

proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 1028.124 Conditions

With respect to any research project or any class of research projects the department or agency head of either the conducting or the supporting Federal department or agency may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2017-19737 Filed 9-15-17; 8:45 am]

BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1229

[Docket No. CPSC-2015-0028]

Safety Standard for Infant Bouncer Seats

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards 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. The Commission is issuing this final rule establishing a safety standard for infant bouncer seats (bouncer seats)

in response to the direction of section 104(b) of the CPSIA. Additionally, the Commission is finalizing an amendment to its regulations regarding third party conformity assessment bodies to include safety standard for bouncer seats in the list of notice of requirements (NORs) issued by the Commission.

DATES: This rule will become effective March 19, 2018. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of March 19, 2018.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The CPSIA was enacted 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) promulgate consumer product safety standards for durable infant and toddler products. Standards issued under section 104 are to be “substantially the same as” the applicable voluntary standards 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.

The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA 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 the statute specifies twelve categories of products that are included in the definition, including walkers, carriers and various types of children’s chairs. When issuing a regulation governing product registration under section 104, the Commission determined that an “infant bouncer” falls within the definition of a “durable infant or toddler product.” 74 FR 68668 (Dec. 29, 2009); 16 CFR 1130.2(a)(15).

On October 19, 2015, the Commission issued a notice of proposed rulemaking (NPR) for infant bouncer seats. 80 FR 63168. The NPR proposed to incorporate by reference the 2015 version of the voluntary standard, ASTM F2167 *Standard Consumer*

Safety Specification for Infant Bouncer Seats (ASTM F2167), as a mandatory consumer product safety rule with several modifications to the content, format, and placement of warning labels and instructions, to strengthen the standard.

In this document, the Commission is issuing a mandatory consumer product safety standard for bouncer seats. As required by section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this rule, largely through the ASTM process. Based on revisions to the voluntary standard since the NPR published, the final rule incorporates by reference the most recent voluntary standard for infant bouncer seats, developed by ASTM International, ASTM F2167-17, with two modifications related to warning label content and placement. These modifications strengthen the standard by requiring a more stringent warning to caregivers to use the restraints, even if an infant falls asleep in the bouncer, and requires the fall hazard warning to be placed on the upper seat back of the bouncer seat, to ensure that caregivers read and heed the warning. The Commission’s more stringent requirements are intended to further reduce the risk of injury to infants that fall from, and with, bouncer seats, especially bouncer seats that are placed on an elevated surface.

Additionally, the final rule amends the list of NORs issued by the Commission in 16 CFR part 1112 to include the standard for infant bouncer seats. Under section 14 of the CPSA, the Commission promulgated 16 CFR part 1112 to establish requirements for accreditation of third party conformity assessment bodies (or testing laboratories) to test for conformity with a children’s product safety rule. Amending part 1112 adds an NOR for the infant bouncer seat standard to the list of children’s product safety rules.

II. Product Description

A. Definition of “Bouncer Seats”

Section 1.2 of ASTM F2167-17 defines an “infant bouncer seat” as: “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.” Additionally, section 1.2 states that infant bouncer seats are intended for “infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age).”

Bouncer seats vary widely in style and complexity, but typically, bouncer seats consist of a cloth cover stretched over a wire or tubular frame. Wire frame bouncers have two designs. The forward bend design is constructed with the seating area supported from the front side of the product. The second wire frame design is a rear bend design. In the rear bend design, the seat is supported from the rear side of the product. Other bouncer designs are also currently available, including, but not limited to, products with individual wire legs, solid bases, and spring designs. These infant bouncer designs use different methods to support the seat and are intended for “bouncing,” as defined in ASTM F2167.

All bouncer seats support the child in an inclined position, and some brands have adjustable seat backs. Various bouncer seat models include a “soothing unit” that vibrates or bounces the chair, and may play music or other sounds. Most bouncer seats also feature an accessory bar with attached toys that are, or at some point will be, within the child’s reach. Most of the bouncer seat models examined by Commission staff provide a 3-point restraint system, consisting of wide cloth crotch restraints and short adjustable waist straps with plastic buckles. Only two models of bouncer seats reviewed by CPSC for the NPR employed upper body restraints. Many bouncer seat brands also include an “infant insert,” intended for use to support smaller babies. Tabs C and D, Staff Briefing Package: Infant Bouncer Seats Notice of Proposed Rulemaking, dated September 30, 2015 (Staff NPR Briefing Package), available at: <http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2015/ProposedRuleSafetyStandardforInfantBouncerSeatSeptember302.pdf>.

B. Market Description

For the final rule, staff identified 23 firms supplying infant bouncer seats to the U.S. market, with several firms moving into or out of the market since the NPR was published. The 23 identified firms primarily specialize in the manufacture and/or distribution of children’s products, including durable nursery products. Eight of the 23 known firms are domestic manufacturers and 8 are domestic importers. The remaining seven firms are foreign (four manufacturers, two importers, and one retailer).¹ Tab C, Staff Briefing Package: Final Rule for Infant Bouncer Seats,

dated August 23, 2017 (Staff Final Rule Briefing Package), available at: <https://www.cpsc.gov/s3fs-public/Final-Rule-Safety-Standard-for-Infant-Bouncer-Seats-August-23-2017.pdf?ctmyMqMkYWQ1t3QN9DUXCDKnJQ5rKCX6>.

Staff expects that the infant bouncer seats of 14 of these firms already comply with ASTM F2167 because the firms either: (1) Have their bouncers certified by the Juvenile Products Manufacturers Association (JPMA) (five firms); (2) claim compliance with the voluntary standard (eight firms); or (3) have been tested to the ASTM standard by CPSC staff (one firm).²

III. Incident Data

For the NPR, CPSC’s Directorate for Epidemiology, Division of Hazard Analysis, described 277 reported incidents involving bouncer seats, including 11 fatalities and 51 injuries, occurring between January 1, 2006 and February 2, 2015. The incidents described in the NPR were based on reports involving victims 12 months old and younger in the Injury or Potential Injury Incident (IPII), In-Depth Investigation (INDP), and Death Certificates (DTHS) databases (collectively referred to as Consumer Product Safety Risk Management System data, or CPSRMS data). A detailed discussion of the incidents and hazard patterns developed for the NPR can be found in Tab A of the Staff NPR Briefing Package.

A. CPSRMS Data

For the final rule, CPSC staff reviewed bouncer seat incident reports in CPSRMS from February 2, 2015 through July 6, 2016. CPSC staff found 70 incident reports in addition to those discussed in the NPR, including one fatality and three injuries. The fatality involved a 4-month-old female who died after suffering a fractured skull injury when the infant bouncer she was seated in fell from a table. Two of the reported injuries were head contusions. A 5-month-old male sustained a head contusion when a bouncer seat bent backward to the floor. A 6-month-old male sustained a head contusion when a bouncer cover came off of the wire frame and the infant flipped forward, striking his head on the battery compartment. In another reported incident, the victim suffered minor leg

burns from a hot metal bar under a bouncer cover. Tab A, Staff Final Rule Briefing Package.

Staff did not identify any hazards in the updated incident data that were not included in the hazard patterns described in the NPR (product design, structural integrity, toy bar-related, stability, chemical/electric hazards, restraints, hazardous environment), which specifically identified product design and structural integrity as the top two product-related hazards (in terms of frequency of occurrence). Staff found that product design and structural integrity continue to be the top two product-related hazards (in terms of frequency) for the updated CPSRMS data. Of the 70 new incident reports involving bouncer seats, 51 incident reports described issues with product design, and 13 incident reports described issues with structural integrity. Staff determined that almost all of the issues with product design were related to lopsided or low-riding bouncer frames. Data for the final rule can be found in Tab A of the Staff Final Rule Briefing Package.

B. NEISS Data

For the NPR, CPSC staff found 672 bouncer-related incidents, including two fatalities, reported in the National Electronic Injury Surveillance System (NEISS) records retrieved for bouncer incidents from January 1, 2006 to December 31, 2013, involving children 12 months old and younger. Staff found that 385 cases, or an estimated 9,200 injuries, occurred in hazardous environments (counters, tables, and other elevated surfaces).

Staff updated information on bouncer-related incidents from the NEISS records for the final rule. From January 1, 2014 through December 31, 2015, staff found 202 additional NEISS records describing infant bouncer incidents. Staff’s inspection of the updated NEISS data revealed that 100 cases, or an estimated 2,800 injuries, took place in hazardous environments. The remaining 102 cases, or an estimated 2,800 injuries, took place on the floor or at an unknown location. Staff found no additional fatalities in the NEISS data during this time frame. Staff estimates that 4,700 (85%) bouncer injuries involved the head and face.

ESTIMATED NEISS BOUNCER INJURIES, 2006–2015

[age 0–1]

Year	Cases	Estimated injuries
2006	67	1,400

¹ Staff categorized each firm using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm Web sites.

² JPMA typically allows six months for products in their certification program to shift to a new standard once it is published. Therefore, firms are likely already complying with ASTM F2167–16, which was published in May 2016. Firms are not expected to comply with the recently published ASTM F2167–17 until December 2017.

ESTIMATED NEISS BOUNCER INJURIES, 2006–2015—Continued
(age 0–1)

Year	Cases	Estimated injuries
2007	66	1,700
2008	74	1,600
2009	86	2,200
2010	94	2,300
2011	121	3,400
2012	90	2,500
2013	74	2,100
2014	98	2,900
2015	104	2,700
2006–2015	877	22,800

Based on the annual estimates provided in the table, staff found a statistically significant upward trend (p-value of 0.006) in the estimated emergency department-treated injuries involving bouncers for victims under 1-year-old from 2006 to 2015.

IV. Product Recalls

The NPR described two recalls of infant bouncer seats since January 2006, involving two different firms, one recall in April 2007³ (involving breakage of a tubular steel frame) and another recall in July 2009⁴ (involving small, sharp metal objects that could protrude through the bouncer fabric). No injuries were associated with either product at the time of the recall. See Tab E, Staff NPR Briefing Package. For the final rule, staff reports that no additional recalls involving bouncer seats have occurred.

V. Overview and Assessment of ASTM F2167

A. Overview

The voluntary standard for infant bouncer seats, ASTM F2167, *Standard Consumer Safety Specification for Infant Bouncer Seats*, is intended to minimize the risk of injury or death to infants in bouncer seats associated with falls from elevated surfaces, product disassembly or collapse, stability, and suffocation. ASTM F2167 was first approved in December 2001, and the standard published in January 2002. Since then, ASTM has revised the standard 11 times. Tab C of the Staff NPR Briefing Package includes a description of these revisions through 2015.⁵

³ CPSC link to recalled product: <http://www.cpsc.gov/en/Recalls/2007/Infant-Bouncer-Seats-Recalled-Due-to-Frame-Failure/>.

⁴ CPSC link to recalled product: <http://www.cpsc.gov/en/Recalls/2009/BabySwede-LLC-Recalls-Bouncer-Chairs-Due-to-Laceration-Hazard/>.

⁵ Prior to the NPR publishing in October 2015, ASTM F2167 was revised several times as part of the rulemaking consultation process. In February

More recently, in May 2016, ASTM revised the standard to add specific developmental guidance for caregivers about when to stop using the bouncer, and ASTM removed a general requirement for banned toys or other articles because those requirements do not apply to infant bouncer seats. As discussed below, the standard was subsequently revised in June of 2017 to incorporate changes recommended by ASTM’s Ad Hoc Task Group⁶ concerning warning label formatting requirements, and to add a requirement that limits the maximum weight of an occupant in an infant bouncer seat. The June 2017 version of the voluntary standard also removed a requirement for manufacturers of bouncer seats to change the model number whenever the product underwent a significant structural or design modification. We agree with ASTM that although changing the model number represents a best practice, most ASTM standards do not include the statement, and such practice does not impact the safety of the product.

B. Assessment of the Voluntary Standard

For the NPR, CPSC staff examined the relationship between the performance requirements in ASTM F2167–15 and each of the hazard patterns staff identified in the incident data for bouncer seats. Tab C, Staff NPR Briefing Package. Based on staff’s assessment, the Commission issued the NPR proposing to incorporate ASTM F2167–15 with the following modifications to warnings content, placement, and format:

- Revised content of the warnings, markings, and instructions: —Modify text in the warnings stating to use the restraints “*even if baby is sleeping*”;

2014 (ASTM F2167–14) the standard was revised to improve the sideward and rearward stability tests. Additionally in 2014, ASTM F2167–14a included changes to the stability test to make the ASTM standard more strict, to address tip-over incidents, and to add requirements and test procedures to address incidents involving battery leakage, corrosion, and overheating.

⁶ The Ad Hoc Task Group was formed by ASTM and consists of members of the various voluntary standards groups whose standards are affected by the durable nursery product rules. The purpose of the Ad Hoc Task Group is to harmonize the wording and warning label format of durable infant and toddler products. Ad Hoc Task Group recommendations for warning statements were originally published as a reference document titled, “Ad Hoc Wording—May 4, 2016,” as part of the F15 Committee Documents, and subsequently, the recommendations were revised and published in October 2016, with the title, “Ad Hoc Approved Wording, Revision A—October 17, 2016” (Ad Hoc Approved Wording).

- change the text in the warnings to read, “stop using when baby starts trying to sit up”; and
- change the developmental guidance in the instructions, if stated, to read: “from birth (or “0”) until baby starts trying to sit up.”

- Restricted the fall hazard label on the front surface of the bouncer to be adjacent to the area where the child’s head would rest, and modified the visibility test to reflect this requirement.

- Specified a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on the product and in the instructions.

The most recent version of the voluntary standard for bouncer seats, ASTM F2167–17, was approved on June 1, 2017, and published in June 2017. ASTM F2167–17 includes modified and new performance and labeling requirements developed by ASTM in conjunction with stakeholders and CPSC staff on the ASTM subcommittee task group, to address the hazards associated with bouncer seats. ASTM F2167–17 addresses several of the hazards identified by the Commission in the NPR. Accordingly, after reviewing and considering comments received in response to the NPR, as well as the work of the Ad Hoc Task Group, the Commission incorporates by reference ASTM F2167–17, with two modifications that were identified in the NPR related to warning content and warning placement, as the mandatory safety standard for infant bouncer seats. Below we assess ASTM F2167–17 and explain how it differs from what the Commission proposed.

1. Content of the Warnings, Markings, and Instructions

The NPR proposed to incorporate by reference ASTM F2167–15, with modifications to warning, marking, and instruction requirements. ASTM F2167–15 advised caregivers: “Always use restraints. Adjust to fit snugly.” Based on the incident data that relate deaths to suffocation among unrestrained infants while they slept, and relate serious head injuries to unrestrained infants due to falls from bouncer seats that are placed on elevated surfaces and falls from bouncer seats that are being carried by caregivers, the Commission stated in the NPR that the voluntary standard was inadequate to address the risk of injury to infants from falls out of bouncer seats, or the risk of suffocation among unrestrained infants who are sleeping. In the NPR, the Commission proposed warning language stating: “Adjust to fit snugly, *even if baby is*

sleeping.” Tab D, Staff NPR Briefing Package.

The newest version of the voluntary standard, ASTM F2167–17, still does not require a warning statement that caregivers should use the restraints, even if an infant is asleep. We disagree with this approach. We note that some NPR commenters were concerned by the addition of language to the product warnings regarding sleep because such language may suggest that bouncer seats are intended to be used for long-term, unattended, sleep. However, CPSC staff advises that young infants, such as those who are intended to use bouncer seats, spend more time asleep than awake.⁷ Infants spending more than brief periods in a bouncer seat will fall asleep on occasion (and caregivers will place infants to sleep in bouncer seats under some circumstances), just as infants will fall asleep in strollers, swings, and car-seat carriers. It may be counterintuitive, and therefore unlikely to occur to consumers, that products made for infants’ use, especially those that have features intended to sooth and comfort infants, would be unsafe places for infants to sleep. In fact, despite claims that bouncer seats are not intended for children to sleep in, CPSC staff found that some manufacturers’ marketing suggests that bouncers are intended for sleep as well as play. Moreover, incident data and Health Sciences’ assessment demonstrate that the severity of injury from a fall from a bouncer seat increases for a child who is unrestrained. Accordingly, in the final rule, the Commission requires that the fall hazard warning state that caregivers should use the restraints, *even if baby falls asleep.*

Based on staff’s recommendation and the work of the Ad Hoc Task Group, the final rule uses the phrase “falls asleep” instead of the phrase “is sleeping” that the Commission had proposed in the NPR. This change aligns with wording approved by the Ad Hoc Task Group, which is “*Never leave child unattended,*

even if child falls asleep.” The Ad Hoc Task Group intends for this warning to be used on products for infants who are likely to fall asleep in the product, but which are not intended for periods of unattended sleep (*i.e.* bouncers, swings, infant rockers, and handheld carriers).⁸ The Commission notes that the final rule does not preclude manufacturers from including an additional statement indicating that bouncers are not intended for long term sleep. Accordingly, the required fall and suffocation warning label text regarding use of restraints for the final rule is:

- Always use restraints and adjust to fit snugly, even if baby falls asleep.

ASTM F2167–17 includes the other modifications the Commission had proposed for warning statement requirements. Specifically, sections 8.5.2.1 and 9.2.1 Fig. 11 of ASTM F2167–17 requires text in the warnings to state: “stop using when baby starts trying to sit up.” ASTM F2167–17 requires additional text in the suffocation hazard warning label to limit the maximum weight for an occupant in an infant bouncer seat. The rationale for ASTM’s change is based on surveillance of the marketplace, which demonstrated that some manufacturers have weight limits that do not correlate to the developmental milestones contemplated in the current warnings. Section 8.5.2.1 of ASTM F2167–17 requires text in the warnings to instruct caregivers to: “STOP using bouncer when baby starts trying to sit up or has reached [insert manufacturer’s recommended maximum weight, not to exceed 20 lb], whichever comes first.”

2. Warning Label Placement and Visibility Test

The NPR proposed a modification to ASTM F2167–15’s requirement for label

placement. ASTM F2167–15 required that the fall hazard label be placed on the front surface of the bouncer seat back so that it is visible when a newborn CAMI dummy is placed in the bouncer seat. In the NPR, the Commission assessed this provision of the voluntary standard and found that it did not adequately address the risk of injury to infants falling from bouncer seats placed on elevated surfaces, a foreseeable misuse of infant bouncer seats. Tab D, Staff NPR Briefing Package. To strengthen the standard and further reduce the risk of injury, the NPR proposed that the fall hazard warning label be on the front surface of the bouncer seat, adjacent to where the child’s head would rest, and the NPR also modified the visibility test. ASTM F2167–17 retains the fall hazard warning placement and corresponding visibility test from ASTM F2167–15. Thus, the current voluntary standard still does not address the Commission’s concern about the visibility of the fall hazard warning.

NPR Commenters expressed concern that some products were designed with insufficient space in the area adjacent to the child’s head to accommodate the necessary warning labels. Commenters were also concerned about the repeatability of the visibility test proposed in the NPR. We note, however, that staff’s research on the seat back space, including models with narrow seat backs, did not corroborate the commenters’ concerns. Nevertheless, to enhance test repeatability and to address the comments regarding insufficient seat back space for warning labels, the final rule allows a larger area for warning label placement than proposed in the NPR and clarifies the corresponding visibility test.

The visibility test in the final rule is based on ASTM F2167–17. Using the CAMI dummy, as shown in Figure 1 below, the allowable area for warning label placement starts from a dotted line that crosses the junctions of underarm and both sides of the torso of the CAMI dummy.

⁷ For example, see the American Academy of Pediatrics Web site, <http://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/default.aspx>.

⁸ During the April 2017 ASTM meetings, several Ad Hoc Task Group members requested the removal of this sentence from the Ad Hoc recommendations because no subcommittee had adopted the sentence. In the discussions, some manufacturers stated that these products are not appropriate for sleep, stating that the language “even if baby falls asleep,” may mislead caregivers. The Ad Hoc Group balloted the removal of the sentence in June 2017; however, the ballot received multiple negative votes and did not pass.

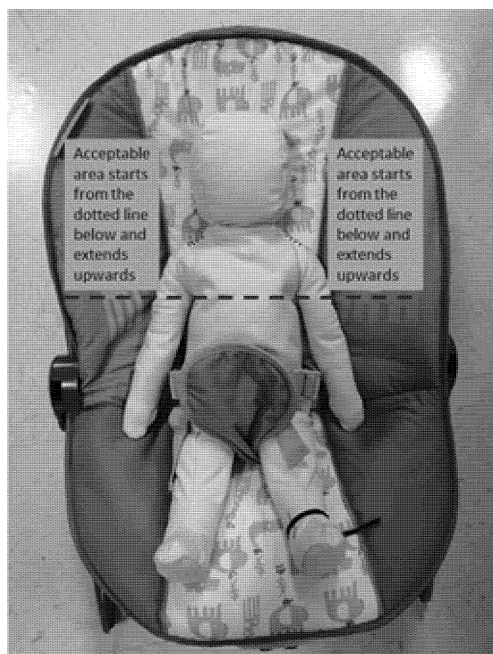


Figure 1. Warning Label Placement

This observable line expands the seat back space allowed for warning labels and clarifies the precision of the visibility test, both of which address commenter concerns.

3. Warning Label Format

The NPR proposed modifications to the requirements in ASTM F2167–15 regarding the format of warning labels noting that ASTM F2167–15 did not provide for a consistent warning label format across infant bouncer seats. Staff evaluated the warnings format in the voluntary standard and recommended that the Commission establish minimum requirements for presenting the hazard information that are consistent with best practices to attract and maintain attention, as well as aid reading and comprehension. Tab D, Staff NPR Briefing Package. Accordingly, the NPR proposed to specify a standard format (including black text on a white background, table design, bullet points, and black border) for the warnings on bouncer seats and in the instructions.

Since the NPR published in 2015, ASTM's Ad Hoc Task Group issued recommendations regarding warnings intended to apply across juvenile products. These recommendations, based on ANSI Z535.4, *American National Standard for Product Safety Signs and Labels*, have been incorporated into ASTM F2167–17. The Commission notes that Human Factors staff regularly cites ANSI Z535.4 as a baseline in developing warning materials, including those proposed in the bouncer seat NPR. The approved Ad

Hoc Task Group recommendations are very similar to the ANSI Z535.4, with modifications to make the recommendations more stringent. The recommendations provide noticeable and consistent warning labels on infant bouncer seats and across juvenile products. Accordingly, for the final rule, the Commission incorporates by reference ASTM F2167–17, without any modifications to the formatting provisions.

VI. Response to Comments

CPSC received six comments in response to the NPR, including a joint letter submitted by four consumer advocacy groups. Three commenters supported the changes proposed in the NPR, and the remaining commenters expressed concern over the Commission's proposed modifications. We summarize and respond to the commenters below.

A. Warning Label Location

Comment 1: One commenter stated that the proposed requirement for the fall hazard warning label to be adjacent to an infant's head would necessitate a wider seat back to accommodate a warning label in multiple languages, which is desirable for international sales. According to the same commenter, the ASTM F15.21 Subcommittee had already evaluated this location and concluded that other locations above and below the infant's head were considered to be just as visible as the locations adjacent to an infant's head. A second commenter

stated that the proposed fall hazard label visibility test procedure is not specific and can be misinterpreted by test labs. This commenter suggested using the test protocol in the current ASTM standard that uses the CAMI newborn dummy.

Response 1: Based on the incident data and research, the final rule requires that the fall hazard warning label be placed near the child's face. This location allows caregivers to notice the label while making eye contact with the infant, and potentially creates mental images of the consequence ("skull fracture") of not complying with the instructions because the warning label would be placed next to the body part at risk. Tab D, Staff NPR Briefing Package.

Commenters claim that the area on the infant bouncer adjacent to an infant's head could be severely limited in some cases due to the design of the seat back and allowance needed for stitching tolerances. CPSC staff's research did not corroborate this claim. Tab D, Staff NPR Briefing Package. Accordingly, the NPR, 80 FR at 63179–80, invited commenters to provide information on costs and design changes that would be required if the label were required to be next to an infant's head. Staff reports that during the ASTM Ad Hoc Task Group meetings held in January and February 2016, manufacturers provided several examples of juvenile products, including infant bouncer seats, to demonstrate difficulties associated with warning label placement in proposed

locations. However, NPR commenters provided neither cost estimates, nor specific comments, other than stating that the location would require a wider seat back and would limit representing multiple languages.

To resolve concerns about the amount of space for warning label placement and address the Commission's concern about an effective warning label, the final rule states the test procedure language in ASTM F2167-17, but clarifies the allowable area for the fall hazard warning label. The fall hazard warning label must be visible when placed above an imaginary horizontal line that crosses through the junctions of underarm and side of the torso (armpits) on both left and right of the CAMI, and not obscured by any part of the dummy. A warning label located at or around the infant's shoulders can address the visibility and caregiver motivational concerns expressed in the Human Factors staff memorandum for the NPR (Tab D), and also provide additional surface area to accommodate the recommended warning label.

B. Warning Label Format

Comment 2: Two commenters recommended against the proposed formatting requirements. Commenters specifically highlighted the following proposed warning formatting requirements:

- A heavy black border around the label,
- Delineating message panels with solid lines,
- Black text on white message panel,
- Bullet points preceding precautionary statements,
- Choosing a background color for the signal word panel based on a best contrast against the product material, and
- Using non-condensed style font.

Commenters stated that, in general, ASTM standards provide flexibility to manufacturers to pick colors and formatting features that are most appropriate for the product. One commenter recommended delaying the publication of the final rule for any and all warnings requirements until the warnings format and content revisions proposed in the NPR can be reviewed by ASTM Ad Hoc Task Group, balloted through the ASTM process, and then implemented into F2167. The same commenter also indicated that the formatting requirements in the bouncer NPR and several other NPRs are inconsistent with each other.

Response 2: Human Factors staff at CPSC employs the ANSI Z535.4, *American National Standard for Product Safety Signs and Labels* as a

baseline to develop warning materials. Since the NPR was published, the ASTM Ad Hoc Task Group met and made recommendations for warning label formatting across juvenile products. The ASTM Ad Hoc Task Group's recommendations are based on ANSI Z535.4 and are more stringent than the ANSI Z535 series. ASTM 2167-17 now incorporates recommendations made by the Ad Hoc Task Group. Accordingly, the final rule incorporates by reference ASTM 2167-17 without any modifications to warning label format.

C. Warning Label Content

Comment 3: Two commenters recommended against the proposed addition of "even if baby is sleeping" to the end of the precautionary statement: "Always use restraints. Adjust to fit snugly." One commenter believes that this statement implies that sleeping in a bouncer is acceptable and may encourage caregivers to use the product for extended periods of sleep. The second commenter believes that this statement contradicts the warning to never leave children unattended.

Response 3: Incident data associated with bouncer seats demonstrate that unrestrained infants suffer serious head injuries from falls and get into compromised positions that may result in suffocation. Tab A, Staff NPR Briefing Package; Tab A, Staff Final Rule Briefing Package. Young infants will sleep in bouncers as they spend more time asleep than awake. Tab D, Staff NPR Briefing Package. Some bouncers in the market include references to calming and soothing features of a bouncer, as well as appropriateness for short periods of sleep in a bouncer, such as "Your child can also sleep for short periods of time in the bouncer if he or she is content doing so." Based on incident data, the final rule requires that the warning statement reference sleep to reflect this foreseeable product use scenario and to address the risk of injury from falls.

In October 2016, the ASTM Ad Hoc Task Group approved a recommended warning to address products likely to be used for short-term sleep.⁹ The Commission agrees with the Ad Hoc Task Group's language and has modified the warning in the final rule to use the phrase "even if child falls asleep" to align with the Ad Hoc Task Group's

⁹The recommended wording is as follows: "Products likely to be used for infants who are sleeping (*i.e.*, bouncers, swings, infant rockers, handheld carriers) that are not intended for periods of unattended sleep, would benefit from this warning about unattended use. *Never leave child unattended, even if child falls asleep.*"

language. Manufacturers who produce bouncers in which infants should not be allowed to sleep may add language to their warnings statements alerting caregivers to this issue.

Comment 4: One commenter recommended that the ASTM subcommittee reach a consensus on the need for the additional proposed language: "Stop using bouncer when baby starts trying to sit up."

Response 4: At the January 12, 2016 ASTM meeting, the F15.18 subcommittee on Infant Bouncer Seats reviewed and agreed with the Commission's proposed language on developmental guidance. ASTM balloted and approved the proposed language, and such language has been included in ASTM F2167 since the 2016 version of the standard.

D. Other Warning Label Issues

Comment 5: Two commenters recommended that the warning label be attached on the product using embroidery or stamping to increase its permanency.

Response 5: The ASTM standard does not require a certain type of attachment for labels but requires the labels to be tested per section 7.8 to determine the labels' permanency. A similar permanency test procedure is used in other ASTM standards. No data were provided by the commenter, and the Commission has no information suggesting that these requirements are ineffective. Accordingly, the Commission incorporates by reference ASTM F2167-17, without any modification to section 7.8.

Comment 6: Three commenters recommended using pictures to clarify warning messages.

Response 6: The Commission acknowledges that well-designed graphics can be useful to increase the noticeability of the warnings as they help capture a user's attention. Pictograms are also helpful for users with limited or no English literacy. However, the design of effective graphics can be difficult. To avoid confusing consumers, a warning pictogram should be developed with an empirical study and well tested on the target audience. Although the Commission may take action in the future if it believes graphic symbols are needed to reduce the risk of injury associated with bouncer seats, the rule permits, but does not mandate, such supporting graphics.

VII. Incorporation by Reference

Section 1229.2(a) of the final rule provides that infant bouncer seats must comply with applicable sections of

ASTM F2167–17. The OFR has regulations concerning incorporation by reference. 1 CFR part 51. These regulations require that, for a final rule, agencies must discuss in the preamble to the rule the way in which materials that the agency incorporates by reference are reasonably available to interested persons, and how interested parties can obtain the materials. Additionally, the preamble to the rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR's requirements, the discussion in section VIII of this preamble summarizes the required provisions of ASTM F2167–17. Interested persons may purchase a copy of ASTM F2167–17 from ASTM, either through ASTM's Web site, or by mail at the address provided in the rule. A copy of the standard may also be inspected at the CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, as discussed above. Note that the Commission and ASTM arranged for commenters to have "read only" access to ASTM F2167–15 during the NPR's comment period.

VIII. Description of the Final Rule

Section 1229.2(a) of the final rule for infant bouncer seats incorporates by reference ASTM F2167–17 with two modifications, as stated in § 1229.2(b), related to the content and placement of warnings. Section 1229.2(a) includes the following key provisions summarized below: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature. As described below, § 1229.2(b) includes modifications to test methods (§ 1229.2(b)(1)), marking and labeling (§ 1229.2(b)(2) and (3)), and instructional literature (§ 1229.2(b)(4)).

Scope. Section 1 of ASTM F2167–17 states the scope of the standard, detailing what constitutes an "infant bouncer seat." As stated in section II.A of this preamble, the Scope section defines an "infant bouncer seat" as "a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means." ASTM F2167–17 states that infant bouncer seats are intended for "infants who have not developed the ability to sit up unassisted (approximately 0 to 6 months of age)."

Terminology. Section 3 of ASTM F2167–17 provides definitions of terms specific to this standard.

General Requirements. Section 5 of ASTM F2167–17 addresses numerous hazards with several general

requirements, most of which are also found in the other ASTM juvenile product standards. Several requirements reference an existing CPSC standard. The following general requirements apply to bouncer seats. Where the ASTM standard relies on a CPSC mandatory standard, the mandatory standard is cited in parentheses next to the requirement:

- Hazardous sharp points and edges (16 CFR 1500.48 and 1500.49);
 - Small parts (16 CFR part 1501);
 - Lead in paint (16 CFR part 1303);
 - Wood parts;
 - Latching and locking mechanisms;
 - Scissoring, shearing, and pinching;
 - Openings;
 - Exposed coil springs;
 - Protective components;
 - Permanency of labels and warnings;
- and
- Toys (ASTM F963).

Performance Requirements and Test Methods. Sections 6 and 7 of ASTM F2167–17 contain performance requirements specific to bouncer seats, as well as test methods that must be used to assess conformity with such requirements. Accordingly, the final rule includes performance requirements for the following:

- Restraints;
- Stability (forward, sideward, and rearward);
- Slip Resistance
- Structural Integrity;
- Dynamic and Static Load;
- Disassembly/Collapse;
- Drop Test;
- Toy Bar Attachment Integrity; and
- Battery Compartment.

Additionally, section 7 of ASTM F2167–17 includes test procedures to ensure the permanency of labels and warnings, and a fall hazard visibility test. The test procedure in § 1229.2(b)(1) of the final rule replaces the fall hazard visibility test in section 7.11.3.1 of ASTM F2167–17, as described in section V.B.2 of this preamble.

Marking and Labeling. Section 8 of ASTM F2167–17 requires products to be marked or labeled with manufacturing information and relevant product warnings. Warning label requirements for bouncer seats in section 8.4.5 of ASTM F2167–17 require two groups of warning statements, a fall hazard warning and a suffocation warning. ASTM F2167–17 includes warning language and formatting requirements for both falls and suffocation warnings. Section 8.4.7.1 requires the fall hazard warning to be placed on the front surface of the infant bouncer seat back, so that it complies with the visibility requirement in section 7.11.

Section 1229.2(b)(2) of the final rule replaces the content of the fall hazard

warning in section 8.5.1.1 of ASTM F2167–17. Section 1229.3(b)(3) of the final rule replaces the content of the suffocation hazard warning in sections 8.5.2.1 and 8.5.3 in ASTM F2167–17. Changes to warning content and the visibility test for the placement of the fall hazard warning are outlined in section V.B.1–2 of this preamble.

Instructional Literature. Section 9 of ASTM F2167–17 requires that instructions be provided with bouncer seats and be easy to read and understand. Additionally, the section contains requirements relating to instructional literature contents, including warnings.

Section 1229.2(b)(4) of the final rule replaces the content of sections 9.2.1 and 9.2.2 of ASTM F2167–17. These sections contain example warning labels or references to example warning labels. The content of the example warning labels in § 1229.2(b)(4) reflects changes to the content of the fall hazard warning and suffocation hazard warning in § 1229.2(b)(2) and (3) of the final rule. Changes to the instructional literature that relate to warnings content are outlined in section V.B.1–2 of this preamble.

IX. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). CPSC generally considers 6 months to be sufficient time for suppliers of durable infant and toddler products to come into compliance with a new standard under section 104 of the CPSIA. Six months is also the period that the Juvenile Products Manufacturers Association (JPMA) typically allows for products in the JPMA certification program to transition to a new standard once that standard is published. The Commission proposed a 6-month effective date in the NPR for infant bouncer seats and we received no comments on the proposed effective date. Accordingly, the final rule for bouncer seats, as well as the amendment to part 1112, has a 6-month effective date.

X. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires that agencies review a proposed rule and a final rule for the rule's potential economic impact on small entities, including small businesses. Section 604 of the RFA generally requires that agencies prepare a final regulatory flexibility analysis (FRFA) when promulgating final rules,

unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Staff prepared a FRFA that is available at Tab C of the Staff Final Rule Briefing Package. We provide a summary of the FRFA below.

The final rule is unlikely to have a significant economic impact on the five domestic manufacturers of infant bouncer seats. Of the six small importers, a significant economic impact cannot be ruled out for four of the importers, either as a result of the final rule requirements or the resulting third party testing costs. Therefore, the Commission cannot rule out a significant economic impact for four of the 11 firms (36 percent) operating in the U.S. market for bouncers.

B. The Product

An infant bouncer seat is defined in ASTM F2167–17, *Standard Consumer Safety Specification for Infant Bouncer Seats*, as “a freestanding product intended to support an occupant in a reclined position to facilitate bouncing by the occupant, with the aid of a caregiver or by other means.” These products vary widely in price; they can be purchased for as little as \$20, but can also easily cost more than \$200.

C. The Market for Infant Bouncer Seats

For the FRFA, the Commission identified 23 firms supplying infant bouncer seats to the U.S. market, with several firms moving into or out of the market since the NPR. These firms primarily specialize in the manufacture and/or distribution of children’s products, including durable nursery products. Eight of the 23 known firms are domestic manufacturers and eight are domestic importers. The remaining seven firms are foreign (4 manufacturers, 2 importers, and 1 retailer).¹⁰ We expect that the infant bouncer seats of 14 of these firms already comply with ASTM F2167 because the firms either: (1) Have their bouncers certified by JPMA (five firms); (2) claim compliance with the voluntary standard (eight firms); or (3) have been tested to the ASTM standard by CPSC staff (one firm).¹¹

¹⁰ Staff categorized each firm using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm Web sites.

¹¹ JPMA typically allows six months for products in their certification program to become compliant with a new voluntary standard once it is published. Therefore, firms are likely already complying with ASTM F2167–16, which was published in May 2016. They are not expected to comply with the recently published ASTM F2167–17 until December 2017.

D. Impact on Small Businesses

The Commission is aware of approximately 23 firms currently marketing infant bouncer seats in the United States, 16 of which are domestic. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of infant bouncer seats is categorized as small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. We have limited our analysis to domestic firms because SBA guidelines and definitions pertain to U.S.-based entities. Based on these guidelines, the Commission determined that about 11 of the 23 firms are small—five domestic manufacturers and six domestic importers. Additional unknown small domestic infant bouncer seat suppliers may be operating in the U.S. market.

1. Small Manufacturers

The economic impact of the final rule for infant bouncer seats should be small for the five small domestic manufacturers. Each firm has an established history of compliance with the ASTM standard for infant bouncers and is therefore expected to be compliant with ASTM F2167–17, the version of the voluntary standard upon which the final rule is based, by the time the mandatory standard becomes final.

None of these firms includes more than four languages in their warnings and redesign is not expected. Based upon staff’s inspection of their products, we expect products to have more than sufficient space for the required warning labels under the modified warning label for the final rule without the products seeming cluttered.

Under section 14 of the CPSA, once the new infant bouncer seat requirements become effective, all manufacturers will be subject to the third party testing and certification requirements under the CPSA and the Testing and Labeling Pertaining to Product Certification rule (16 CFR part 1107) (1107 rule). Third party testing will include any physical and mechanical test requirements specified in the final infant bouncer seats rule. Manufacturers and importers should already be conducting required lead testing for bouncer seats.

Third party testing costs are in addition to the direct costs of meeting the infant bouncer seats standard. The Initial Regulatory Flexibility Analysis (IRFA) prepared for the NPR concluded that we could not rule out a significant economic impact, given that we do not know specifically how much the third

party requirement adds to testing costs or precisely how many models are needed to meet the “high degree of assurance” standard but that it was unlikely to be economically significant for most small manufacturers (*i.e.*, testing costs would be less than 1 percent of gross revenue). Given that these firms are already testing to the voluntary standard and the Commission received no public comments about third party testing, the Commission believes that it is unlikely that third party testing would have a significant economic impact on any of the five small manufacturers.

2. Small Importers

a. Small Importers With Compliant Infant Bouncer Seats

As noted in the IRFA, imported bouncers tend to be produced to meet the requirements for several trading partners simultaneously, including their different labeling requirements. Producers for international markets typically address labeling requirements for their various trading partners by simply providing a warning that covers all required safety issues in multiple languages. Specificity regarding warning label location impacts the practicability of replicating the warning label in multiple languages. This could mean that foreign producers will need to design a product for the U.S. market or reduce the number of languages used for warnings on U.S.-bound bouncer seats.

The final rule provides additional space for warning label placement than that proposed in the NPR. With this additional space, reducing on-product warning languages should be a more viable alternative for firms than it was under the NPR proposal. Firms would not need to reduce the number of languages for their on-product warnings for the final rule as significantly as that required in the NPR. The additional space addresses the location requirement in the final rule, while ensuring that the appearance of bouncers remains comparable to firms’ competitor products (for which one to three languages is typical).

Three small importers of infant bouncer seats are currently in compliance with the voluntary standard; these firms likely would continue compliance as new versions of the voluntary standard are published. One importer is unlikely to experience a significant economic impact, even if the importer opted to redesign its bouncers to accommodate more than eight warning label languages. The cost estimate to redesign an infant bouncer (based on information from several

firms) is between \$200,000 and \$300,000, which is less than 1 percent of this firm's revenue. The remaining two small importers of compliant bouncer seats might experience significant economic costs, based on the same comparison (*i.e.*, \$200,000 to \$300,000 could represent more than 1 percent of their annual revenue). Although the Commission does not expect that these firms would require space for warning labels in more than eight languages, we cannot rule out a significant economic impact for one of these two firms, given an extremely low revenue level compared to estimated costs for redesign. The second firm appears to have the option of exiting the bouncer market without experiencing a significant impact.

b. Small Importers With Noncompliant Infant Bouncer Seats

Three firms import bouncers that do not comply with the voluntary standard. The bouncers for these firms will require changes to come into compliance with the voluntary standard as well as modifications to meet the warning label requirements in the final rule. In the absence of information on precisely what changes would be required to bring the bouncer seats supplied by all three firms into compliance with the final rule (as well as information on sales revenue for all three firms), the Commission cannot rule out a significant economic impact for any of these firms.

The magnitude of the economic impact on the three firms with noncompliant infant bouncer seats will depend upon the cost of the changes required and the degree to which their supplying firms pass on any increases in production costs associated with changes to the product needed to meet the mandatory standard (a redesign is estimated to cost between \$200,000 to \$300,000). Two of the firms are directly tied to their foreign suppliers and therefore, finding an alternate supply source would not be a viable alternative. However, given this close relationship, it seems likely that their foreign suppliers would have an incentive to work with their U.S. subsidiaries to maintain an American market presence. One of those two firms likely would only avoid a significant economic impact if their supplier absorbed 100 percent of the cost of a redesign. The third firm imports and wholesales a wide variety of children's products. We do not know, however, how much of the firm's revenue is due to bouncer sales and cannot determine what impact discontinuing bouncer sales might have on the third firm should the firm be

unable to find a supplier of bouncers that comply with the standard.

Based on the additional space provided in the final rule for placement of the fall hazard warning label, two of these firms should not require modifications to meet the requirement in the final rule (although they would have required modifications under the NPR).

c. Third Party Testing Costs for Small Importers

As with manufacturers, all importers will be subject to third-party testing and certification requirements, and consequently, will be subject to costs similar to those for manufacturers if their supplying foreign firm(s) does not perform third party testing. Half of the bouncer seat importers (3 of 6) are already testing their products to verify compliance with the ASTM standard, and any costs would be limited to the incremental costs associated with third party testing over the current testing regime.

The Commission was able to obtain revenue data for one of the small importers with noncompliant bouncers. For that importer, third party testing costs, considered alone and apart from any additional performance requirements due to the final rule, would not exceed one percent of gross revenue unless around 12 units per model required testing to provide the "high degree of assurance" required by 16 CFR part 1107. The Commission has no basis for estimating the size of the impact for the remaining two importers of noncompliant bouncers.

E. Summary of Impacts

The Commission is aware of 11 small firms, five domestic manufacturers and six domestic importers, currently marketing infant bouncer seats in the United States. With regards to the five domestic manufacturers, the Commission considers it unlikely that testing costs would have a significant impact on any of these firms. Of the six small importers, a significant economic impact cannot be ruled out for four of the importers either as a result of the final rule requirements or the resulting third party testing costs. Therefore, the Commission cannot rule out a significant economic impact for four of the 11 firms (36 percent) operating in the U.S. market for bouncers.

F. Alternatives

One of the alternatives to reduce the impact on small entities discussed in the NPR was to adopt the voluntary standard with all of the modifications to the on-product warning labels, except

for the location specificity (*i.e.*, next to the child's head). Based on comments received, the requirements regarding on-product warning label placement have been modified in the final rule (*i.e.*, up from the child's armpits on either side). This modification provides additional room and will reduce the economic impact of the warning label location specificity on small suppliers. The Commission could further reduce the economic impact on small entities by eliminating the location requirement for the fall hazard warning entirely. However, this would reduce the effectiveness of the fall hazard warning label. The location for the fall hazard warning "allows caregivers to notice the label while making eye contact with the infant, and potentially creates mental images of the consequence ("skull fracture") of not complying with the instructions . . ." Tab D, Staff NPR Briefing Package; Tab B, Staff Final Rule Briefing Package.

The Commission considered two additional alternatives discussed in the NPR that might minimize the economic impact on small entities: (1) Adopt ASTM F2167-17 with no modifications; and (2) allow a later effective date.

Section 104 of the CPSIA requires that the Commission promulgate a standard that is either substantially the same as the voluntary standard or more stringent. Therefore, adopting ASTM F2167-17 with no modifications is the least stringent rule allowed by law. This alternative would reduce the impact on all of the known small businesses supplying infant bouncers to the U.S. market. If it were adopted, it should eliminate any economic impact related to warning label changes, but firms would continue to be affected by third party testing requirements. However, adopting ASTM F2167-17 without modification would not adequately address the fall hazard scenario identified in the incident data and would reduce the effectiveness of the fall hazard warning label.

Finally, the Commission could reduce the final rule's impact on small businesses by setting a later effective date. A later effective date would reduce the economic impact on firms in two ways. Firms would be less likely to experience a lapse in production/importation, which could result if they are unable to comply and third party test within the required timeframe. Also, firms could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. However, the Commission received no comments asserting that firms would not have sufficient time to comply with the

proposed 6 month effective date. Accordingly, the Commission declines to extend the effective date of the final rule.

G. Small Business Impacts of the Accreditation Requirements for Testing Laboratories

In accordance with section 14 of the CPSA, all children’s products that are subject to a children’s product safety rule must be tested by a CPSC-accepted third party conformity assessment body (i.e., testing laboratory) for compliance with applicable children’s product safety rules. Testing laboratories that want to conduct this testing must meet the NOR pertaining to third party conformity testing. NORs have been codified for existing rules at 16 CFR part 1112. Consequently, the Commission finalizes an amendment to 16 CFR part 1112 that establishes an NOR for those testing laboratories that want to test for compliance with the bouncers final rule. This section assesses the impact of the amendment on small laboratories.

A FRFA was conducted as part of the promulgation of the original 1112 rule (78 FR 15836, 15855–58) as required by the RFA. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were

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.

Based on similar reasoning, amending the rule to include the NOR for the bouncer standard will not have a significant adverse impact on small laboratories. Moreover, based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the infant bouncer seat standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards, and the only costs to them would be the cost of adding the bouncer standard to their scope of accreditation, a cost that test laboratories have indicated is extremely low when they are already accredited for other section 104 rules. As a consequence, the Commission certifies that the NOR for the infant bouncer seat standard will not have a significant impact on a substantial number of small entities.

XI. Environmental Considerations

The Commission’s regulations address whether the agency is required to prepare an environmental assessment or

an environmental impact statement. Under these regulations, a rule that has “little or no potential for affecting the human environment,” is categorically exempt from this requirement. 16 CFR 1021.5(c)(1). The final rule for bouncer seats falls within the categorical exemption.

XII. Paperwork Reduction Act

The final rule for infant bouncer seats contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The preamble to the proposed rule (80 FR at 63181–82) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. OMB has assigned control number 3041–0174 to this information collection. We did not receive any comment regarding the information collection burden of the proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated manufacturers subject to the information collection burden is now estimated at 23 manufacturers rather than the 22 manufacturers initially estimated in the proposed rule.

Accordingly, the estimated burden of this collection of information is modified as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

16 CFR Section	Number of respondents	Frequency of responses	Total annual responses	Hours per response	Total burden hours
1229	23	4	92	1	92

Our estimate is based on the following:

Section 8.1 of ASTM F2167–17 requires that all infant bouncer seats and their retail packaging be permanently marked or labeled as follows: The manufacturer, distributor, or seller name, place of business (city, state, mailing address, including zip code), and telephone number; and a code mark or other means that identifies the date (month and year as a minimum) of manufacture.

CPSC is aware of 23 firms that supply bouncer seats in the U.S. market. For PRA purposes, we assume that all 23 firms use labels on their products and on their packaging already. All firms will need to make some modifications to their existing labels. We estimate that the time required to make these modifications is about 1 hour per

model. Each of the 23 firms supplies an average of four different models of bouncer seats. Therefore, we estimate the burden hours associated with labels to be 92 hours annually (1 hour × 23 firms × 4 models per firm = 92 hours annually).

We estimate the hourly compensation for the time required to create and update labels is \$33.58 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2017, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, we estimate the annual cost to industry associated with the labeling requirements in the final rule to be approximately \$3,089 (\$33.58 per hour × 92 hours = \$3,089.36). This collection of information does not

require operating, maintenance, or capital costs.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this final rule to the OMB.

XIII. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under

certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules.” Therefore, the preemption provision of section 26(a) of the CPSA applies to this final rule issued under section 104.

XIV. Amendment to 16 CFR Part 1112 To Include NOR for Bouncer Seat Standard

The CPSA establishes certain requirements for product certification and testing. Products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Certification of children’s products subject to a children’s product safety rule must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* 2063(a)(2). The Commission must publish an NOR for the accreditation of third party conformity assessment bodies to assess conformity with a children’s product safety rule to which a children’s product is subject. *Id.* 2063(a)(3). The *Safety Standard for Infant Bouncer Seats*, to be codified at 16 CFR part 1229, is a children’s product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third-Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which is codified at 16 CFR part 1112 (referred to here as part 1112). Part 1112 became effective on June 10, 2013 and establishes requirements for accreditation of third-party conformity assessment bodies (or laboratories) to test for conformance with a children’s product safety rule in accordance with section 14(a)(2) of the CPSA. Part 1112 also codifies a list of all of the NORs that the CPSC had published at the time part 1112 was issued. All NORs issued after the Commission published part 1112, such as the standard for bouncer seats, require the Commission to amend part 1112. Accordingly, the Commission is now amending part 1112 to include the standard for infant bouncer seats in the list of other children’s product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third-party conformity assessment body to test to the new standard for infant bouncer seats would be required to meet the third-party conformity assessment body accreditation requirements in 16 CFR part 1112, *Requirements Pertaining to*

Third-Party Conformity Assessment Bodies. When a laboratory meets the requirements as a CPSC-accepted third-party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1229, *Safety Standard for Infant Bouncer Seats*, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC Web site at: www.cpsc.gov/labsearch.

As required by the RFA, staff conducted a FRFA when the Commission issued the part 1112 rule (78 FR 15836, 15855–58). Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small test laboratories because no requirements were imposed on test laboratories that did not intend to provide third-party testing services. The only test laboratories that were 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. Moreover, a test laboratory would only choose to provide such services if it anticipated receiving revenues sufficient to cover the costs of the requirements.

Based on similar reasoning, amending 16 CFR part 1112 to include the NOR for the infant bouncer seats standard will not have a significant adverse impact on small test laboratories. Moreover, based upon the number of test laboratories in the United States that have applied for CPSC acceptance of accreditation to test for conformance to other mandatory juvenile product standards, we expect that only a few test laboratories will seek CPSC acceptance of their accreditation to test for conformance with the infant bouncer seats standard. Most of these test laboratories will have already been accredited to test for conformity to other mandatory juvenile product standards, and the only costs to them would be the cost of adding the infant bouncer seats standard to their scope of accreditation. For these reasons, the Commission certifies that the NOR amending 16 CFR part 1112 to include the infant bouncer seats standard will not have a significant impact on a substantial number of small entities.

List of Subjects

16 CFR Part 1112

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

16 CFR Part 1229

Bouncer seats, Chairs, Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Seats, and Toys.

For the reasons discussed in the preamble, the Commission amends title 16 of the Code of Federal Regulations 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)(42) to read as follows:

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

* * * * *

(b) * * *
(42) 16 CFR part 1229, *Safety Standard for Infant Bouncer Seats*.

* * * * *

- 3. Add part 1229 to read as follows:

PART 1229—SAFETY STANDARD FOR INFANT BOUNCER SEATS

Sec.
1229.1 Scope.
1229.2 Requirements for infant bouncer seats.

Authority: Sec. 104, Pub. L. 110–314, 122 Stat. 3016 (15 U.S.C. 2056a).

§ 1229.1 Scope.

This part establishes a consumer product safety standard for infant bouncer seats.

§ 1229.2 Requirements for infant bouncer seats.

(a) Except as provided in paragraph (b) of this section, each infant bouncer seat must comply with all applicable provisions of ASTM F2167–17, *Standard Consumer Safety Specification for Infant Bouncer Seats*, approved on June 1, 2017. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>. You may inspect a copy at the Office of the Secretary, 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: www.archives.gov/federal-register/cfr/ibr-locations.html.

(b) Comply with ASTM F2167-17 with the following additions or exclusions:

(1) Instead of complying with section 7.11.3.1 of ASTM F2167-17, comply with the following:

(i) 7.11.3.1 *Visibility With CAMI Dummy Restrained in Seat*—While standing in front of the product with the Newborn CAMI dummy installed, verify that the required warnings are visible and placed above an imaginary horizontal line that crosses through the

junctions of under arm and side of the torso armpits on both left and right and not obscured by any part of the dummy (as shown in paragraph (b)(1)(ii), “Fig. 10”).

(ii) *Fig. 10: CAMI Dummy Restrained in Seat; Allowable area for warning label placement starts from the dotted line that crosses the junctions of underarm and both sides of the torso.*

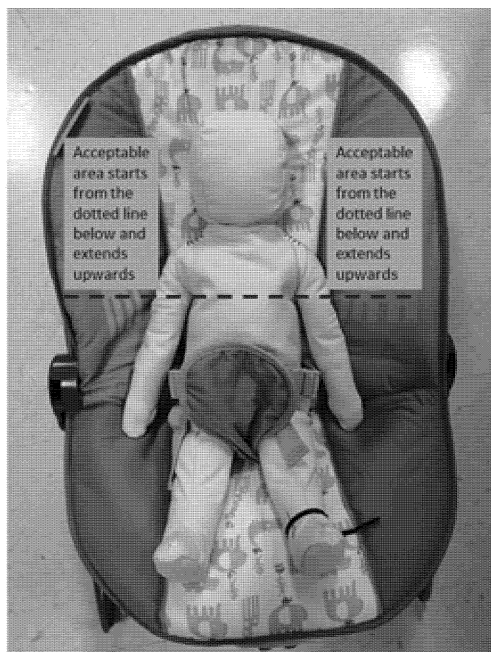


Fig 10. Allowable area for warning label placement starts from the dotted line that crosses the junctions of underarm and both sides of the torso.

(2) In section 8.5.1.1 of ASTM F2167-17, replace the warning statement “ALWAYS use restraints. Adjust to fit snugly” with “ALWAYS use restraints and adjust to fit snugly, even if baby falls asleep.”

(3) In section 8.5.2.1 of ASTM F2167-17, replace the warning statement

“ALWAYS use restraints. Adjust to fit snugly” with “ALWAYS use restraints and adjust to fit snugly, even if baby falls asleep.”

(4) In section 8.5.3 of ASTM F2167-17, replace the reference to “Figs. 10 and 11” with “Figs. 11 and 12.”

(5) In section 9.2.1 of ASTM F2167-17:

(i) Replace the reference to “Fig. 12” with “Fig. 13.”

(ii) Replace Fig. 10 with paragraph (b)(5)(iii), “Fig. 11”.

(iii) *Fig. 11: Fall Hazard Warning.*

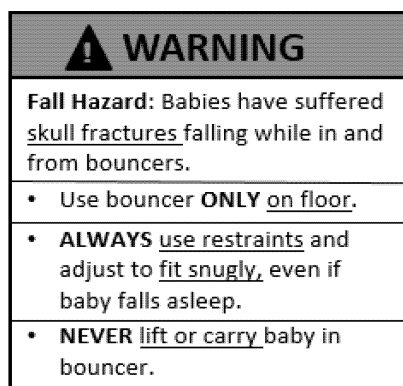


Fig. 11 Fall Hazard Warning

(iv) Replace Fig. 11 with paragraph (b)(5)(v), “Fig. 12”.

(v) Fig. 12: Suffocation Hazard Warning.

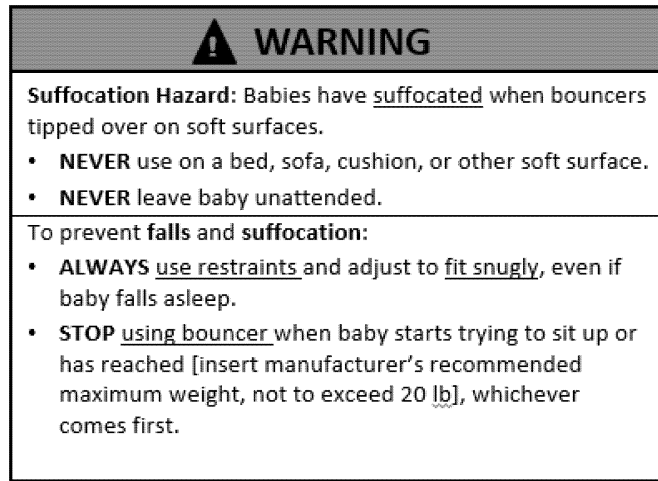


Fig. 12 Suffocation Hazard Warning

(vi) Replace Fig. 12 with paragraph (b)(5)(vii), “Fig. 13”.

(vii) Fig. 13: Instruction Warning Statements.

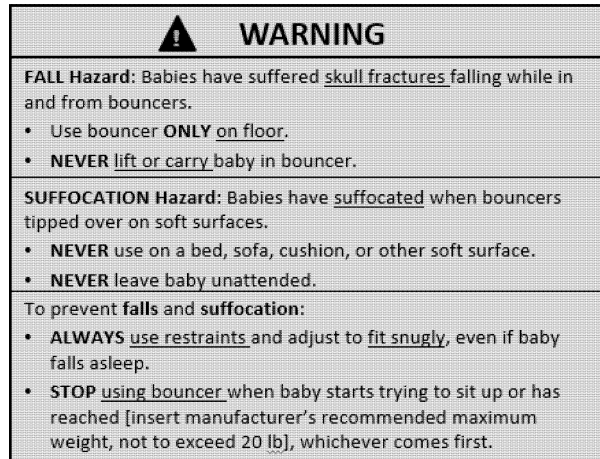


Fig. 13 Instruction Warning Statements

(6) In section 9.2.2 of ASTM F2167–17, replace the reference to “Fig. 12” with “Fig. 13.”

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–19255 Filed 9–15–17; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 558

[Docket No. FDA–2017–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor’s Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for a new animal drug application (NADA) and abbreviated new animal drug applications (ANADAs) during March and April 2017. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a change of a sponsor’s address and to make technical amendments to improve the accuracy of the regulations.

DATES: This rule is effective September 18, 2017.