



**Billing Code 6355-01-P**

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 CFR Parts 1112 and 1226**

**Docket No. CPSC-2013-0014**

**Safety Standard for Soft Infant and Toddler Carriers**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice of Proposed Rulemaking.

**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 concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for soft infant and toddler carriers in response to the direction under Section 104(b) of the CPSIA.<sup>1</sup>

**DATES:** Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature of the proposed rule should be directed to the Office of

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<sup>1</sup> The Commission voted 2–1 to approve publication of this proposed rule. Chairman Inez M. Tenenbaum and Commissioner Robert S. Adler voted to approve publication, and Commissioner Nancy A. Nord voted against publication. Commissioner’s statements concerning this or any other Commission action may be viewed by clicking on a specific Commissioner’s name and selecting “Statements” on the Commission’s website at <http://www.cpsc.gov/en/About-CPSC/Commissioners/>, or obtained from the Commission’s Office of the Secretary.

Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

Other comments, identified by Docket No. CPSC-2013-0014, may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except through [www.regulations.gov](http://www.regulations.gov). The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions in the following way: Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, and insert the docket number, CPSC-2013-0014, into the “Search” box, and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Gregory K. Rea, Project Manager, Director, Division of Mechanical Engineering, Directorate for Laboratory Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2258; e-mail: [grea@cpsc.gov](mailto:grea@cpsc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background and Statutory Authority**

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub Law 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, 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. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes 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.”

In this document, the Commission is proposing a safety standard for soft infant and toddler carriers. “Infant carriers” are specifically identified in section 104(f)(2)(H) of the CPSIA as durable infant or toddler products. The Commission has identified at least four types of products that fall within the product category of “infant carriers,” including: frame backpack carriers, handheld infant carriers, slings, and soft infant and toddler carriers. This proposed rule

addresses hazards associated only with soft infant and toddler carriers. Recently, the Commission issued a proposed rule on handheld infant carriers (77 FR 73354 (Dec. 10, 2012)). Hazards associated with frame backpack carriers and slings will be addressed separately in future rulemaking proceedings.

Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this proposed standard, largely through the ASTM process. The proposed rule is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2236-13, “Standard Consumer Safety Specification for Soft Infant and Toddler Carriers” (ASTM F2236-13), without alteration. The ASTM standard is copyrighted, but it can be viewed as a read-only document during the comment period on this proposal only, at: <http://www.astm.org/cpsc.htm>, by permission of ASTM.

## **II. Product Description**

### **A. Definition of a Soft Infant and Toddler Carrier**

ASTM F2236-13 defines “soft infant and toddler carrier” as “a product, normally of sewn fabric construction, which is designed to contain a full term infant to a toddler, generally in an upright position, in close proximity to the caregiver.” Additionally, soft infant and toddler carriers are generally designed to carry a child “between 7 and 45 pounds.” ASTM F2236-13 explains that soft infant and toddler carriers are “normally ‘worn’ by the caregiver with a child positioned in the carrier and the weight of the child and carrier suspended from one or both shoulders of the caregiver. These products may be worn on the front, side, or back of the caregiver’s body, with the infant either facing towards or away from the caregiver.” Typically

children are carried in soft infant and toddler carriers on the front of a caregiver, but some products on the market can be configured to carry a child upright on a caregiver's front, back, or hip.

Two broad classes of soft infant and toddler carriers are available in the United States: structured and nonstructured. Structured soft infant and toddler carriers contain straps and waist belts that connect, to the seat area of the carrier and each other, with buckles, straps, and other mechanical fasteners. The straps, belts, and seating area of these products are often stiffened with padding and typically have a heavy textile covering. Nonstructured products, such as the mei-tai design, consist of a flat, textile center that acts as the seat area with waist straps and very long (5 to 6 feet) upper straps. The upper straps wrap over the caregiver's shoulders, cross in the back, and are brought around the waist to the front of the caregiver. The upper straps are then secured over the child's legs to form the leg openings and secure the child in an upright position. ASTM F2236-13 does not distinguish between products based on whether they are structured or nonstructured; requirements apply equally to all types of soft infant and toddler carriers.

The definition of a "soft infant and toddler carrier" is intended to distinguish it from other types of infant carriers that are also worn by a caregiver but that are not covered under ASTM F-2236-13, specifically slings (including wraps), and framed backpack carriers. Soft infant and toddler carriers are designed to carry a child in an upright position. Slings are designed to carry a child in a reclined position; although some slings may also be used to carry a child upright. Thus, the primary distinction between a sling and a soft infant and toddler carrier is the sling's design that allows for carrying a child in a reclined position. Different hazard patterns arise from carrying a child in a reclined position. Accordingly, slings are not included in the standard for soft infant and toddler carriers. Like soft infant and toddler carriers, framed backpack carriers

are intended to carry a child in an upright position, but are distinguishable because typically, they are constructed of sewn fabric over a rigid metal structure and are solely intended for carrying a child on the caregiver's back.

#### B. Market Description

Soft infant and toddler carriers are generally produced and/or marketed by juvenile product manufacturers and distributors. Several of these firms focus exclusively on soft infant and toddler carriers, as well as substitute products, such as slings. CPSC staff believes that at least 39 firms supply soft infant and toddler carriers to the U.S. market. Thirty-one domestic firms supply soft infant and toddler carriers to the U.S. market: 15 are domestic manufacturers; eight are domestic importers; and the supply sources of eight domestic firms are unknown. Five foreign firms supply soft infant and toddler carriers to the U.S. market: three are foreign manufacturers; one is a foreign importer; and one firm has an unknown supply source. Insufficient information is available on the remaining three firms to categorize them.

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 51 percent of new mothers own soft infant and toddler carriers. Approximately 30 percent of soft infant and toddler carriers were handed down or purchased secondhand, meaning that about 70 percent of the products were acquired new. This suggests that approximately 1.5 million soft infant and toddler carriers are sold to households annually ( $.51 \times .70 \times 4.1$  million births per year). Typically, soft infant and toddler carriers are used during a child's first year, with some caregivers continuing to use these products into the second year. We estimate use into a child's second year under the assumption that approximately 25–50 percent of caregivers continue to use these products. Based on data from the *2006 Baby Products Tracking Study*, approximately 2.1 million soft infant and toddler carriers are owned by

new mothers. Thus, we estimate that approximately 2.6–3.2 million households have soft infant and toddler carriers available for use annually.

### **III. Incident Data**

CPSC’s Directorate for Epidemiology, Division of Hazard Analysis is aware of 93 incidents related to soft infant and toddler carriers—reported over a period of nearly 13 years—beginning in January 1999 through early September 2012. Two incidents involved a fatality, and 91 incidents were nonfatal.

#### **A. Fatalities**

Two suffocation fatalities were reported to CPSC from January 1999 to September 2012. The first fatality involved a 5-week-old male who fell asleep in the soft infant and toddler carrier after a feeding. About 20 minutes after the feeding, he appeared unresponsive. The official cause of death was listed as positional asphyxia. The second fatal incident occurred when a 2-month-old female fell asleep in a soft infant and toddler carrier worn by her parent. The parent lay down on a couch to sleep for the night while still wearing the carrier with the infant inside. The parent awoke the next morning to find the child unresponsive with her face pressed into the parent’s chest. Staff could not directly attribute the two reported fatalities to product design or mechanical failure of the soft infant and toddler carrier.

#### **B. Nonfatalities**

Approximately 33 percent (30) of the 91 nonfatal incidents involved reports of an injury to an infant during use of a soft infant and toddler carrier. A majority of the injuries resulted from falls from the carrier. All of the injuries in which the age of the victim was available were reportedly sustained by infants who were 1 month to 13 months old. However, most of the incidents involved infants 6 months and younger. Although the remaining 61 nonfatal incidents

reported that no injury had occurred, many of the descriptions indicated the potential for a serious injury or death.

Eight of the nonfatal incident reports involved skull fractures as a result of the child falling out of the product. Five skull fracture injuries reportedly required hospitalization; the three remaining skull fracture injury reports did not mention any hospitalizations. Some of the remaining injuries reported included: collarbone and limb fractures, contusions, abrasions, blisters, and scratches.

### C. Hazard Pattern Identification

The primary hazard associated with use of a soft infant and toddler carrier is falling, either caregivers falling while wearing the carrier and injuring the child in the carrier, or children falling or facing the risk of falling from the carrier due to fastener problems, large leg openings, stitching or seam problems, or straps that slip. A majority of the reported incidents summarized in Table 1 below, and all seven of the recalls described in section III.E, involved an actual fall or potential risk of a child falling from a carrier.

Staff classified the 93 reported incidents by the issues—product feature, design element, or failure—primarily responsible for the incident and summarized this data in Table 1, below. An explanation of the categories represented in Table 1 follows.

***Fastener problems:*** Twenty-five of the 93 incidents (27 percent) were related to fastener problems, such as snaps breaking/unexpectedly releasing, or buckles breaking/detaching/pinching/unexpectedly releasing. Six injuries, but no fatalities, were included among these reports.

***Structure, fit, and position issues:*** Fourteen of the 93 incidents (15 percent) were related to aspects of the leg- and torso-opening design, how the carrier held the infant, and where the



carrier was positioned on the caregiver. Examples of scenarios reported include: an infant slipping down far into the carrier and suffering an injury when the caregiver went into a bent position; an infant falling out of the carrier when the caregiver bent forward; and leg circulation-related injuries. There were 10 injuries reported in this category. No reported fatalities were associated with this issue.

***Problems with large leg openings:*** Twelve of the 93 incidents (13 percent) were related to leg openings that were too large and that allowed the infant to slip through completely and fall out of the carrier. While there were no fatalities among these reports, there were seven injuries; three involved infants who were hospitalized for skull fractures.

***Issues with stitching/seams:*** Ten reports (11 percent) were received about stitching on the carrier coming undone or seams ripping, resulting in other components, like straps, detaching and creating a fall hazard. One injury was included among these reports.

***Design and finish-related issues:*** Eight reports (nine percent) of inadequate back support, rough fabric, poor air flow in the carrier insert, and other design issues were received. No fatalities were noted, but two injuries were associated with these issues.

***Strap issues:*** Eight incidents (nine percent) reported issues with straps, mostly about the adjuster breaking or slipping. No injuries or fatalities were reported in this category.

***Other issues:*** Eleven reports (12 percent) were related to issues other than those described above. Two fatalities and four injuries, including two hospitalizations, were reported in this category. The two fatalities—one case of a parent falling asleep while wearing the carrier with the infant inside, and the other case of an infant suffering respiratory distress while being carried around facing in—are included in this category. In each case, CPSC staff concluded that there were too many confounding factors reported to determine that a specific factor contributed

predominantly to the deaths. The remaining reports were of unspecified falls, an nonspecific abrasion injury, and an incidental injury to the infant, due to a caregiver's fall.

**Table 1. Distribution of Reported Incidents by Hazard Patterns**  
**Associated with Soft Infant and Toddler Carriers**  
**Reporting Period: January 1, 1999–September 10, 2012**

<i><b>Issues</b></i>	<i><b>Total Reports</b></i>		<i><b>Deaths</b></i>		<i><b>Injuries</b></i>	
	<i>Count</i>	<i>Percentage</i>	<i>Count</i>	<i>Percentage</i>	<i>Count</i>	<i>Percentage</i>
<b>Mechanical Issues</b>	<b>77</b>	<b>83</b>	<b>0</b>	<b>0</b>	<b>26</b>	<b>87</b>
<i>Fasteners</i>	25	27	0	0	6	20
<i>Structure, fit, and position</i>	14	15	0	0	10	33
<i>Large leg openings</i>	12	13	0	0	7 (3 hosp.)	23
<i>Stitching/seams</i>	10	11	0	0	1	3
<i>Design and finish</i>	8	9	0	0	2	7
<i>Straps</i>	8	9	0	0	0	0
<b>Other</b>	<b>11</b>	<b>12</b>	<b>2</b>	<b>100</b>	<b>4</b> (2 hosp.)	<b>13</b>
<b>Consumer Comments</b>	<b>5</b>	<b>5</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total</b>	<b>93</b>	<b>100</b>	<b>2</b>	<b>100</b>	<b>30</b>	<b>100</b>

**Source:** U.S. Consumer Product Safety Commission's epidemiological databases IPII, INDP, and DTHS.

**Note:** The percentages have been rounded to the nearest integer. Subtotals do not necessarily add to heading totals.

#### D. NEISS Data

In addition to the 93 incident reports received by the Commission, we estimated the number of injuries treated in U.S. hospital emergency departments using the CPSC's National Electronic Injury Surveillance System (NEISS). We estimate that over a 13-year-period, a total of 1,400 injuries related to soft infant and toddler carriers were treated in U.S. hospital emergency departments from 1999 through 2011. Because CPSC's NEISS data for 2012 will be finalized in spring 2013, partial estimates for 2012 are not available. The injury estimates for individual years are based on very small samples and are not reportable. According to the 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 percent or smaller. Moreover, due to the unreliability of the yearly estimates, a trend analysis is not feasible.

No fatalities were reported through NEISS. Although data extraction criteria included ages up to 4 years, all of the injured children were reported to be less than 2 years of age. A breakdown of the characteristics among the emergency department-treated injuries associated with soft infant and toddler carriers is presented in the bullets below.

- Hazard – Getting struck while in the carrier when caregiver fell (65%); falling out of the carrier (21%).
- Injured body part – Head (63%); face (11%).
- Injury type – Internal organ injury (48%); contusions/abrasions (19%); and fractures (12%).
- Disposition – Treated and released (79%); hospitalized (10%); and treated and transferred (9%).

#### E. Product Recalls

Seven product safety recalls, recalling 652,250 units, were announced between January 1, 1999 and June 17, 2010 that involved a fall hazard related to use of a soft infant and toddler carrier. These recalls related to 130 incident reports received by the CPSC. A breakdown of the specific product defect necessitating the recall, product units involved, and the number of incident reports received is presented in the chart below. At the time the products were recalled, nine infants had been injured significantly in incidents that ranged from bruises to skull fractures. Additional information on these recalls can be found on the Commission's websites at:

[www.cpsc.gov](http://www.cpsc.gov) or [www.saferproducts.gov](http://www.saferproducts.gov).

<b>Soft Infant and Toddler Carrier Recall Summary</b> January 1, 1999 through June 17, 2010						
<b>Manufacturer</b>	<b>Model</b>	<b>Year Recalled</b>	<b>Units Recalled</b>	<b>Reason</b>	<b>Incident Reports</b>	<b>Injury Reports</b>
Evenflo Company & Hufco-Delaware, Inc.	Model 070 & 080 Snuggli® Front and Back Pack™	1999	327,000	Infant shifts to side & slips through leg opening, falls out.	13	One - fractured skull; two - bruises
Baby Swede, LLC	Baby Bjorn	1999	240,000 (Recall to Repair)	Infants slip through leg openings - fall. Infants < 2 months - highest risk.	9	Six fractured skulls
Baby Swede, LLC	Baby Bjorn Carrier Active	2004	49,000	Back support buckles detach from shoulder straps - pose fall hazard.	93	No injuries reported.
Playtex Products, Inc.	Playtex Hip Hammock	2005	32,000	Shoulder strap detaches from Hammock, posing fall hazard.	2	No injuries reported.
Beco Baby Carrier, Inc.	Beco Baby Carrier Butterfly	2008	2,000	Shoulder strap buckles unexpectedly release tension - straps slip through - pose fall hazard.	8	No injuries reported.
Optave, Inc.	Action Baby Carrier	2008	250	Chest strap can detach from shoulder straps, posing fall hazard to infant.	2	No injuries reported.
Regal Lager, Inc.	CYBEX 2. GO Infant Carriers	2010	2,700 U.S. 400 Canada	Shoulder strap slider buckle can break, posing fall hazard to infant.	3	No injuries reported.

#### **IV. Soft Infant and Toddler Carrier International Standard and ASTM Voluntary Standard**

Section 104(b)(1)(A) of the CPSIA requires the Commission to consult representatives of “consumer groups, juvenile product manufacturers, and independent child product engineers and experts” to “examine and assess the effectiveness of any voluntary consumer product safety standards for durable infant or toddler products.” As a result of fall-related incidents and recalls of soft infant and toddler carriers, CPSC staff previously requested ASTM to develop voluntary requirements to address the hazards related to large leg openings. Through the ASTM process, we

consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public. The voluntary standard for soft infant carriers was first approved and published in April 2003, as ASTM F2236-03, *Standard Consumer Safety Performance Specification for Soft Infant Carriers*. It has been revised six times since then. The current version, ASTM F2236-13, renamed *Standard Consumer Safety Performance Specification for Soft Infant and Toddler Carriers*, was approved on March 1, 2013 and published in March 2013.

In addition to reviewing the ASTM standard, we reviewed the only international standard for soft infant carriers of which we are aware, EN13209-2:2005 *Child Use and Care Articles – Baby Carriers – Safety Requirements and test Methods – Part 2: Soft Carrier*.

#### A. International Standard

CPSC evaluated requirements in ASTM F2236-13 and EN13209-2:2005 and determined that the requirements in ASTM F2236-13 are more stringent than EN13209-2:2005, and that they address the incidents seen in the data and reduce the risk of injury from these products. The few EN13209-2:2005 requirements without an ASTM F2236-13 counterpart address hazard patterns not found in the incident reports considered for this proposed rule.

#### B. Voluntary Standard – ASTM F2236

##### 1. History of ASTM F2236

Initially, ASTM F2236-03 addressed falls related to large leg openings. The standard's bounded leg opening performance requirement limited the size of the leg opening to prevent infants from falling through large adjustable leg openings. The standard also established requirements to address sharp points and edges, small parts, lead in paints, wood parts, locking and latching of fasteners, dynamic load testing, static load testing, and product labeling. The

scope of the standard was based on the manufacturers' recommended use of the product with infants weighing 7 to 25 pounds.

The next update of the voluntary standard was published in March 2008. ASTM F2236-03 addressed fall issues with bounded leg openings that were too large but did not consider the ability of an *unbounded* leg opening to retain the occupant. An unbounded leg opening is created by placing the soft carrier on a caregiver's torso, with a leg opening circumference comprised of carrier materials and the caregiver's torso. Accordingly, to address additional fall hazards, an unbounded leg opening performance requirement was added to ASTM F2236-08. ASTM F2236-08a was published in November 2008, to add general requirements included in other ASTM standards for durable children's products that address hazards associated with toy accessories and flammability.

ASTM F2236-09 was published in April 2009. The statement that the child occupant must face the caregiver until the child can hold its head upright was moved in this version of the standard from the warning label to be an informational statement. ASTM F2236-10, published in December 2010, clarified further that the informational statement for a child to face the caregiver until the child can hold its head upright was unnecessary for soft infant carriers that have only one use position with the child facing the caregiver.

ASTM F2236-12 was published in December 2012. Several sections of the voluntary standard were revised based on input from CPSC staff. The scope was expanded to increase the upper weight limit of products within the scope of the standard from 25 to 45 pounds and to include specifically in the title of the standard the word "toddler." ASTM F2236-12 also included a new definition in the terminology section of the standard for "carrying position," to clarify procedures for dynamic and static load testing. Finally, the test methods for dynamic

No and static load testing were modified to increase the weight load required for testing to ensure adequate testing of products that are designed to carry heavier children.

## 2. Description of the Current Voluntary Standard – ASTM F2236-13

ASTM F2236-13 was published in March 2013. Together with the changes described in ASTM F2236-12, ASTM F2236-13 reflects the most significant revisions to the standard, to date. Revisions include modified and new requirements developed by CPSC staff, working with stakeholders on the ASTM subcommittee task group, to address the hazards associated with soft infant and toddler carriers. ASTM F2236-13 includes the following key provisions: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature.

Scope. The scope of the standard was updated in December 2012, to broaden the upper weight limit from 25 to 45 pounds for products falling within the standard. Expanding the scope of the standard ensures that all soft infant and toddler carrier products currently on the market are covered by the standard. The name of the standard was altered at the same time to include the word “toddler,” to clarify that toddlers can also be carried in these products. The scope of the standard also distinguishes soft infant and toddler carriers from other wearable infant carrier products, by describing that soft infant and toddler carriers are “normally of sewn fabric construction,” hold the child “generally in an upright position,” and “may be worn on the front, side, or back of the caregiver’s body.” Finally, the scope of the standard states that it does not apply to infant slings.

Terminology. Section 3.1 of the standard includes 14 definitions that help to explain general and performance requirements. Section 3.1.7 of the standard explains that a “leg opening” is the “opening in the soft carrier through which the occupant’s legs extend when the

product is used in the manufacturer's recommended use position." Sections 3.1.4 and 3.1.13 of ASTM F2236-13, respectively, explain that a "dynamic load" is the "application of impulsive force through free fall of a weight," and that a "static load" is a "vertically downward force applied by a calibrated force gage or by dead weights." A new definition for "carrying position" was added in ASTM F2236-12, to clarify methods for dynamic and static load testing in section 7 of the standard. Also, a new definition for "fastener" was included in ASTM F2236-13, to aid in a new test for fastener strength and strap retention.

General Requirements. ASTM F2236-13 includes general requirements that the products must meet, as well as specified test methods to ensure compliance with the general requirements, which include:

- Restrictions on sharp points or edges, as defined by 16 CFR §§ 1500.48 and .49;
- Restrictions on small parts, as defined by 16 CFR part 1501;
- Restrictions on lead in paint, as set forth in 16 CFR part 1303;
- Requirements for locking and latching devices;
- Requirements for permanent warning labels;
- Restrictions on flammability, as set forth in 16 CFR part 1610;
- Requirements for toy accessories, as set forth in ASTM F 963.

The flammability requirement in section 5.7 of the standard was changed in ASTM F2236-13 from a flammable solids requirement (16 CFR § 1500.3(c)(6)(vi)) to meet the more stringent flammability requirement for wearing apparel (16 CFR part 1610). The flammability requirement was altered to be consistent with other wearable infant carriers made of sewn fabric, such as slings, to prevent a foreseeable fire hazard in all wearable infant carriers.



Performance Requirements and Test Methods. ASTM F2236-13 provides performance requirements and test methods that are designed to protect against falls from the carrier due to large leg openings, breaking fasteners or seams, and straps that slip, including:

*Leg Openings* – Tested leg openings must not permit passage of a test sphere weighing 5 pounds that is 14.75 inches in circumference.

*Dynamic and Static Load* – Beginning with the 2012 version of ASTM F2236, the dynamic load test was strengthened from requiring a 25-lb. shot bag to be dropped, free fall, from 1 inch above the seat area onto the carrier seat 1,000 times, to requiring testing with a 25-lb, shot bag, or a shot bag equal to the manufacturer’s maximum occupant weight limit, whichever is heavier. Also, the static load test was altered from requiring a 75-lb. weight for testing, to requiring a 75-lb. weight, or a weight equal to three times the manufacturer’s recommended maximum occupant weight, whichever is greater, to be placed in the seat area of the carrier for 1 minute. This revision means that products with a maximum recommended weight of 45 pounds must be tested to a 135-pound weight instead of 75 pounds, an 80 percent increase in the severity of the requirement.

Testing with the new required loads must not result in a “hazardous condition,” as defined in the general requirements, or result in a structural failure, such as fasteners breaking or disengaging, or seams separating when tested in accordance with the dynamic and static load testing methods. Additionally, dynamic and static load testing must not result in adjustable sections of support/shoulder straps slipping more than 1 inch per strap from their original adjusted position after testing.

*Fastener Strength and Strap Retention* – ASTM F2236-13 added a new component-level performance requirement to evaluate the strength of fasteners and strap retention to help prevent

falls. Products recalled due to an occupant fall hazard were caused by broken fasteners that passed the static and dynamic performance requirements in ASTM F2236-10. Accordingly, the new performance requirement, section 6.4 of ASTM F2236-13, states that load-bearing fasteners at the shoulder and waist of soft infant and toddler carriers, such as buckles, loops, and snaps, may not break or disengage, nor may their straps slip more than 1 inch when subjected to an 80-pound pull force. Adjustable leg opening fasteners must also be tested, but are subjected to lower loads, a 45-pound pull force, because these fasteners do not carry the same load as fasteners at the shoulders and waist. When tested, fasteners must not break or disengage, and adjustable elements must not slip more than 1 inch.

*Unbounded Leg Opening* – ASTM F2236-13 clarifies the unbounded leg opening test procedure to improve test repeatability. An unbounded leg opening must not allow complete passage of a truncated test cone that is 4.7 inches long, with a major diameter of 4.7 inches and a minor diameter of 3 inches. The test cone is pulled through the leg opening with a 5-pound force for 1 minute.

Marking, Labeling, and Instructional Literature. ASTM F2236-13 requires that each product and its retail package be marked or labeled with certain information and warnings. The warning label requirement was updated to address fall and suffocation hazards. The warning label must provide a fall hazard statement addressing that infants can fall through wide leg openings or out of the carrier. The following fall-related warnings must be addressed on the warning label: adjust leg openings to fit baby's legs snugly; before each use, make sure all [fasteners/knots] are secure; take special care when leaning or walking; never bend at waist, bend at knees; only use this carrier for children between \_\_\_ lbs. and \_\_\_ lbs. Additionally, a suffocation hazard statement must address that infants under 4 months old can suffocate in the carrier if the

child's face is pressed tightly against the caregiver's body. The warning label must also address the following suffocation-related warnings: do not strap infant too tightly against your body; allow room for head movement; keep infant's face free from obstructions at all times. Products must also contain an informational statement that a child must face toward the caregiver until he or she can hold his or her head upright. Instructional literature must be provided with all products that includes: assembly, use, maintenance and cleaning, and required warnings.

Additionally, ASTM F2236-13 now includes an example warning label that identifies more clearly the hazards, the consequences of the ignoring the warning, and what to do to avoid the hazards. The format of the label was designed to convey more effectively these warnings to the caregiver (Fig. 1). The rectangular shape of this label may be altered to fit on shoulder straps, if the manufacturer chooses not to place label in the occupant space; however, the label must be placed in a prominent and conspicuous location where the caregiver will see it when placing the soft infant and toddler carrier on their body.


 WARNING
FALL AND SUFFOCATION HAZARD
<p><b>FALL HAZARD</b> - Infants can fall through a wide leg opening or out of carrier.</p> <ul style="list-style-type: none"> <li>• Adjust leg openings to fit baby's legs snugly.</li> <li>• Before each use, make sure all ____ are secure.</li> <li>• Take special care when leaning or walking.</li> <li>• Never bend at waist; bend at knees.</li> <li>• Only use this carrier for children between ____ lb. and ____ lb.</li> </ul> <p><b>SUFFOCATION HAZARD</b> – Infants under 4 months can suffocate in this product if face is pressed tight against your body.</p> <ul style="list-style-type: none"> <li>• Do not strap infant too tight against your body.</li> <li>• Allow room for head movement.</li> <li>• Keep infant's face free from obstructions at all times.</li> </ul>

Figure 1. ASTM F2236-13 Example Warning label.

## **V. Assessment of Voluntary Standard ASTM F2236-13**

In this section of the preamble, we evaluate ASTM F2236-13 to determine whether adopting this voluntary standard as a mandatory standard will address the incidents described in section III of this preamble, or whether more stringent standards are required to reduce further the risk of injury associated with soft infant and toddler carriers.

### **A. Large Leg Openings**

Twenty-three percent of the injuries (7 of 30), including three hospitalizations, were caused when a child fell out of a large leg opening. The last incident occurred in 2005, involving a product purchased initially in 2000. The prevalence of this hazard led to product recalls in 1999 (see section III.E above) and led to the creation of ASTM F2236, whose first performance requirement (6.1 and corresponding test 7.1) was developed to limit the size of a soft infant and toddler carrier leg opening. New reports involving the large leg opening hazard ceased within 2 years of the first version of ASTM F2236's publication in 2003. This, combined with CPSC detailed incident reviews, lead us to conclude that the current ASTM standard adequately addresses the large leg opening hazard scenario.

### **B. Structure, Fit, and Position**

Thirty-three percent of injuries reported to the CPSC (10 of 30) were related to the structure of the occupant seat area; fit of the occupant in the carrier; and the position of the soft infant and toddler carrier or the position of the wearer, or the position of the child in the seat area. These incidents occurred, for example, when an infant tucked down into the carrier and the caregiver bent at the waist breaking the child's leg; an infant fell out of the top of the carrier when the caregiver bent forward abrasions and/or blisters on infants from prolonged rubbing against the carrier while in use; and when infants suffered leg circulation-related injuries. New

language in ASTM F2236-13 requires that warning labels address ensuring that fasteners and knots are secure before each use, taking special care when leaning or walking, and bending at the knees, not at the waist, while wearing the carrier. The standard also includes requirements on the format of the label to enhance the label's effectiveness (Fig. 1).

Updated warning language on the product and in the instructional literature may address hazards arising from structure, fit, and position problems if consumers read, understand, and comply with the warnings. The diverse size of potential occupants, the broad range of caregiver sizes and shapes, and numerous possible motions and activities that could lead to injury cannot be reliably replicated in a laboratory setting, making development of a repeatable test for structure, fit, and position types of injuries prohibitively difficult. A warning label would likely not address the hazard with circulation-related injuries because that hazard may be due to a design issue. The Commission will continue to study incoming reports of leg circulation-related injuries and determine whether any additional action is necessary.

### C. Fasteners

Twenty percent of the injuries (6 of 30) were caused by fastener failures when a fastener suddenly broke or separated and the child fell to the ground. Although no hospitalizations resulted from breaking fasteners, three children suffered fractured collarbones, along with contusions and abrasions to heads and faces. The caregiver in a majority of the incidents was able to catch the child and prevent a fall. Fastener failures led to four of the five voluntary product recalls conducted since 2005.

ASTM F2236-13 addresses the hazards posed by fastener failures with a new performance requirement for fastener strength and strap retention, published in section 6.4 and a new test in section 7.7. New requirements state that all load-bearing fasteners, such as buckles,

loops, and snaps may not break or disengage, nor may their straps slip more than 1 inch, when an 80-pound pull force is applied across the fasteners. An exception is made for adjustable leg opening fasteners, which must be subjected to a 45-pound pull force. Adjustable leg opening fasteners see substantially less load than other load-bearing fasteners during foreseeable use and abuse, such as fasteners securing shoulder and waist straps. The fastener strength and strap retention requirements do not apply to non-load-bearing fasteners that attach accessories, such as bibs, rain hoods, and toys to the soft infant and toddler carrier. The Commission believes that the inclusion of this new requirement in ASTM F2236-13 will adequately address the fall hazard related to fastener failures.

#### D. Design and Finish

Seven percent of the soft infant and toddler injuries (2 of 30) are attributable to design and finish issues. Complaints include inadequate back support, rough fabric, poor air flow in the carrier insert, and one report of high lead levels in a zipper pull. The injuries consist of a pinched finger and a cut on the nose. ASTM F2236-13 includes language prohibiting sharp points and edges, but the standard does not specifically mention pinching. A pinching-shearing-scissoring hazard exists typically in products with rigid parts that move past one another; such a hazard does not generally exist with soft products. No changes to the voluntary standard for design and finish issues are recommended at this time. Section 101 of the CPSIA requires that children's products, such as soft infant and toddler carriers, not contain lead content in excess of 100 parts per million. Accordingly, such requirement does not need to be repeated in ASTM F2236-13.

#### E. Stitching/seams

Although only three percent of the injuries (1 of 30) involve stitching and seams, 11 percent of the total soft infant carrier reports (10 of 93) describe incidents in which stitching became undone or seams ripped, resulting in other components, like straps, becoming detached. One injury was reported when a seam failed, causing a 4-month-old child to fall and receive minor contusions. The new fastener strength test, and the more stringent dynamic and static load tests in sections 7.7 and 7.2 of ASTM F2236-13, respectively, all apply loads to soft infant and toddler carrier seams and sewn attachment points. The Commission believes that incidents related to ripping seams are adequately addressed by these new requirements in the voluntary standard, and therefore, we are not proposing any additional changes at this time.

#### F. Straps

Although there were no injuries related to soft infant carrier straps, nine percent of the reported incidents (8 of 93) involve issues with straps. The problems reported include broken strap length adjustment mechanisms and straps that permit unexpected slippage. The new fastener strength and strap retention requirements, and the more stringent dynamic and static load tests in sections 7.7 and 7.2 of ASTM F2236-13, respectively, all apply loads to soft infant and toddler carrier straps, and require that they not break or allow more than 1 inch of slippage. Accordingly, the Commission believes that incidents related to breaking and slipping straps are adequately addressed by these new requirements in the voluntary standard and is not proposing any additional changes at this time.

#### G. Other

Thirteen percent of the injury reports (4 of 30), including two deaths, contain insufficient information for the CPSC to determine the exact nature of the product's contribution to the

incident. This category includes two fatalities and four injuries, including two hospitalizations. The two fatalities discussed above in section III.A, both involving suffocation, are included in this category. In each case, CPSC staff concluded that there were too many confounding factors reported to determine that a specific factor contributed predominantly to the deaths. ASTM F2236-13 does, however, address in the warning label requirements a suffocation hazard arising from use of soft infant and toddler carriers. The new warning label requirements state that products must address the fact that infants under 4 months old can suffocate if their face is too tight against a caregiver's body, and the label also advises caregivers not to strap the infant too tightly against the body to allow room for head movement and to keep an infant's face free from obstruction at all times.

## **VI. Effective Date**

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for manufacturers of soft infant and toddler products to come into compliance, the Commission proposes that the standard become effective 6 months after publication of a final rule in the *Federal Register*. The Commission invites comment on whether 6 months will be sufficient time for soft infant and toddler carrier manufacturers to come into compliance with the rule.

## **VII. Regulatory Flexibility Act**

### **A. Introduction**

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that CPSC staff prepare an initial regulatory flexibility analysis and make it available to the public for comment when the general notice of proposed rulemaking is



published. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

- a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the types of professional skills necessary for the preparation of reports or records; and
- identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

#### B. Market for Soft Infant and Toddler Carriers

Soft infant and toddler carriers are generally produced and/or marketed by juvenile product manufacturers and distributors. Several of these firms focus exclusively on soft infant and toddler carriers, as well as substitute products, such as slings. CPSC staff believes that there are at least 39 suppliers to the U.S. market. Thirty-one domestic firms supply soft infant and toddler carriers to the U.S. market: 15 are domestic manufacturers; eight are domestic importers; and the supply sources of eight domestic firms are unknown. Five foreign firms supply soft infant and toddler carriers to the U.S. market: three are foreign manufacturers; one is a foreign

importer; and one firm has an unknown supply source. Insufficient information is available to categorize the remaining three firms.<sup>2</sup>

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), 51 percent of new mothers own soft infant and toddler carriers.<sup>3</sup> Approximately 30 percent of soft infant and toddler carriers were handed down or purchased secondhand.<sup>4</sup> Thus, about 70 percent of soft infant and toddler carriers were acquired new. This suggests that approximately 1.5 million soft infant and toddler carriers are sold to households annually ( $.51 \times .70 \times 4.1$  million births per year).<sup>5</sup>

Many soft infant and toddler carriers have expanded their maximum weight limits in recent years to accommodate older children. Staff believes, however, that most adult users would not be comfortable carrying older, heavier children in soft infant and toddler carriers. This belief is supported by a lack of incident data for children over 2 years old. It appears that soft infant and toddler carriers are used during a child's first year, with some caregivers continuing to use these products into the second year. We do not know the proportion who continues to use these products into the second year; accordingly, we estimate risk under the assumption that approximately 25–50 percent will do so. Based on data from the *2006 Baby Products Tracking Study*, approximately 2.1 million soft infant and toddler carriers are owned by new mothers.

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<sup>2</sup> Staff made these determinations using information from Dun & Bradstreet and Reference USA Gov, as well as firm websites.

<sup>3</sup> The data collected for the *Baby Products Tracking Study* does not represent an unbiased statistical sample. The sample of 3,600 new and expectant mothers is drawn from American Baby magazine's mailing lists. Also, because the most recent survey information is from 2005, it may not reflect the current market.

<sup>4</sup> The data on secondhand products for new mothers was not available. Instead, data for new mothers and experienced mothers were combined and broken down into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage of soft infant and toddler carriers that were handed down or purchased secondhand.

<sup>5</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, "Births: Final Data for 2009," *National Vital Statistics Reports* Volume 60, Number 1 (November 2011): Table I. Number of live births in 2009 is rounded from 4,130,665.

Therefore, approximately 2.6–3.2 million households have soft infant and toddler carriers available for use annually. Based on Epidemiology staff’s estimate of 1,400 injuries treated nationally in emergency departments from 1999 to 2011, it is estimated that an average of 108 emergency department-treated injuries involving children under age 2 related to soft infant and toddler carriers are treated annually. Therefore, about 0.34– 0.40 emergency department-treated injuries may occur annually for every 10,000 soft infant and toddler carriers available for use in the households of new (and second year) mothers.

#### C. Reason for Agency Action and Legal Basis for the Draft Proposed Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards that are substantially the same as, or more stringent than, the voluntary standard for a durable infant or toddler product. CPSC staff worked closely with ASTM to develop the new requirements and test procedures that have been incorporated into ASTM F2236-13, which forms the basis of the proposed rule.

#### D. Requirements of the Proposed Rule

The requirements of the proposed rule are set forth above in section IV.B.2 of this preamble, which describes ASTM F2236-13.

#### E. Other Federal Rules

Section 14(a)(2) of the CPSA requires every manufacturer and private labeler of a children’s product that is subject to a children’s product safety rule to certify, based on third party testing conducted by a CPSC-accepted laboratory, that the product complies with all applicable children’s product safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards, by rule, for among other things, ensuring that a children’s product is tested periodically and where there has been a material change in the

product, and for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler. A final rule implementing sections 14(a)(2) and 14(i)(2) of CPSA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107, became effective on February 13, 2013 (the 1107 rule).

Soft infant and toddler carriers will be subject to a mandatory children's product safety rule, so they will also be subject to the third party testing requirements of section 14 of the CPSA and the 1107 rule when the final rule and the notice of requirements become effective.

#### F. Impact on Small Businesses

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of soft infant and toddler carriers is small if it has 500 or fewer employees; and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, 26 of the 31 domestic firms supplying soft infant and toddler carriers to the U.S. market are small firms—12 manufacturers, six importers, and eight firms whose supply source is unknown. Additional unknown small soft infant and toddler carrier suppliers may operate in the U.S. market as well.

*Small Manufacturers.* The expected impact of the proposed rule on small manufacturers will differ, based on whether their soft infant and toddler carriers are already compliant with ASTM F2236-10. Although ASTM F2236-12 was published in December 2012, and ASTM F2236-13 was published in March 2013, new standards are not in effect until 6 months after publication. Accordingly, firms are likely to be still testing to ASTM F2236-10. In general, firms whose soft infant and toddler carriers meet the requirements of ASTM F2236-10 are likely to continue to comply with the voluntary standard as new versions are published. In addition, they are likely to meet any new standard within 6 months because this is the amount of time

JPMA allows for products in its certification program to shift to a new standard. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice.

The impact on seven of 12 domestic manufacturers who comply with ASTM F2236-10 is expected to be small. Firms already in compliance with ASTM F2236-10 may require slight, if any, modifications, in order to bring their product(s) into compliance with the current voluntary standard. Any strap/fastener modifications are expected to incur minimal costs, as are changes to the warning label.

Meeting ASTM F2236-13's requirements could necessitate some product redesign for five of the 12 domestic manufacturers who are not believed to be compliant with ASTM F2236-10. These redesigns would likely involve adding or changing straps, fasteners, or fabrics; and partial redesigns are generally less expensive than complete redesigns, based on past discussions with manufacturers. For the types of changes that might be required to be made to these products, staff does not believe that complete redesigns (*e.g.*, engineering time, prototype development, and tooling) would be required for any known products. Therefore, in most cases, the impact of the proposed rule is not expected to have a significant effect on products that are not believed to be compliant with ASTM F2236-10.

It is possible that some firms whose soft infant and toddler carriers are neither certified as compliant, nor claim compliance with ASTM F2236-10 (or a similar standard), in fact, are compliant with the standard. CPSC staff has identified many such cases with other infant and toddler products. To the extent that some of these firms may supply compliant soft infant and toddler carriers and have developed a pattern of compliance with the voluntary standard, the direct impact of the proposed rule will be less significant than described above.

Eight small firms have unknown supply sources, three of which appear to be compliant with ASTM F2236-10. If these firms are manufacturers, they will be affected as described above. If these firms are distributors or wholesalers, the impact will be similar to the impact on importers, as discussed below.

In addition to the direct impact of the proposed rule, indirect impacts exist. These impacts are considered indirect because they do not arise directly as a consequence of the proposed rule's requirements. Once the rule becomes final and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements. This will include any physical and mechanical test requirements specified in the final rule. Because lead and phthalates testing are already required for soft infant and toddler products, they are not included in this discussion.

Staff estimates that testing to the ASTM voluntary standard could cost about \$500–\$600 per model sample. On average, each small domestic manufacturer supplies two different models of soft infant and toddler carriers to the U.S. market annually. Therefore, if third party testing is conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about \$1,000–\$1,200 annually. Based on a review of firms' revenues, the impact of third party testing to ASTM F2236-13—if only one soft carrier sample per model is required—is unlikely to be significant. However, these costs could be more significant if multiple models are needed for testing.

*Small Importers.* Most importers would not experience significant impacts as a result of the proposed rule. Five of the six small importers are believed to be compliant with the voluntary standard. In the absence of regulation, these firms would likely continue to comply with the voluntary standard as it evolves and would likely comply with the final mandatory

standard as well. The remaining importer might need to find an alternate source of soft infant and toddler carriers if its existing supplier does not come into compliance with the requirements of the proposed rule. Alternatively, the firm may discontinue importing soft infant and toddler carriers altogether and perhaps substitute another product.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements, and consequently, they will experience the associated costs if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers who must perform the testing themselves if more than one sample per model is required. In addition, the impacts could be higher than those incurred by domestic manufacturers if importers have to test each batch imported in the case where the foreign manufacturer does not conduct testing.

#### G. Alternatives

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative would be to set an effective date later than the proposed 6 months, which is generally considered sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule. Setting a later effective date would allow suppliers additional time to modify and/or develop compliant soft infant and toddler carriers and spread the associated costs over a longer period of time.

### **VIII. Environmental Considerations**

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. If our rule has "little or no potential for affecting the human environment," it will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

## **IX. Paperwork Reduction Act**

The proposed rule 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. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Soft Infant and Toddler Carriers

Description: The proposed rule would require each soft infant and toddler carrier to comply with ASTM F2236-13, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*. Sections 8.1 and 9.1 of ASTM F2236-13 contain requirements for marking, labeling, and instructional literature that are disclosure requirements, thus falling within the definition of “collections of information” at 5 C.F.R. 1320.3(c).

Description of Respondents: Persons who manufacture or import soft infant and toddler carriers.

Estimated Burden: We estimate the burden of this collection of information 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
1226	39	2	78	1	78

Our estimate is based on the following:

Section 8.1 of ASTM F2236-13 requires that all soft infant and toddler carrier products and their retail packaging be marked or labeled as follows: the manufacturer, distributor, or seller name, and either the place of business (city, state, mailing address including zip code), or telephone number, or both; and a code mark or other means that identifies the date (month and year as a minimum) of manufacture.

CPSC is aware of 39 firms that supply soft infant and toddler carriers in the U.S. market. All 39 firms are assumed to use labels on their products and on their packaging already, but they might need to make some modifications to their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each of these firms supplies an average of two different models of soft infant and toddler carrier; therefore, the estimated burden hours associated with labels is 1 hour x 39 firms x 2 models per firm = 78 hours annually.

We estimate the hourly compensation for the time required to create and update labels is \$27.92 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” September 2012, Table 9, total compensation for all sales and office workers in goods-producing private industries: <http://www.bls.gov/ncs/>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$2,177.76 (\$27.92 per hour x 78 hours = \$2,177.76). No operating, maintenance, or capital costs are associated with the collection.

Section 9.1 of ASTM F2236-13 requires that all soft infant and carrier products provide instructions that are easy to read and understand. Where applicable, instructions for assembly, use, maintenance and cleaning of the product, and warnings, must also be included. Soft infant and toddler carriers are products that do not generally require installation but require instruction for proper use, fit, and adjustment on a caregiver's body. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the 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" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." Therefore, because we are unaware of soft infant and toddler carriers that lack any instructions to the user about proper use, fit, and assembly, we estimate tentatively that there are no burden hours associated with section 9.1 of ASTM F 2236-13 because any burden associated with supplying instructions with soft infant and toddler carriers would be "usual and customary" and would not fit within the definition of "burden" under the OMB's regulations.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to submit comments regarding information collection by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

Pursuant to 44 U.S.C. 3506(c)(2)(A), we invite comments on:

- whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility;

- the accuracy of the CPSC’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

## **X. Preemption**

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where 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,” thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

## **XI. Certification and Notice of Requirements (NOR)**

Section 14(a) of the CPSA imposes the requirement that 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). Section 14(a)(2) of the CPSA requires that certification of children's products subject to a children's product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children's product safety rule to which a children's product is subject. The proposed rule for 16 CFR part 1226, "Safety Standard for Soft Infant and Toddler Carriers," when issued as a final rule, will be a children's product safety rule that requires the issuance of an NOR.

Effective June 10, 2013, the Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 Fed. Reg. 15836 (March 12, 2013), which codifies 16 CFR part 1112. Part 1112 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. The final rule also codifies all of the NORs that the CPSC has published to date. All new NORs, such as the soft infant and toddler carrier standard, require an amendment to part 1112. Accordingly, the proposed rule would amend part 1112 to include the soft infant and toddler standard along with the 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 soft infant and toddler carriers would be required to meet the third party conformity assessment body accreditation requirements in part 1112. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, it can apply to the CPSC to have 16 CFR part 1226, *Safety Standard for Soft*

*Infant and Toddler Carriers*, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: [www.cpsc.gov/labsearch](http://www.cpsc.gov/labsearch).

CPSC staff previously conducted an analysis of the potential impacts on small entities of the proposed rule for part 1112, and published an Initial Regulatory Flexibility Analysis (IRFA) in 77 FR 31086, 31123-26 (May 24, 2012). The IRFA concluded that the requirements in part 1112 would not have a significant adverse impact on a substantial number of small laboratories because no requirements are imposed on laboratories that do not intend to provide third party testing services under Section 14(a)(2) of the CPSA. The only laboratories that are expected to provide such services are those that anticipate receiving sufficient revenue from providing the mandated testing to justify accepting the requirements as a business decision. Laboratories that do not expect to receive sufficient revenue from these services to justify accepting these requirements would likely not pursue accreditation for this purpose.

Amending part 1112 to include the NOR for the soft infant and toddler standard would also not have a significant adverse impact on small laboratories. 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 soft infant and toddler standard. Most of these laboratories already will have been accredited to test for conformance to other juvenile product standards, and the only cost to them would be the cost of adding the soft infant and toddler standard to their scope of accreditation. As a consequence, the Commission could certify that the proposed NOR for the soft infant and toddler standard will not have a significant impact on a substantial number of small entities.

The final NOR will base the CPSC laboratory accreditation requirements on the performance standard set forth in the final rule for the safety standard for soft infant and toddler carriers and the test methods incorporated within that standard. The Commission may recognize limited circumstances in which it will accept certification based on product testing conducted before the Commission's acceptance of accreditation of laboratories for testing soft infant and toddler carriers (also known as retrospective testing) in the final NOR. The Commission seeks comments on any issues regarding the testing requirements of the proposed rule for soft infant and toddler carriers and the accompanying proposed NOR.

## **XII. Request for Comments**

This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for soft infant and toddler carriers. We invite all interested persons to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

### **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 1226**

Consumer protection, Imports, Incorporation by reference, Infants and Children, Labeling, Law Enforcement, and Toys.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations by amending part 1112 and adding a new part 1226, 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. In § 1112.15 add paragraph (b)(36) 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) \* \* \*

\* \* \* \* \*

(36) 16 CFR part 1226, Safety Standard for Soft Infant and Toddler Carriers.

**3. Add Part 1226 to read as follows:**

**PART 1226-SAFETY STANDARD FOR SOFT INFANT AND TODDLER CARRIERS**

Sec.

1226.1 Scope.

1226.2 Requirements for Soft Infant and Toddler Carriers.

**Authority:** The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, § 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112-28, 125 Stat. 273 (August 12, 2011).

**§ 1226.1 Scope.**

This part establishes a consumer product safety standard for soft infant and toddler carriers.

**§ 1226.2 Requirements for Soft Infant and Toddler Carriers.**

(a) Each soft infant and toddler carrier must comply with all applicable provisions of ASTM F2236-13, Standard Consumer Safety Specification for Soft Infant and Toddler Carriers, approved on March 1, 2013. 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:

[http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(b) Reserved

Dated: March 29, 2013

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Todd A. Stevenson,  
Secretary, Consumer Product Safety Commission

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