edges or surfaces. A total of 1,166 incident reports CPSC received between January 1, 2013 and February 20, 2019 involved toy accessory issues (CPSC received 1,075 of these before the NPR and 91 after the NPR). Of these 1,166 incidents, 169 reportedly resulted in injuries, including 15 injuries treated in U.S. EDs (CPSC received 156 of these reports before the NPR and 91 after the NPR).

Strap issues. These incidents involved torn, fraying, twisted, or detached straps. Typically, the strap system on a SAC is attached to a support spring and serves as the primary means of support for most spring-supported SACs. If the strap fails, the SAC may be unsupported on one side and often results in a child falling. A total of 513 incident reports CPSC received between January 1, 2013 and February 20, 2019, involved strap issues (CPSC received 306 of these before the NPR and 207 after the NPR). Of these 513 incidents, 42 reportedly resulted in injuries, including one injury treated in a U.S. ED (CPSC received 30 of these reports before the NPR and 12 after the NPR).

Structural integrity problems. These incidents involved a problem with structural components, such as frame tube damage, broken battery cover tabs, loose screws or small parts, broken activity bars, and problems with locks, which led to product collapse, detachment of the top and bottom parts of the SAC, or failure of the height adjustment mechanism. A total of 166 incident reports CPSC received between January 1, 2013 and February 20, 2019, involved structural integrity issues (CPSC received 158 of these before the NPR and 8 after the NPR). Twelve of these incidents reportedly resulted in injuries (CPSC received all 12 of these reports before the NPR).

Problems with seats or seat pads. These incidents included stitching on the seat pad fraying or tearing; tabs used to attach the pad to the seat frame breaking, tearing, or separating; attachments disassembling and causing the seat pad to fall; inadequately constrictive leg openings; seat fabric detaching from pegs; ripped seat pads; and rough seat pad material. A total of 136 incident reports CPSC received between January 1, 2013 and February 20, 2019, involved seat or seat pad issues (CPSC received 122 of these before the NPR and 214 after the NPR). Thirteen of these incidents reportedly resulted in injuries (CPSC received 12 of these reports before the NPR and 1 after the NPR).

Stability issues. These incidents involved SACs leaning to one side, lifting off the floor, or tipping over during use. A total of 112 incident reports CPSC received between January 1, 2013 and February 20, 2019, involved stability issues (CPSC received 76 of these before the NPR and 36 after the NPR). Thirteen of these incidents reportedly resulted in injuries, including two injuries treated in U.S.

[5] Total does not sum to 100 percent due to rounding.

[6] Total does not sum to 100 percent due to rounding.

[7] Total does not sum to 100 percent due to rounding.

EDs (CPSC received four of these reports before the NPR and nine after the NPR).

Design issues. These incidents involved problems with the design of the SAC, such as entrapment of limbs or extremities, failure of the seat to contain a child, placement of structural components that made it easier for a child to get hurt during routine use, mold buildup in a wire compartment, the base of the product disassembling while a child jumped in it, and straps that loosen when a baby kicks them. A total of 59 incident reports CPSC received between January 1, 2013 and February 20, 2019, involved design issues (CPSC received 32 of these before the NPR and 27 after the NPR). Of these 59 incidents, 26 reportedly resulted in injuries, including two injuries treated in U.S. EDs (CPSC received 20 of these reports before the NPR and six after the NPR).

Electrical problems. These incidents involved melting, leaking, or corroded batteries, or failure of the circuit board on the product. A total of 38 incident reports CPSC received between January 1, 2013 and February 20, 2019, involved electrical issues (CPSC received 36 of these before the NPR and 2 after the NPR). Two of these incidents reportedly resulted in injuries (CPSC received both of these reports before the NPR).

Miscellaneous or other problems. These incidents involved the product falling from an elevated surface; a rough surface, sharp edges, or protrusions; problems with the paint or finish; problems with the product packaging; allergic reactions to the product; and a loose unraveling string. A total of 31 incident reports CPSC received between January 1, 2013 and February 20, 2019, involved miscellaneous or other issues (CPSC received 22 of these before the NPR and 9 after the NPR). Eighteen of these incidents reportedly resulted in injuries, including five injuries treated in U.S. EDs (CPSC received 13 of these reports before the NPR and 5 after the NPR).

Multiple problems. These incidents involved more than one of the hazard patterns listed above. CPSC staff could not determine the priority of the hazard patterns involved. A total of 32 incident reports CPSC received between January 1, 2013 and February 20, 2019, involved multiple issues (CPSC received 20 of these before the NPR and 12 after the NPR). Nine of these incidents reportedly resulted in injuries (CPSC received five of these reports before the NPR and four after the NPR).

Unspecified or unknown problems. These reports provided incomplete or unclear descriptions of the incident. A total of 26 incident reports CPSC received between January 1, 2013 and February 20, 2019, involved unspecified or unknown issues (CPSC received 24 of these before the NPR and 2 after the NPR). Twenty-five of these incidents reportedly resulted in injuries, mostly resulting from falls, and included 17 injuries treated in U.S. EDs (CPSC received 23 of these reports before the NPR and 2 after the NPR).

D. Recalls

In the preamble to the NPR, the Commission reported that one consumer-level recall between January 2013 and March 2018, involved a SAC.[8] The hazard that prompted the recall was a toy attachment on the SAC, which posed an impact hazard when it rebounded. The firm received 100 reports of incidents, including 61 reported injuries. The injuries included bruises and lacerations to the face, a 7-month-old child who sustained a lineal skull fracture, and an adult who sustained a chipped tooth. The recall involved 400,000 units in the United States. There have not been any additional consumer-level recalls of SACs since the NPR.

V. ASTM F2012–18$^{\varepsilon 1}$

A. History of ASTM F2012

ASTM F2012 addresses the hazard patterns associated with SACs. ASTM first approved and published the standard in 2000, as ASTM F2012–00, *Standard Consumer Safety Specification for Stationary Activity Centers.* ASTM has revised the standard several times since then. In the NPR, the Commission proposed to incorporate by reference the then-current version of the standard, ASTM F2012–118$^{\varepsilon 1}$, with no modifications. ASTM approved ASTM F2012–18$^{\varepsilon 1}$ on March 1, 2018, and published it in March 2018. ASTM F2012–18$^{\varepsilon 1}$ is still the current version of the standard.

B. Assessment of ASTM F2012–18$^{\varepsilon 1}$

ASTM F2012–18$^{\varepsilon 1}$adequately addresses the risk of injuries and deaths associated with SACs. The standard addresses multiple hazards, including the hazard patterns that make up the majority of incidents and injuries in the SAC incident data. ASTM F2012–18$^{\varepsilon 1}$ includes requirements to address the following hazards:

- Sharp edges and points;
- small parts;
- latching or locking mechanisms to prevent unintentional folding;
- openings;
- scissoring, shearing, and pinching;
- exposed coil springs;
- toy accessories sold with SACs;
- protective components;
- spring failures on spring-supported SACs;
- structural integrity;
- leg openings;
- stability (including tip overs and seat tilt); and
- motion resistance.

The standard also includes requirements for warning labels and instructional literature. On-product warning labels inform caretakers of the risks of strangulation and occupants falling from SACs; the potential severity of resulting injuries; and how to avoid these hazards. The instructions that accompany SACs also include these warnings, as well as developmental criteria to explain when to begin using the product and when to discontinue use.

ASTM F2012–18$^{\varepsilon 1}$ addresses the four primary hazard patterns associated with SACs in the incident data. These are: (1) Spring issues (44 percent of incidents); (2) problems with toy accessories (29 percent of incidents); (3) strap issues (13 percent of incidents); and (4) structural integrity problems (4 percent of incidents). This section discusses how ASTM F2012–18$^{\varepsilon 1}$ addresses each of these hazard patterns.

Spring issues. Spring issues typically involve SACs in which the activity tray and child hang from springs at multiple points. These incidents often involve one or more parts of the spring system failing, which can result in the child falling out of the SAC when it tilts, tips, topples, or leans from the manufacturer's recommended-use position. ASTM F2012–18$^{\varepsilon 1}$ addresses this hazard with a performance requirement that support springs withstand 100 drops from a 33-pound weight from a height of at least 1 inch. In addition, based on input from CPSC staff, ASTM F2012–18$^{\varepsilon 1}$ requires a secondary support for load-bearing springs, so that there is a redundant system to prevent the seat from falling if a spring fails. CPSC concludes that these requirements adequately address the spring issues indicated in the incident data.

Problems with toy accessories. The majority of reported problems with toy accessories involve detached small parts causing choking or gagging, toys striking children in the face, pinch or entrapment points created by small gaps, and lacerations from sharp edges. ASTM F2012–18$^{\varepsilon 1}$ addresses these hazards by requiring toy accessories for SACs, and their means of attachment, to meet relevant requirements in ASTM

[8] CPSC website link to the recalled product: *https://www.cpsc.gov/Recalls/2013/Kids-II-Recalls-Baby-Einstein-Activity-Jumpers/.*

F963–17, *Standard Consumer Safety Specification for Toy Safety* (ASTM F963). ASTM F963 includes requirements that address the hazards evident in the injury data, including choking, ingestion, and inhalation hazards from small objects; sharp edges, hazardous points, and hazardous projections; folding mechanisms and hinges; and entanglement and strangulation hazards from cords, straps, and elastics. CPSC concludes that ASTM F963 adequately addresses the majority of hazards related to toy accessories on SACs.

Strap issues. The strap system on a SAC supports the occupant's weight and allows the occupant to bounce. The strap system is the primary means of support for most spring-supported SACs. A typical spring-supported SAC includes a strap system that connects at the top to the frame structure, and at the bottom to the side or underside of the carrier, to support the occupant. The length of the strap system typically consists of an upper segment that serves as the frame support strap, a lower segment that serves as the occupant support strap, and a middle section that consists of a spring to allow the occupant to bounce. Because the strap system serves as the primary means of support for most spring-supported SACs, if the strap fails, the SAC may be unsupported on one side, resulting in a child falling. Incidents involving strap issues include torn, fraying, twisted, or detached straps.

To address this hazard, ASTM F2012–18$^{\varepsilon 1}$ requires dynamic and static loading at the seat of the product to evaluate the durability of the support structures for the seat. This testing also stresses the structural integrity components of the product, such as straps. The standard requires that the product show no failure of seams, material breakage, or changes of adjustments that could cause the product to not fully support the child. CPSC staff concludes that these provisions adequately address the strap issues indicated in the incident data.

As the NPR discussed, while preparing the NPR, CPSC staff learned of one product in which the occupant support strap frayed and broke because the strap rubbed against a metal buckle during normal use. The support structure durability requirements in ASTM F2012–18$^{\varepsilon 1}$ do not address this scenario. On April 27, 2018, CPSC staff requested that ASTM address this hazard scenario, and ASTM created a task group to review the issue. The NPR requested comments about this issue, but CPSC received none. CPSC staff is participating in the ASTM task group, and the task group is making progress toward developing a requirement to address fraying straps. In this final rule, the Commission is not adopting an additional requirement to address this hazard because: (1) The ASTM task group has made progress toward developing a requirement to address fraying straps; (2) CPSC is aware of only one product that involved this issue; and (3) the one product has been redesigned with parts that will not cause the strap to fray.

Structural integrity problems. Incidents involving structural integrity problems include frame tube damage; loose screws; broken activity bars; and problems with locks that lead to the product collapsing, the top and bottom parts of the product detaching, or the height adjustment mechanism failing. To address these issues, ASTM F2012–18$^{\varepsilon 1}$ requires dynamic and static loading at the seat of the SAC to evaluate the durability of the support structures for the seat. This testing also stresses the structural integrity components of the SAC. The standard requires that the product show no failure of seams, material breakage, or changes of adjustments that could cause the product to not fully support the occupant. CPSC concludes that these requirements are adequate to address the structural integrity issues indicated in the incident data.

VI. Comments Filed in Response to the NPR

CPSC received two comments in response to the NPR. The comments are available in the docket for this rulemaking, CPSC–2018–0015, at: *www.regulations.gov.*

The first comment, from JPMA (a national non-profit trade association that represents producers, importers, and distributors of childcare articles), expressed support for the proposed rule and CPSC staff's collaboration with ASTM. The second comment also expressed general support for the proposed rule, but stated that there should be oversight of small manufacturers and importers. It appears that the commenter misunderstood the Regulatory Flexibility Act (RFA) analysis to mean that the rule would not apply to small entities; this is incorrect. The rule applies to all manufacturers and importers of SACs sold in the United States.

VII. Incorporation by Reference

The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. These regulations require the preamble to a final rule to summarize the material the agency is incorporating by reference, discuss how the material is reasonably available to interested parties, and explain how to obtain the material. 1 CFR 51.5(b). This section summarizes ASTM F2012–18$^{\varepsilon 1}$, and describes how to obtain a copy of the standard.

ASTM F2012–18$^{\varepsilon 1}$ contains test methods and requirements regarding:

- Sharp edges or points;
- small parts;
- latching or locking mechanisms to prevent unintentional folding;
- openings;
- scissoring, shearing, or pinching;
- exposed coil springs;
- toy accessories sold with SACs;
- protective components;
- spring failures on spring-supported SACs;
- structural integrity;
- leg openings;
- stability (including tip overs and seat tilt);
- motion resistance;
- warnings and labels; and
- instructional literature.

Interested parties may obtain a copy of ASTM F2012–18$^{\varepsilon 1}$ from ASTM, through its website (*http://www.astm.org*), or by mail from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428. Alternatively, interested parties may inspect a copy of the standard at CPSC's Division of the Secretariat.

VIII. Final Rule

Section 1238.2 of the final rule requires SACs to comply with ASTM F2012–18$^{\varepsilon 1}$ and incorporates the standard by reference. Section VII of this preamble describes the OFR requirements for incorporating material by reference. To comply with those requirements, section VII summarizes ASTM F2012–18$^{\varepsilon 1}$, explains how the standard is reasonably available to interested parties, and indicates how to obtain a copy of the standard.

The final rule also amends 16 CFR part 1112 to add a new § 1112.15(b)(48) that lists 16 CFR part 1238, *Safety Standard for Stationary Activity Centers,* as a children's product safety rule for which the Commission has issued an NOR. Section XV of this preamble provides additional information about certifications and NORs.

IX. Effective Date

The Administrative Procedure Act (5 U.S.C. 551–559) generally requires that agencies set an effective date for a final rule that is at least 30 days after the **Federal Register** publishes the final rule. *Id.* 553(d). The NPR proposed that the final rule for SACs, and the

amendment to part 1112, would take effect 6 months after publication. CPSC did not receive any comments about this timeline. Six months is generally enough time for firms to modify their products to meet a new standard, it is consistent with other CPSIA section 104 rules, and JPMA typically allows six months for products in its certification program to shift to a new standard. For these reasons, this rule will take effect 6 months after publication in the **Federal Register**, and will apply to products manufactured or imported on or after that date.

X. Paperwork Reduction Act

This rule contains information collection requirements that are subject to public comment and Office of Management and Budget (OMB) review under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). Under the PRA, CPSC must estimate the ''burden'' associated with each ''collection of information.'' 44 U.S.C. 3506(c).

In this rule, section 8 of ASTM F2012–18$^{\varepsilon 1}$ contains labeling requirements that meet the definition of ''collection of information'' in the PRA. *Id.* 3502(3). In addition, section 9 of ASTM F2012–18$^{\varepsilon 1}$ requires instructions be provided with SACs; however, CPSC staff believes this requirement can be excluded from the PRA burden estimate. OMB allows agencies to exclude from the PRA burden estimate any ''time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities,'' if the disclosure activities required to comply are ''usual and customary.'' 5 CFR 1320.3(b)(2). CPSC staff is not aware of SACs that require use or assembly instructions but lack such instructions, so staff believes that providing instructions with SACs is ''usual and customary.'' For this reason, the burden estimate includes only the labeling requirements.

The preamble to the NPR discussed the information collection burden of the proposed rule and requested comments on the accuracy of CPSC's estimates. 83 FR 28395. CPSC did not receive any comments about the information collection burden of the proposed rule. The information collection burden has not changed since the NPR. The estimated burden of this collection of information is as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN

16 CFR section	Number of respondents	Frequency of responses	Total annual responses	Hours per response	Total burden hours
1238.2	11	4	44	1	44

CPSC staff is aware of 11 suppliers of SACs to the U.S. market. This estimated reporting burden assumes that all 11 suppliers may need to modify their labels to comply with the final rule. CPSC staff estimates that it will take about one hour per model to make these modifications and, based on staff's evaluation of product lines, that each firm supplies an average of four models of SACs. Therefore, CPSC staff estimates that the burden associated with the labeling requirements is: 11 entities × 1 hour per model × 4 models per entity = 44 hours. CPSC staff estimates that the hourly compensation for the time required to create and update labels is $34.50 (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' Dec. 2018, total compensation for all sales and office workers in goods-producing private industries: *http://www.bls.gov/ncs/*). Therefore, the estimated annual cost associated with the labeling requirements is: $34.50 per hour × 44 hours = $1,518. CPSC staff does not expect there to be operating, maintenance, or capital costs associated with this information collection.

As the PRA requires, CPSC has submitted the information collection requirements of this final rule to OMB. 44 U.S.C. 3507(d). OMB has assigned control number 3041–0179 to this information collection.

XI. Regulatory Flexibility Act

A. Introduction

The RFA (5 U.S.C. 601–612) requires agencies to consider the potential economic impact of a proposed and final rule on small entities, including small businesses. An agency must prepare and publish a final regulatory flexibility analysis (FRFA) when it issues a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 604(a), 605(b). If, rather than publishing a FRFA, the head of the agency makes the above certification, the agency must publish the certification and a statement of the factual basis for it in the **Federal Register** with the final rule. *Id.* 605(b).

The Commission made the above certification in the NPR because staff found that the cost of modifying products to meet the standard would not be significant, and the SACs of all seven small manufacturers were JPMA certified. JPMA certification indicates that the products comply with the ASTM standard and undergo third party testing. The Commission does not have any new information that would change that conclusion. Therefore, the Commission certifies that this rule, incorporating by reference ASTM F2012–18$^{\varepsilon 1}$ as a CPSC standard, will not have a significant economic impact on a substantial number of small entities involved in manufacturing or importing SACs.

B. Comments Relevant to the RFA Analysis

CPSC did not receive any comments addressing the RFA analysis or from the Chief Counsel for Advocacy of the SBA, but did receive one comment regarding small entities. The commenter stated that there should be oversight of small manufacturers or importers if the rule does not apply to them. It appears that the commenter misunderstood the RFA analysis to mean that the rule would not apply to small entities; this is not correct. The rule applies to all manufacturers and importers of SACs sold in the United States.

XII. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that, before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The submission must indicate whether the rule is a ''major rule.'' The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a ''major rule.''

Pursuant to the CRA, OIRA designated this rule as not a ''major rule,'' as defined in 5 U.S.C. 804(2). In addition, to comply with the CRA, the Office of the General Counsel will

submit the required information to each House of Congress and the Comptroller General.

XIII. Environmental Considerations

CPSC's regulations list categories of agency actions that ''normally have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c). Such actions qualify as ''categorical exclusions'' under the National Environmental Policy Act (42 U.S.C. 4321–4370m–12), which do not require an environmental assessment or environmental impact statement. One categorical exclusion listed in CPSC's regulations is for rules or safety standards that ''provide design or performance requirements for products.'' 16 CFR 1021.5(c)(1). Because the final rule for SACs creates design or performance requirements, the rule falls within the categorical exclusion.

XIV. Preemption

Under section 26(a) of the CPSA, no state or political subdivision of a state may establish or continue in effect a requirement dealing with the same risk of injury as a Federal consumer product safety standard under the CPSA unless the state requirement is identical to the Federal standard. 15 U.S.C. 2075(a). However, states or political subdivisions of states may apply to CPSC for an exemption, allowing them to establish or continue such a requirement if the state requirement ''provides a significantly higher degree of protection from [the] risk of injury'' and ''does not unduly burden interstate commerce.'' *Id.* 2075(c).

Section 104 of the CPSIA requires the Commission to issue consumer product safety standards for durable infant or toddler products. As such, consumer product safety standards that the Commission creates under CPSIA section 104 are covered by the preemption provision in the CPSA. Therefore, the preemption provision in section 26 of the CPSA applies to the mandatory safety standard for SACs.

XV. Testing, Certification, and Notification of Requirements

Section 14(a) of the CPSA requires the manufacturer or private labeler of a children's product that is subject to a children's product safety rule to certify that, based on a third party conformity assessment body's (*i.e.,* third party laboratory's) testing, the product complies with the relevant children's product safety rule. 15 U.S.C. 2063(a)(2)(A), 2063(a)(2)(B). The Commission must publish an NOR for a third party laboratory to obtain accreditation to assess conformity with a children's product safety rule. 15 U.S.C. 2063(a)(3)(A).

Effective June 10, 2013, the Commission adopted 16 CFR part 1112, which sets out the general requirements and criteria concerning third party laboratories. 78 FR 15836 (Mar. 12, 2013). Part 1112 includes procedures for CPSC to accept a third party laboratory's accreditation and lists the children's product safety rules for which the Commission has published NORs. When the Commission issues a new NOR, it must amend part 1112 to include that NOR.

Because this final rule is a children's product safety rule, the Commission is amending part 1112 to include an NOR for the SACs standard. Third party laboratories that apply for CPSC acceptance to test SACs for compliance with the new SAC rule will have to meet the requirements in part 1112. When a laboratory meets the requirements of a CPSC-accepted third party conformity assessment body, the laboratory can apply to CPSC to include 16 CFR part 1238, *Safety Standard for Stationary Activity Centers,* in the laboratory's scope of accreditation of CPSC safety rules listed on the CPSC website at: *www.cpsc.gov/labse*arch.

As the RFA requires, CPSC staff prepared a FRFA for the Commission's part 1112 rulemaking. 78 FR 15836, 15855 (Mar. 12, 2013). The FRFA concluded that the accreditation requirements would not have a significant economic impact on a substantial number of small laboratories because no requirements applied to laboratories that did not intend to provide third party testing services. The only laboratories CPSC expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

For the same reasons, adding an NOR for the SACs standard to part 1112 will not have a significant economic impact on small test laboratories. Because only a small number of laboratories in the United States have applied for accreditation to test for conformance to existing juvenile product standards, CPSC expects that only a few laboratories will seek accreditation to test for compliance with the SACs standard. Of those that seek accreditation, CPSC expects that most already will have accreditation to test for conformance to other juvenile product standards. The only costs to those laboratories will be the cost of adding the SACs standard to their scopes of accreditation. For these reasons, CPSC certifies that amending 16 CFR part 1112 to include an NOR for the SACs standard will not have a significant economic impact on a substantial number of small entities.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third-party conformity assessment body.

16 CFR Part 1238

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Toys.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

■ 1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063; Pub. L. 110–314, section 3, 122 Stat. 3016, 3017 (2008).

■ 2. Amend § 1112.15 by adding paragraph (b)(48) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * *

(b) * * *

(48) 16 CFR part 1238, Safety Standard for Stationary Activity Centers.

* * * * *

■ 3. Add part 1238 to read as follows:

PART 1238—SAFETY STANDARD FOR STATIONARY ACTIVITY CENTERS

Sec.

1238.1 Scope.

1238.2 Requirements for Stationary Activity Centers.

Authority: 15 U.S.C. 2056a.

§ 1238.1 Scope.

This part establishes a consumer product safety standard for stationary activity centers.

§ 1238.2 Requirements for stationary activity centers.

Each stationary activity center shall comply with all applicable provisions of ASTM F2012–18$^{\varepsilon 1}$ *Standard Consumer Safety Performance Specification for Stationary Activity Centers*, approved on March 1, 2018. 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. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; *http://www.astm.org*. You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1305, and 1308

[Docket No. DEA–375]

Schedules of Controlled Substances: Placement of Thiafentanil in Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: On August 26, 2016, the Drug Enforcement Administration (DEA) published in the **Federal Register** an interim final rule with request for comments placing the substance thiafentanil, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers, in schedule II of the Controlled Substances Act. This final rule adopts that interim final rule without change.

DATES: The effective date of this rule is June 18, 2019.

FOR FURTHER INFORMATION CONTACT: Lynnette M. Wingert, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89), where the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has indexed a drug under section 572 of the Federal Food, Drug, and Cosmetic Act (FDCA), the DEA is required to issue an interim final rule, with opportunity for public comment and to request a hearing, controlling the drug not later than 90 days after receiving such notification from HHS and subsequently to issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to section 811(j), the DEA must apply the scheduling criteria of subsections 811(b), (c), and (d) and section 812(b). 21 U.S.C. 811(j)(3).

Background

On August 26, 2016, the DEA published an interim final rule with request for comments [81 FR 58834] to make thiafentanil (including its salts) a schedule II controlled substance(s). See 21 CFR 1308.12(c)(29) (DEA Controlled Substance Code 9729).

Over time, alternative chemical names have been used to describe this same specific substance. In the preamble to the interim final rule, the DEA provided ''4-(methoxycarbonyl)-4-(N-phenmethoxyacetamido)-1-[2-(thienyl)ethyl]piperidine'' [1] as the chemical name for thiafentanil. However, the DEA believes it is more accurate to use ''methyl 4-(2-methoxy-*N*-phenylacetamido)-1-(2-(thiophen-2-yl)ethyl)piperidine-4-carboxylate)'' [2] in the preamble of this final rule. It bears emphasis that the chemical that is the subject of this final rule is the same substance that was the subject of the interim final rule. The DEA simply is using an alternative chemical description to refer to that same substance in this preamble.

Thiafentanil, a potent opioid, is an analogue of fentanyl. In June 2016, the Food and Drug Administration (FDA) reviewed and determined that the product Thianil (thiafentanil oxalate, a salt form of thiafentanil) met the requirements for addition to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index) (21 U.S.C. 360ccc–1) as set forth by the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act).[3] As discussed in the preamble to the interim final rule, the HHS provided the requisite notification to DEA that HHS/FDA added Thianil (thiafentanil oxalate) to the Index (Minor Species Index File (MIF) 900000) under section 572 of the FDCA.

The DEA based its scheduling decision, and issuance of the interim final rule, on 21 U.S.C. 811(j), the HHS's November 2011 scientific and medical evaluation and scheduling recommendation, the HHS's March 2016 supplemental analysis, the MUMS Act indication by the HHS/FDA, and the DEA's determination. The interim final rule provided an opportunity for interested persons to file written comments, as well as a request for hearing or waiver of hearing, on or before September 26, 2016.

Comments Received

The DEA received one comment from the American Veterinary Medical Association supporting the interim final rule to control thiafentanil as a schedule II substance of the CSA.

DEA Response. The DEA appreciates the support for this rulemaking.

The DEA did not receive any requests for hearing or waiver of hearing. Based on the rationale set forth in the interim final rule, the DEA adopts the interim final rule, without change.

Requirements for Handling Thiafentanil

As indicated above, thiafentanil has been a schedule II controlled substance for more than two years by virtue of the interim final rule issued by the DEA in 2016. Thus, this final rule does not alter the regulatory requirements applicable to handlers of thiafentanil that have been in place since that time. Nonetheless, for informational purposes, we restate here those requirements. Thiafentanil is subject to the CSA's schedule II regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule II substances, including the following:

1. *Registration.* Any person who desires to handle thiafentanil

[1] The interim final rule also mentioned the other chemical name, 4-(methoxycarbonyl)-4-(*N*-phenylmethoxyacetamido)-1-[2-(2-thienyl)ethyl]piperidine in the section entitled ''Background, Legal Authority, and Basis for This Scheduling Action''.

[2] Other chemical names have been used for thiafentanil. The HHS referred to the substance as ''4-(methoxycarbonyl)-4-(N-phenymethoxyacetamido)-1-[2-(thienyl)ethyl]piperidine'' and ''4-methoxycarbonyl-4(*N*-phenyl-methoxyacetamido)-1-(2′-(2″-thienyl)ethyl]-piperidine'' in its November 2011 scientific and medical evaluation and scheduling recommendation, and as ''4-(methoxycarbonyl)-4-(N-phenmethoxyacetamido)-1-[2-(thienyl)ethyl]piperidium'' in its March 2016 supplemental analysis.

[3] The MUMS Act amended the FDCA to allow for the legal marketing of unapproved new animal drugs intended for use in minor species.