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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91205483
Party	Plaintiff Baba Slings Pty Ltd
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Date	07/02/2014
Attachments	Updated Exhibit List.pdf(7375 bytes) Exhibit 14 - Proposed Rules for Slings.pdf(247495 bytes) Exhibit 15 - Proposed Rules for Soft Carriers.pdf(184308 bytes) Exhibit 16 - Final Rules for Soft Carriers.pdf(269695 bytes)

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

In the Matter of Trademark Application No.: 79/103197

Mark: theBabaSling

Filed on: September 6, 2011

Baba Slings Pty Ltd,)	
)	
Opposer,)	Opposition No: 91205483
)	
vs.)	
)	
BabaSlings Limited,)	
)	
Applicant.)	
_____)	

UPDATED EXHIBIT LIST

Exhibit	Description
1	Declaration of Shanti McIvor
2	Opposition
3	Answer
4	theBabaSlings Application file wrapper
5	Baba Slings Application file wrapper
6	Portions of Applicant's Responses to Interrogatories
7	Applicant's Responses to Requests for Production of Documents
8	Portions of Opposer's Website, Amazon.com, and other Internet Documents
9	Summary of Opposer's Website Traffic
10	Recent instances of Consumer Confusion
11	Shareholder's Agreement Babaslings Limited
12	CONFIDENTIAL – Emails concerning early sales
13	CONFIDENTIAL – Select Sales and Other Information of Opposer
14	Proposed Rule: Safety Standard for Sling Carriers
15	Proposed Rule: Safety Standard for Soft Infant and Toddler Carriers
16	Final Rule: Safety Standard for Soft Infant and Toddler Carriers

EXHIBIT 14

EXHIBIT 14



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

This document has been electronically
approved and signed.

DATE: June 11, 2014

**THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.
A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: [TBD]**

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Elliot F. Kaye, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Barbara E. Little, Attorney, OGC

SUBJECT: Proposed Rule: Safety Standard for Sling Carriers

The Office of the General Counsel is providing for Commission consideration the attached draft proposed rule for publication in the *Federal Register*. The proposed rule would establish a safety standard for sling carriers pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008.

Please indicate your vote on the following options:

- I. Approve publication of the attached document in the *Federal Register*, as drafted.

(Signature)

(Date)

II. Approve publication of the attached document in the *Federal Register*, with changes.
(Please specify.)

(Signature)

(Date)

III. Do not approve publication of the attached document in the *Federal Register*.

(Signature)

(Date)

IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Proposed Rule to Establish a Safety Standard for Sling Carriers

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1228

Docket No. CPSC-2014-XXXX

Safety Standard for Sling 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 sling carriers in response to the direction under Section 104(b) of the CPSIA.

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

ADDRESSES: You may submit comments related to the Paperwork Reduction Act (PRA) aspects of the marking, labeling, and instructional literature of the proposed rule to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to: oir_submission@omb.eop.gov.

You may submit other comments, identified by Docket No. _____, by any of the following methods:

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. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

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

Instructions: All submissions received must include the agency name and docket number for this notice. 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 _____, into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Hope E J. Nesteruk, Project Manager, Division of Human Factors, Directorate for Engineering Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2579; e-mail: hnesteruk@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.

Section 104(f) states:

As used in this section, the term “durable infant or toddler product”—

(1) means a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years; and

(2) includes-- ... (H) infant carriers.

Section 104 also requires manufacturers of durable infant or toddler products to comply with a registration program that the Commission establishes. Section 104(d).

In this document, the Commission is proposing a safety standard for sling carriers. Section 104(f)(2)(H) of the CPSIA lists “infant carriers” as one of the categories of durable infant or toddler products identified for purposes of section 104. As indicated by a review of ASTM’s standards and retailers’ websites, the category of “infant carriers” includes hand-held infant carriers, soft infant carriers, frame backpack carriers, and sling carriers. The Commission has issued final rules for hand-held infant carriers (78 Fed. Reg. 73415 (December 6, 2013)) and

soft infant carriers (78 Fed. Reg. 20511 (April 5, 2013)) and a proposed rule on frame backpack carriers (79 Fed. Reg. 28458 (May 16, 2014)). In the Commission's product registration card rule identifying additional products that the Commission considered durable infant or toddler products necessitating compliance with the product registration card requirements, the Commission specifically identified infant slings, or sling carriers, as a durable infant or toddler product. 76 Fed. Reg. 68668 (December 29, 2009). The durability of infant slings is discussed in section II.B. of this document.

Because the voluntary standard on infant slings, ASTM 2907-14a, "Standard Consumer Safety Specification for Sling Carriers," refers to "infant slings" as "sling carriers," the notice of proposed rulemaking refers to infant slings as "sling carriers." The terms are intended to be interchangeable and have the same meaning.

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. CPSC staff participated in the ASTM sling carrier subcommittee meetings and task group meetings and worked with the ASTM sling carrier task groups to develop ballot language for revisions to the sling carrier voluntary standard. The proposed rule is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2907-14a, "Standard Consumer Safety Specification for Sling Carriers" (ASTM F2907-14a), without change.

The ASTM standard is copyrighted, but the standard is available as a read-only document during the comment period on this proposal only, at:

<http://www.astm.org/Standards/F2907.htm>, by permission of ASTM.

II. Product Description

A. Definition of Sling Carrier

ASTM F2907-14a “Standard Consumer Safety Specification for Sling Carriers” defines a “sling carrier” as “a product of fabric or sewn fabric construction, which is designed to contain a child in an upright or reclined position while being supported by the caregiver’s torso.” These products generally are intended for children starting at full-term birth until a weight of about 35 pounds. The designs of infant slings vary, but the designs generally range from unstructured hammock-shaped products that suspend from the caregiver’s body, to long lengths of material or fabric that are wrapped around the caregiver’s body. Infant slings normally are worn with the infant positioned on the front, hip, or back of the consumer, and with the infant facing toward or away from the consumer. As stated in the sling carrier definition, these products generally allow the infant to be placed in an upright or reclined position. However, the reclined position is intended to be used only when the infant is worn on the front of the consumer. The ability to carry the infant in a reclined position is the primary feature that distinguishes sling carriers from soft infant and toddler carriers, another subset of sling carriers.

The Commission identified three broad classes of sling carrier products available in the United States:

- Ring slings are hammock-shaped fabric products, in which one runs fabric through two rings to adjust and tighten the sling.
- Pouch slings are similar to ring slings but do not use rings for adjustment. Many pouch slings are sized rather than designed to be adjustable. Other pouch slings are more structured and use buckles or other fasteners to adjust the size.

- Wrap slings are generally composed of a long length of fabric, upwards of six yards long, and up to two feet wide. A wrap sling is completely unstructured with no fasteners or other means of structure; instead, the caregiver uses different methods of wrapping the material around the caregiver's body and the child's body to support the child. Wrap-like slings mimic the manner in which a wrap supports the child but use fabric in other manners, such as loops, to reduce the need for caregivers to learn wrapping methods.

Ring slings, modifications of wraps and pouch slings, and other products that meet the definition of a sling carrier contain parts that are also considered durable from an engineering perspective and suggest they were selected for long-term use. In addition, the test methods in ASTM F2907-14a combine to ensure that slings meet a minimum level of durability.

ASTM F2907 does not distinguish among the type of slings. The voluntary standard's requirements apply equally to all slings.

B. Sling Carrier Use

ASTM F2907 – 14a states that sling carriers generally are intended for children starting at full-term birth, until a weight of about 35 pounds (15.9 kg). According to the data tables used to produce the 2000 Centers for Disease Control and Prevention (CDC) U.S. growth charts, the median (50th percentile) weight of a child does not exceed 35 pounds until about 46 months for boys and 49 months for girls (CDC, 2000). Moreover, the 5th percentile bodyweight of a child does not exceed 35 pounds until about 65 months for boys and 69 months for girls. This means that more than half of all 3-year-olds are likely to be at or below the maximum weight of 35 pounds, and that even some 5-year-olds are likely to be at or below this upper weight limit.

Although the Commission believes that sling carriers are most likely to be used with infants, it

seems reasonably foreseeable that some portion of the user population will use these carriers with preschool-aged children.

Evidence suggests that sling carriers are often reused for multiple children. For example, according to a 2005 survey conducted by the American Baby Group (2006 *Baby Products Tracking Study*), nearly one-third (31 percent) of mothers who own slings had a sling that was handed down or purchased secondhand. Preliminary data from CPSC's Durable Nursery Products Exposure Survey found that 21 percent of sling owners acquired the sling used. The Survey also found that after the owner discontinued use of the sling, only 4 percent threw away the sling; 96 percent of owners stored the sling for future use, sold the sling, gave the sling away, or returned the sling to the original owner. These results suggest that most sling owners at least perceive sling carriers to have a future useful life, even if the sling had been used previously.

The Commission is aware of several online websites, forums, and "babywearing" groups dedicated to buying, selling, and trading previously used sling carriers. ("Babywearing" is commonly used to describe the wearing or carrying of a baby in a sling or similar carrier.) For example, a simple search of sold listings for a used "baby sling" on eBay resulted in more than 1,700 listings during a roughly 3-month period. Although some of the products in these ads do not meet the definition of a "sling carrier," a brief examination of the most recent 200 sales suggests that a very large percentage of these products would be considered a sling carrier. Thus, many consumers appear to be purchasing slings secondhand.

C. Market Description

The Commission has identified 47 suppliers to the U.S. market, but there may be hundreds more suppliers that produce small quantities of slings. (The Commission made these determinations using information from Dun & Bradstreet and Reference USA Gov, as well as

firm websites.) Websites such as Etsy show thousands of listings for artisans producing slings and wraps (although each firm may have multiple listings), which accounts for additional suppliers who are not among the 47 suppliers identified. Sling carriers are distributed by a variety of methods, such as mass merchandisers, small specialty juvenile products stores, and Internet-only distributors.

Of the 47 sling carrier suppliers identified, 33 companies are based in the United States: 25 are manufacturers, and four are importers. Available information does not identify the supply source for four firms. There are also 14 foreign companies that export directly to the United States via Internet sales or directly to U.S. retailers.

A sling carrier is an uncomplicated product to produce, typically requiring only fabric, thread, rings (and in some cases, fasteners), and a sewing machine. A common scenario for a sling manufacturer starts with a mother using various slings or soft carriers and then deciding to make her own design in her home. Some of these home businesses grow into larger businesses that become more specialized and sophisticated, typically designing and marketing their own products but having the product manufactured overseas. However, the newer home businesses may be relatively unsophisticated and may not be aware of the sling carrier voluntary standard effort or know that sling carriers may be subject to existing federal regulations on children's products.

According to a the 2006 *Baby Products Tracking Study*, 17 percent of new mothers own sling carriers. As noted previously, approximately 31 percent of sling carriers were handed down or purchased secondhand. Thus, about 69 percent of sling carriers were acquired new. (The data collected for the *Baby Products Tracking Study* do not represent an unbiased statistical sample. American Baby Products surveyed potential respondents from its mailing lists to

generate a sample of 3,600 new and expectant mothers. Additionally, because the most recent survey information is from 2005, the data may not reflect the current market.) This information suggests annual sales of about 471,000 sling carriers (.17 x .69 x 4 million births per year), with prices ranging from \$30 to around \$150. (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 61, Number 1 (August 28, 2012): Table I. Number of births in 2010 is rounded from 3,999,386.)

However, this sales estimate may be a substantial underestimate for two reasons: (1) industry sources state that slings have increased in popularity since the survey was done in 2005; and (2) other products like wraps, pouches, and some soft carriers, which fall under the standard, may not have been included in the *Baby Products Tracking* study. Based on discussions with an industry representative, sales of these other products that fall under the proposed rule for sling carriers could increase the Commission’s sales estimate to about 600,000 to 1 million units annually.

III. Incident Data

The Commission is aware of a total of 122 incidents (16 fatal and 106 nonfatal) related to sling carriers, which were reported to have occurred from January 1, 2003 through October 27, 2013. Because reporting is ongoing, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future. Given that reporting is incomplete, the Commission strongly discourages drawing inferences based on the year-to-year increase or decrease shown in the reported data. (The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, the Death Certificate (DTHS) file, and the

National Electronic Injury Surveillance System (NEISS). These reported deaths and incidents do not provide a complete count of all deaths and incidents that occurred during that time period. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to sling carriers.)

Among the incidents in which age was reported, all but one of the children were 12 months old or younger; the age of the oldest child was reported to be 3 years. Some incident reports did not indicate the age because there was no injury involved or age was unknown. Table 1 provides the age breakdown as reported in the 122 incidents.

**Table 1: Age Distribution as Reported in Sling Carrier-Related Incidents
01/01/03–10/27/13**

<i>Age of Child</i>	<i>All Incidents</i>		<i>Fatal and Nonfatal Injuries</i>	
	<i>Frequency</i>	<i>Percentage</i>	<i>Frequency</i>	<i>Percentage</i>
Unreported*	31	25	1	1
One – Three Months	70	57	54	77
Four – Six Months	11	9	8	11
Seven – Nine Months	7	6	4	6
Ten – Twelve Months	2	2	2	3
Three Years	1	1	1	1
Total	122	100	70	100

Source: CPSC epidemiological databases IPII, INDP, DTHS, and NEISS.

Note: Percentages do not add to 100 due to rounding.

* : Age was unknown or the incident reported no injury.

A. Fatalities

CPSC received reports of 16 fatalities associated with the use of a sling carrier that occurred during the period from January 1, 2003 through October 27, 2013. Eleven of the 16 decedents were 1-month olds; the remaining five were between 3- and 5-months old. Nine of the decedents were described as having died of smothering, (also known as “suffocation,” or “positional asphyxia.”) Suffocation can occur when babies are contained entirely within the pouch of a sling. Infants who are placed with their heads below the rim of the sling are likely to

stay in the same position because they are surrounded by unyielding fabric under the tension of their weight, and are tightly confined within the product, typically with their faces directed towards or held against the parent's body. The highest risk of suffocation occurs when the infant's face (nose and mouth) is pressed against the mother's body, blocking the infant's breathing, and rapidly suffocating the baby within a few minutes. The cause of death was undetermined for the remaining decedents.

One fatal victim was 5 months old. The age range of the remaining 15 fatal victims was from birth to 3 months; 11 infants were ages 1 month and younger, and the remaining four were 3 months old. Infants younger than 4 months old are at a high risk for suffocation because they have relatively immature physiological systems controlling breathing and arousal.

B. Nonfatalities

Of the 106 sling carrier-related nonfatal incidents that were reported to have occurred from January 1, 2003 through October 27, 2013, 54 reports reflected an injury to the infant during use of the product. Age was unreported for one of the injured, and one report stated that a 3-year-old was injured. For the rest of the incidents, the child's age ranged from 1 month to 11 months.

Among the 54 reported nonfatal injuries, nine were reported as involving hospitalizations. Among the hospitalizations, one injury was described as a permanent brain injury due to breathing difficulties suffered by the infant. The rest of the hospitalizations were serious head injuries, such as a fracture and/or brain hemorrhage, which resulted from infants falling from the carrier. Eleven additional skull/face/wrist fracture injuries were reported, but none of these incidents was reported to involve hospitalizations. The remaining non-hospitalized injuries included closed-head injuries, contusions/abrasions, lacerations/scratches, among others.

(A closed head injury is a head injury where the skull remained intact. A closed head injury can range from a minor bump to the head to a severe life threatening traumatic brain injury.) A majority of the injuries resulted from falls from the carrier; most of these falls resulted from the caregiver slipping, tripping, or bending over while carrying the infant in the sling. The remaining injuries were due to miscellaneous product-related issues or other caregiver missteps, such as the caregiver not allowing enough safety clearance for the child in the sling carrier while the caregiver performed daily activities.

The remaining 52 incident reports stated that no injury had occurred or provided no information about any injury.

C. Hazard Pattern Identification

The Commission considered all 122 reported incidents (16 fatal and 106 nonfatal) to identify hazard patterns associated with sling carriers. In order of frequency of incident reports, the Commission grouped the hazard patterns into the following categories:

1. Problems with the *positioning* of the infant in the sling carrier: Thirty-one of the 122 reported incidents (25 percent) were in this category. Among them were nine deaths due to smothering, one permanent brain impairment injury due to breathing difficulty, and two other injuries—one related to breathing difficulty and the other related to blood-circulation in the infant's leg. The rest of the incidents reported that the infant suffered breathing problems while in the carrier or that the caregiver had difficulty safely positioning the infant in the sling carrier to avoid the potential for suffocation.
2. *Caregiver missteps*: Twenty of the 28 incidents (23 percent) in this category were reported to have occurred when the caregiver slipped, tripped, or bent over, causing the infant in the sling to either fall with the caregiver or fall out of the carrier. Eight

additional incidents among the 28 reported in this category occurred when caregivers dropped the infant during placement into/removal out of the carrier or failed to provide enough safety clearance for the infant in the carrier as the caregivers conducted their daily activities. Examples of the latter scenario include an infant getting struck by a door or a falling object, or an infant hitting a wall. Although these 28 incidents did not involve any fatalities, all but one incident resulted in an injury to the infant. These incidents included 11 reports of skull fractures and one report of bleeding in the brain. Other injuries included closed-head injuries, contusions of the head/leg/back, and a finger laceration.

3. ***Undetermined*** or ***unspecified*** cause: Twenty five reported incidents (20 percent) included seven fatalities, two hospitalized injuries, and 13 non-hospitalized injuries, with very little information available on the circumstances leading to the incidents. The official reports did not indicate a specific cause of death. Among the injuries, which included fractures of the skull/wrist, as well as other serious head injuries, most were reported through hospital emergency departments with very little scenario-specific information.
4. Problems with ***buckles***: Twelve of the 122 incidents (10 percent) reported buckles releasing, slipping, or breaking, causing infants to fall or nearly fall. There was one hospitalization for a skull fracture and two non-hospitalized injuries. There were no fatalities in this category.
5. ***Miscellaneous product-related*** issues: There were nine incident reports (seven percent) in which consumers complained of a design flaw posing a possible strangulation hazard, a broken component, rough fabric, or a sharp surface; or consumers indicated an

unspecified product failure. Although these reports did not include any fatalities, there were six injuries reported in this category, including one skull fracture.

6. **Consumer comments:** There were 17 non-event reports (14 percent) of consumer comments or observations of perceived safety hazards. In most of these cases, the consumer did not own the sling carrier in question. None of these reports indicates that any event actually occurred.

D. Product Recalls

Since January 1, 2003, the CPSC has issued five consumer-level recalls involving sling carriers. All five recalls were for product defects that created a substantial product hazard and resulted in the recall of about 1.1 million sling carriers. Two of the recalled products posed a suffocation hazard, while three recalls were related to structural integrity and fall or potential fall hazards.

IV. Other Standards

A. International Standards

The Commission identified one European standard that covers fabric carriers without rigid structure. In addition, a guideline for sling carriers is under development in Europe.

1. British Standard EN13209-2:2005, *Child Use and Care Articles – Baby Carriers – Safety Requirements and Test Methods – Part 2: Soft Carriers* (27 September 2005), is the European standard for soft, fabric carriers. However, EN13209 specifically states that the scope is intended for a “product [that] has holes designed to accommodate the child's legs.” Sling carriers do not have holes through which a child's legs pass. Although some individual requirements in the EN13209 standard may be more stringent than those in F2907-14a, the reported incidents do not suggest

that these are prevalent hazard patterns associated with sling carriers. Therefore, the Commission does not believe that incorporating these more stringent requirements would further reduce the risk of injury associated with sling carriers.

2. CEN/TR 16512, *Child use and care articles - Guidelines for the safety of children's slings*, is a guideline that is under development in Europe. However, because this guideline, once completed would not be a standard, CEN/TR 16512 is not an option for consideration. The Commission expects that this guideline, when published, will contain recommendations similar to EN13209, but with recommendations adapted for the unique attributes of sling carriers.

The Commission notes that the ASTM F15.21 subcommittee has worked to make F2907 the most appropriate standard for the unique nature of sling carriers by harmonizing with other standards (*e.g.*, EN13209 and ASTM F2236), when appropriate, but also addressing the uniqueness of sling carriers, when needed. The Commission believes that ASTM F2907-14a is the most comprehensive standard that addresses the incident hazard patterns and that F2907-14a adequately addresses the hazards identified to date.

Voluntary Standard – ASTM F2907

1. Description of Standard

ASTM F2907, “Standard Consumer Safety Performance Specification for Sling Carriers,” establishes safety performance requirements, test methods, and labeling requirements to minimize the hazards to children presented by sling carriers. ASTM first published a consumer product safety standard for sling carriers in 2012. ASTM has revised the voluntary standard five times since then. The current version, ASTM F2907-14a, was approved on February 15, 2014, and published in March 2014. ASTM F15.21 subcommittee issued a ballot on May 16, 2014, that proposed a

modification in the occupant retention test pass/fail criteria. According to the ballot, “the current Occupant Retention test criteria (section 6.3) are not accurately separating good ring slings from poorly-constructed ring slings.” The modification ASTM has proposed would increase from 1 inch to 3 inches the amount the ring sling attachment system may slip while still passing the standard. At the time of writing, the Commission does not have sufficient information to assess this change. Staff welcomes comments on the issue.

The current version of the sling carrier standard, ASTM F2907-14a, contains requirements to address the following issues:

- Laundering;
- Hazardous sharp points or edges;
- Small parts;
- Lead in paint;
- Wood parts;
- Locking and latching;
- Openings;
- Scissoring, shearing, and pinching;
- Monofilament threads;
- Flammability;
- Marking and labeling; and
- Instructional literature.

In addition, F2907-14a includes construction, quality, and durability test methods that are specific to sling carriers in the static, dynamic, occupant retention, and restraint system tests.

These test methods combine to ensure that slings meet a minimum level of durability.

- **Static load test:** This test checks that the sling can support the sling’s maximum recommended weight with a safety factor of three, by gradually applying a weight of three times the manufacturer’s maximum recommended weight, or 60 lbs., whichever is greater, in the support area of the sling, and maintain the weight for one minute.
- **Dynamic load test:** This test assesses the durability of the sling and proper functioning of the sling’s fasteners by dropping a 35-lb. load into the sling’s support area in each recommended carrying position every 4 seconds for up to 1,000 cycles.
- **Occupant retention test:** This test assesses whether the sling retains the occupant as the caregiver moves about. The test also assesses the sling’s durability. The sling is attached to a test torso, and a test mass is placed in the sling. The test torso will move up and down at a rate of two times per second (approximately a brisk walking speed). The sling is tested to determine whether the adjustment mechanisms (*e.g.* rings, knots) release.
- **Restraint system test:** This test assesses whether any child restraints used by the sling are sufficient. Each restraint system is tested with a 45-lb. force on the restraint and again with a CAMI dummy. The anchorages for the restraint system are not to separate from their attachment points during or after testing.

2. *Adequacy of Requirements in Addressing Identifiable Hazard Patterns*

Positioning. The Commission identified positioning as the primary hazard pattern in 31 cases. This includes nine deaths due to smothering, one permanent brain impairment injury due to breathing difficulty, and two other injuries—one related to breathing difficulty and the other related to blood circulation in the infant’s leg.

As noted previously, the Commission identified suffocation/asphyxia related to positioning as a risk associated with sling carriers. Suffocation can occur when babies are

contained entirely within the pouch of a sling. The highest risk of suffocation occurs when the infant's face (nose and mouth) is pressed against the mother's body, blocking the infant's breathing and rapidly suffocating a baby within a few minutes. Furthermore, because of its shape and lack of support, a sling carrier can facilitate an infant being positioned within the confines of the sling in a manner that causes acute neck hyper-flexion (chin touching the chest). Infants found in this compromised position are likely to stay in the position because infant neck muscles are too weak to support the weight of their head. Infants who stay for prolonged periods of time in this position can experience compromised airflow to the lungs, resulting in an inadequate supply of oxygen to the brain. Oxygen deprivation to the brain can lead to loss of consciousness and death.

Although there is no performance test for positioning in ASTM F2907-14a, ASTM F2907-14a requires statements in the warnings and instructions for sling carriers to caution against the hazards identified by the Commission through examination of the sling carrier incidents. Section 8.3.3 of F2907-14a specifies the warnings that must appear on each sling and addresses each of the hazard patterns the Commission found in the suffocation data. In short, all sling carriers must: (1) include a safety alert symbol (\triangle) and the signal word "WARNING," (2) warn that failure to follow the manufacturer's instructions can result in "death or serious injury," (3) state the minimum and maximum recommended weights for the sling, and (4) warn about the potential suffocation and fall hazards associated with sling carriers.

More specifically, according to ASTM F2097-14a, the warnings that pertain to suffocation and positioning must address:

- the risk of suffocation to infants younger than 4 months if the infant's face is pressed against the caregiver's body within the confines of the sling and the

increased risk of suffocation to infants born prematurely or those with respiratory problems;

- the need to check often to make sure that the infant's face remains uncovered, clearly visible to the caregiver, and away from the caregiver's body at all times;
- the importance of making sure that the infant does not curl into a position with the chin resting on or near the infant's chest, which can interfere with breathing even when nothing is covering the nose or mouth;
- the need to reposition the infant after nursing so the infant's face is not pressed against the caregiver's body; and
- the importance of never using the sling with infants smaller than 8 pounds, without seeking the advice of a healthcare professional.

Lastly, the warning label prescribed by ASTM F2907-14a must include a pictogram that illustrates proper and improper infant positioning within the sling. ASTM F2907-14a includes an example of the type of pictogram sought but does not specify a particular design.

Section 9 of ASTM F2907-14a specifies what instructional literature must be provided with the sling. This section requires that the instructions contain an image of each manufacturer's recommended carrying position, include all of the warning statements that are required to appear on the sling, and provide several additional instructions.

ASTM subcommittees for other durable nursery product standards have also tried to address positioning hazards related to a C-shaped curl in an infant's head, neck, and torso area; however, there has been no repeatable performance test identified. The Commission attempted to address the positioning hazard associated with sling carriers in a new manner, based on the recognition that a sling carrier is worn by the caregiver and involves direct contact with the

caregiver, thereby allowing for the possibility of the caregiver seeing a child who is in distress. Specifically, the Commission explored a “face exposure” test that, at a minimum, could keep a sling from preventing the caregiver from observing the infant’s face. The Commission pursued this possible test with the ASTM task group but found that the available anthropomorphic mannequins, *e.g.*, CAMI dummies, do not accurately represent the manner in which a child sits in a sling, and that the variable nature of sling products makes the repeatability of a test questionable. Together with the ASTM task group, the Commission concluded that a test to address positioning hazards is technically infeasible at this point.

Ultimately, the Commission concluded that warning requirements about proper and improper infant positioning present in ASTM F2907-14a is the only feasible hazard-mitigation strategy at this time. The Commission will continue to consider possible performance requirements pertaining to this issue and will pursue such an approach with the ASTM Subcommittee in the future, if an approach becomes feasible. Because there is no feasible performance test and because the warning statements in ASTM F2907 were developed considering both known hazard patterns for sling carriers and established practices for warning labels, the Commission believes that the warnings and instructions published in ASTM F2907-14a are adequate to inform caregivers about how to reduce the likelihood of positioning incidents.

Caregiver Missteps. Incidents involving caregiver missteps included 11 reports of skull fractures and one episode of bleeding in the brain. Other injuries included closed head injuries, contusions of the head/leg/back, and a finger laceration. The Commission determined that these incidents were related directly to the actions, often accidental, of the caregiver. Examples include a caregiver slipping or tripping while wearing the sling carrier with the child inside, or

incidental contact occurring between the child and an object, such as a door or wall. Although these types of incidents cannot be addressed directly through a performance test, the standard addresses these incidents by alerting caregivers of the hazard and making sure that the sling contains the infant. ASTM F2907-14a requires the following statement to appear on the on-product label to address the fall hazard to infants associated with “caregiver missteps,” such as tripping or bending over:

FALL HAZARD – Leaning, bending over, or tripping can cause baby to fall.

Keep one hand on baby while moving.

In addition, the occupant retention test in ASTM F2907-14a is intended to reduce the likelihood that the child will fall out of the sling due to a caregiver misstep. ASTM F2907-14a requires the test mass to be contained within the sling for the duration of the test.

Buckles. Twelve of the incidents involved buckles releasing, slipping, or breaking, and included a hospitalization for a skull fracture and two non-hospitalized injuries. ASTM F2907-14a addresses this hazard in several ways, using the static, dynamic, occupant retention, and restraint system tests. For the reasons described previously, the Commission believes that the performance tests in F2907-14a adequately address hazards associated with buckle failure.

IV. Effective Date

The Administrative Procedure Act (APA) 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). The Commission generally considers 6 months sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule. Six months is the period the Juvenile Products Manufacturers Association (JPMA) typically allows for products in JPMA’s certification program to shift to a new voluntary standard once that new voluntary standard is published.

Therefore, juvenile product manufacturers are accustomed to adjusting to new standards with this time frame. However, in this instance, a large number of very small suppliers potentially will experience significant economic impacts complying with the rule. In addition, because ASTM F2907 has only been in existence for approximately 2 years, there is relatively little information regarding compliance with the voluntary standard. Thus, the Commission is proposing a 12-month effective date. The Commission invites comment on whether 12 months is an appropriate length of time for sling carrier manufacturers to come into compliance with the rule.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies to review proposed rules for a rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency publishes a general notice of proposed rulemaking. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the IRFA 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.

1. Reason for Agency Action and Legal Basis for the Proposed Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards for nursery products that are substantially the same as, or more stringent than, the voluntary standard. The Commission worked closely with ASTM to develop the new requirements and test procedures that have been incorporated into ASTM F2907-14a, which the Commission proposes to incorporate by reference.

2. Compliance Requirements of the Proposed Rule

The Commission is incorporating by reference the current voluntary standard, with no revision, to form the proposed rule. Some of the more significant requirements of the current voluntary standard for sling carriers (ASTM F2907–14a) include static and dynamic load testing to verify the structural integrity of the sling carriers and occupant retention testing to help ensure that the child is not ejected from the sling carrier. The ASTM standard requires that the buckles, fasteners, and knots that secure the sling carrier remain in position before and after these three performance tests. There is also a separate restraint system test to help ensure that any restraints used by the sling do not release while in use.

The voluntary standard also includes:

- requirements for several features to prevent cuts (hazardous sharp points or edges, and wood parts);
- small parts;

- marking and labeling requirements;
- flammability requirements;
- requirements for the permanency and adhesion of labels; and
- requirements for instructional literature.

The updated warning statements provide additional details of the fall and suffocation hazards and are intended to address the primary fatality risk associated with infant slings, suffocation.

3. Other Federal Rules

Section 14(a)(2) of the Consumer Product Safety Act (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, making sure that a children's product is tested periodically and when there has been a material change in the product, and safeguarding against the exercise of undue influence by a manufacturer or private labeler against a conformity assessment body. 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). When the sling carrier rule is finalized, sling carriers will be subject to a mandatory children's product safety rule. Accordingly, sling carriers will also be subject to the third party testing requirements of section 14 of the CPSA and the 1107 rule. Slings are already subject to lead and phthalates testing under the 1107 Rule. This rule adds certain mechanical tests and other requirements to the third party testing requirement.

In addition, the 1107 rule requires certifiers to use CPSC-accredited laboratories to conduct the third party testing of children's products. Section 14(a)(3) of the CPSA required the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformance assessment bodies (*i.e.*, testing laboratories) to test for conformance with each children's product safety rule. The NORs for existing rules are set forth in 16 CFR part 1112. Consequently the Commission is proposing an amendment to 16 CFR part 1112 that would establish the requirements for the accreditation of testing laboratories to test for compliance with the sling carrier final rule.

4. Impact on Small Businesses

Of the 47 identified suppliers of sling carriers to the U.S. market, 33 are domestic firms. (We limit our analysis to domestic firms because U.S. Small Business Administration (SBA) guidelines pertain to U.S.-based entities.) Under SBA guidelines, a manufacturer of sling carriers is small if it has 500 or fewer employees, and importers and wholesalers are small if the importers or wholesalers have 100 or fewer employees. Based on these guidelines, 31 of the domestic firms supplying sling carriers to the U.S. market appear to be small businesses. These businesses consist of 23 manufacturers, four importers, and four firms with unknown supply sources.

Additionally, as noted previously, an unquantified number of producers supply baby slings to the U.S. market via websites such as Etsy. Although we have no information on these suppliers, based on the general nature of suppliers selling products on Etsy and similar markets, we assume that these suppliers are well within SBA criteria for small business. For purposes of analysis, we refer to these suppliers as "very small manufacturers" to distinguish them from the more established manufacturers, but this is not an official SBA designation.

Before preparation of a regulatory flexibility analysis, the Commission conducts a screening analysis to determine whether a regulatory flexibility analysis or a certification statement of no significant impact on a substantial number of small entities is appropriate for a proposed rule. The SBA gives considerable flexibility in defining the threshold for “no significant economic impact.” However, the Commission typically uses 1 percent of gross revenue as a threshold; unless the impact is expected to fall below the 1 percent threshold for the small businesses evaluated, the Commission prepares a regulatory flexibility analysis. Because we were unable to demonstrate that the draft proposed rule would impose an economic impact less than 1 percent of gross revenue for the affected firms, the Commission did not prepare a certification statement, but conducted an IRFA.

Small Manufacturers

JPMA and the Baby Carrier Industry Alliance (BCIA) have advised some manufacturers of F2907-12, F2907-13a, F2907-13b, and F2907-14. These organizations are offering assistance to member manufacturers on testing and compliance with the ASTM sling carrier standards. However, the ASTM sling carrier standards are relatively new, and there is no established history of compliance among manufacturers.

As of January 2014, only two of the 23 known small manufacturers of sling carriers are listed on the JPMA website as certified compliant. Based on our review of small firm websites and a conversation with a small ring sling manufacturer, we have identified three additional firms (not JPMA certified) that have conducted testing to some version of the ASTM standard, for a total of five firms that have conducted testing to some version of the ASTM standard. These firms may have already experienced the impacts of the proposed rule and may not

experience any additional impacts. The remaining firms are likely to incur some cost associated with the proposed rule.

Due to the nature of the product and the relative ease of production, the Commission believes that most of the physical changes needed to meet the standard, such as changing fabrics, changing stitching, adding reinforcements, changing buckles, changing rings, changing labels, and changing instructions, are unlikely to be costly. Because sling carriers are largely made of fabric, tooling costs are not usually a large factor.

Some manufacturers of ring slings are having difficulties with their products passing the occupant retention tests consistently. The problem appears to be variation in testing results based on how the sling is positioned on the test fixture. At this time, the precise cost of changes necessary to satisfy testing under the ASTM standard is unknown; and we cannot rule out the potential for costs high enough to lead to significant economic impacts, especially for the very small manufacturers.

According to one manufacturer, changes to warning labels required under the proposed rule may have an impact on very small suppliers. We do not have sufficient data to determine whether this impact is expected to be economically significant. For example, if the cost of printing and sewing in the labels is 30 cents per sling, then the impact would be 1 percent of the sales price for a \$30 sling. CPSC staff contacted a representative from the BCIA to obtain label prices but has no independent estimate at this time. An additional consideration is that the labels are relatively large and may reduce the appeal of the product if they cannot be readily concealed. However, this impact will apply to all sling manufacturers.

Another manufacturer also expressed concerns that minor deviations from the font sizes required by the standard on the labels could force manufacturers to redo portions of the testing.

This phenomenon may diminish as businesses become familiar with the requirements. Testing costs are discussed below.

The majority of the costs associated with the proposed standard will probably be related to testing. Few of the sling carrier manufacturers have the technical capability or the equipment to conduct any testing in house; and most small and very small manufacturers probably will have to rely on third party testing during product development. Some small and very small manufacturers could experience significant costs simply testing to find out initially whether their products comply with the proposed standard and with any additional testing necessary to develop complying products.

In addition, under section 14 of the CPSA, sling carriers are subject to third party testing and certification. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, Testing and Labeling Pertaining to Product Certification (16 CFR part 1107). This will include any physical and mechanical test requirements specified in the final rule; lead and phthalates testing, if applicable, are already required; hence, lead and phthalates testing are not included in this discussion.

According to a BCIA representative, third party testing to the ASTM sling carrier voluntary standard could cost around \$500–\$1,050 per model sample, with \$700 as an average cost. Third party testing consists of two costs: the testing costs unique to F2907 associated with the dynamic load test, the static load test, the occupant retention test, and the restraints test; and the general testing costs associated with testing for flammability, small parts, sharp edges, instructions, and labels. The testing costs unique to sling carriers vary widely, from \$210 to \$650, depending on whether the testing is done in China or the United States and whether a

discount, such as the discount negotiated by the BCIA for its members, is applied. The general testing costs may amount to \$300 to \$400. The very small firms that manufacture in the United States will probably also test in the United States to avoid logistical difficulties, thus incurring higher costs.

The \$700 estimate for average testing costs includes all the required testing, such as flammability, sharp edges, etc. If a very small manufacturer with one model only needed to conduct one third party test annually, the costs of testing would amount to \$700. A very small manufacturer producing 20 to 30 low-priced slings a month might have annual revenues of \$10,800 (30 slings per month x 12 months x \$30 per sling). Testing one sample at \$700 would amount to 6.5 percent ($\$700/\$10,800$) of annual revenue for this hypothetical very small manufacturer, which we would clearly classify as a significant economic impact. Even if this manufacturer could sell its slings for \$150, testing one sample at \$700 would amount to 1.3 percent of annual revenue of \$54,000 ($360 \text{ slings} * \150 per sling).

As a comparison, third party testing costs for soft infant and toddler carriers (SITCs) were estimated at \$500–\$600 per sample for the SITC standard, ASTM F2236-14. However, the higher testing costs for slings could reflect additional testing for occupant retention, which is not part of the SITC standard.

Based upon the previous example, even in the unlikely case that very small sling manufacturers are able to develop a complying product without incurring significant economic impacts, very small sling manufacturers are still likely to incur significant economic impacts complying with section 14 of the CPSA. These types of impacts would apply to the very small producers marketing their products primarily via Etsy and other websites.

Although information on sales revenue is limited to half of all manufacturers, we estimate that most of the 23 small domestic manufacturers have substantially larger sales volumes than the example above, with annual sales ranging between \$200,000 and \$16 million. Thus, product development and testing costs would be a lower percentage of sales revenue than the example above. At the lower range of \$200,000 in revenues, significant economic impacts would occur if the producer had to test three models per year. Firms with revenues closer to the upper end of the range, \$16 million, would need to test more than 200 models per year to experience significant economic impacts from testing. The number of tests needed for product development purposes or to meet the "high degree of assurance" criteria under section 14 of the CPSA is not known.

About a third of firms (8 of 23) also have other product lines, which may cushion the impact of design changes and increased testing costs for sling carriers. These other products may be similar products, such as mei tais (a traditional Asian unstructured soft carrier falling under the SITC standard) or SITCs, or these other products may be completely unrelated juvenile products.

Small Importers

At this time, only one of the four importers identified is in compliance with F2907-12, F2907-13a or F2907-13b. Depending upon the costs of coming into compliance incurred by the importers' suppliers and whether the importers' suppliers are able to pass on the costs, the other three importers could experience a significant economic impact. Three of the four importers are owned by foreign parent companies that supply the importers' slings. These parent companies must make the business decision to comply or to discontinue U.S. operations. Two of the four

importers could respond by simply discontinuing their sling product line altogether because these importers have varied product lines.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements. Consequently, these importers will experience the associated costs of compliance. The resulting costs could have a significant impact on these small importers.

As mentioned previously, four of the small domestic firms have unknown supply sources, and none of these supply sources has claimed compliance with any version of F2907. However, two firms have varied product lines and may be in a better position to comply without incurring significant economic impacts. The other two appear to be small firms specializing in slings, and therefore, these small firms may be impacted more heavily by compliance and testing costs.

5. 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 12 months. Setting a later effective date would reduce the economic impact on firms in two ways. First, firms would be less likely to experience a lapse in production, which could result if firms are unable to comply within the required timeframe. Second, firms could spread costs over a longer time period, thereby reducing their annual costs and the present value of their total costs. Given the large number of very small suppliers who potentially will experience significant economic impacts, a later effective date may warrant consideration. The Commission welcomes comments regarding an appropriate effective date.

VI. 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,” our rule will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

VII. Paperwork Reduction Act

This 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 Sling Carriers

Description: The proposed rule would require each sling carrier to comply with ASTM F2907-14a, *Standard Consumer Safety Specification for Sling Carriers*. Sections 8 and 9 of ASTM F2907-14a contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. § 3502(3).

Description of Respondents: Persons who manufacture or import sling 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
1228	47	3	141	1	141

Our estimates are based on the following:

Section 8.1.1 of ASTM F2907-14a requires that the name and the place of business (city, state, mailing address, including zip code, or telephone number) and website, if applicable, of the manufacturer, distributor, or seller be marked clearly and legibly on each product and its retail package. Section 8.1.2 of ASTM F2907-14a requires a code mark or other means that identifies the date (month and year, as a minimum) of manufacture.

There are 47 known entities supplying sling carriers to the U.S. market. All 47 firms are assumed to use labels already on both their products and their packaging, but the firms 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 entity supplies an average of three different models of sling carrier; therefore, the estimated burden associated with labels is 1 hour per model x 47 entities x 3 models per entity = 141 hours. We estimate the hourly compensation for the time required to create and update labels is \$27.71 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” September 2013, 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 \$3,907.11

(\$27.71 per hour x 141 hours = \$3,907.11). There are no operating, maintenance, or capital costs associated with the collection.

Section 9.1 of ASTM F2907-14a requires instructions to be supplied with the product. Sling carriers do not generally require assembly, but require instructions for proper use, fit, and adjustment on a caregiver's body, as well as maintenance, cleaning, and storage. 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 sling carriers that generally require some instructions for use, but lack any instructions to the user, we estimate tentatively that there are no burden hours associated with section 9.1 of ASTM F803-13 because any burden associated with supplying instructions with sling carriers would be "usual and customary" and would not within the definition of "burden" under the OMB's regulations.

Based on this analysis, the proposed standard for sling carriers would impose a burden to industry of 141 hours, at an estimated cost of \$3,907.11 annually.

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 the 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.

VIII. 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.” Therefore, the preemption provision of section 26(a) of the CPSA would apply to a rule issued under section 104.

IX. Certification and Notice of Requirements (NOR)

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 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. *Id.* 2063(a)(3). Thus, the proposed rule for 16 CFR part 1228, "Safety Standard for Sling Carriers," when issued as a final rule, will be a children's product safety rule that requires the issuance of an NOR.

To meet the requirement that the Commission issue an NOR for the sling carrier standard, the Commission proposes to amend an existing rule. 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). This rule took effect on June 10, 2013. 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 had published to date. All new NORs, such as the sling carrier standard, require an amendment to part 1112. Accordingly, the proposed rule would amend part 1112 to include the sling carrier 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 sling 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, the laboratory can apply to the CPSC to have 16 CFR part 1228, *Safety Standard for Sling Carriers*, included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

As required by the RFA, staff conducted a final regulatory flexibility analysis (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 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 16 CFR part 1112 rule to include the NOR for the sling carrier 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 sling carrier 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 sling carrier standard to their scope of accreditation. As a consequence, the Commission certifies that the NOR for the sling carrier standard will not have a significant impact on a substantial number of small entities.

X. 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 sling 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 1228

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 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 Section 1112.15, by adding paragraph (b)(39) 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)(39) 16 CFR part 1228, Safety Standard for Sling Carriers.

PART 1228-SAFETY STANDARD FOR SLING CARRIERS

Sec.

1228.1 Scope.

1228.2 Requirements for Sling 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).

§ 1228.1 Scope.

This part establishes a consumer product safety standard for sling carriers.

§ 1228.2 Requirements for Sling Carriers.

(a) Each sling carrier must comply with all applicable provisions of ASTM F2907-14a, Standard Consumer Safety Specification for Sling Carriers, approved on February 15, 2014. 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.

(b) [Reserved]

Dated: _____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission

EXHIBIT 15

EXHIBIT 15

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Rolls-Royce plc: Docket No. FAA–2013–0029; Directorate Identifier 2013–NE–01–AD.

(a) Comments Due Date

We must receive comments by June 4, 2013.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce plc (RR) RB211–535E4–B–37 series turbofan engines.

(d) Unsafe Condition

This AD was prompted by recalculating the life of certain life limited parts operated to certain flight profiles. We are issuing this AD to prevent the failure of critical rotating parts, which could result in uncontained failure of the engine and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Within 30 days after the effective date of this AD for engines that have operated to Flight Profile D or E, recalculate the life of the low-pressure (LP) turbine disc stage 2, intermediate-pressure (IP) compressor rotor shaft (stage 1 to 6), high-pressure (HP) compressor rear rotor shaft assembly, and HP turbine disc installed on that engine. Use the part lives, prorated life formulas, and flight profiles in Appendices 2, 4, and 5 of RR Alert Non-Modification Service Bulletin (NMSB) No. RB.211–72–AG875, dated December 13, 2012, to make that calculation.

(2) Within 30 days after the effective date of this AD for engines that will operate to Flight Profile D or E, assign the Maximum Approved Lives defined in Appendix 2 of RR Alert NMSB No. RB.211–72–AG875, dated December 13, 2012, to the LP turbine disc Stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, and HP turbine disc based on the flight profile that will be flown.

(3) For engines that have only operated to, and will continue to operate to, Flight Profile

C, as defined in Appendix 5 of RR Alert NMSB No. RB.211–72–AG875, dated December 13, 2012, no further action is required by this AD.

(4) For engines that incorporate an LP turbine disc stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, or HP turbine disc whose part life is defined by paragraph (e)(1) of this AD that have an engine shop visit (ESV) after the effective date of this AD, remove each part from service before the part exceeds the part life assigned in paragraph (e)(2) of this AD.

(5) For those engines that incorporate an LP turbine disc stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, or HP turbine disc whose part life is defined by paragraph (e)(1) of this AD, that do not have an ESV after the effective date of this AD before the part exceeds the part life assigned in paragraph (e)(2) of this AD, remove the part from service at the next ESV.

(f) Installation Prohibition

After the effective date of this AD, any LP turbine disc stage 2, IP compressor rotor shaft (stage 1 to 6), HP compressor rear rotor shaft assembly, or HP turbine disc whose part life is defined by paragraph (e)(1) of this AD that is re-installed in any engine after the effective date of this AD must be removed from service before the part exceeds the part life assigned in paragraph (e)(2) of this AD.

(g) Definitions

For the purpose of this AD, ESV is whenever engine maintenance performed prior to reinstallation requires the separation of a pair of major mating engine module flanges. Separation of flanges solely for the purpose of shipment without subsequent internal maintenance, is not an ESV.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(i) Related Information

(1) For more information about this AD, contact Robert Green, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; email: robert.green@faa.gov; phone: 781–238–7754; fax: 781–238–7199.

(2) Refer to EASA AD 2012–0265, dated December 18, 2012, for related information.

(3) For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE248BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936 or email from http://www.rolls-royce.com/contact/civil_team.jsp, or download the publication from <https://www.aeromanager.com>. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

Issued in Burlington, Massachusetts, on March 29, 2013.

Colleen M. D'Alessandro,

Assistant Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2013–07935 Filed 4–4–13; 8:45 am]

BILLING CODE 4910–13–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.¹

DATES: Submit comments by June 19, 2013.

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 Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202–395–6974, or emailed to oir_submission@omb.eop.gov.

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

¹ 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 Web site at <http://www.cpsc.gov/en/About-CPSC/Commissioners/>, or obtained from the Commission’s Office of the Secretary.

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 (email), except through 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; email: 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, a 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

Issues	Total reports		Deaths		Injuries	
	Count	Percentage	Count	Percentage	Count	Percentage
Mechanical Issues	77	83	0	0	26	87
Fasteners	25	27	0	0	6	20
Structure, fit, and position	14	15	0	0	10	33
Large leg openings	12	13	0	0	17	23
Stitching/seams	10	11	0	0	1	3
Design and finish	8	9	0	0	2	7
Straps	8	9	0	0	0	0
Other	11	12	2	100	24	13
Consumer Comments	5	5	0	0	0	0
Total	93	100	2	100	30	100

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

Note: The percentages have been rounded to the 2nearest integer. Subtotals do not necessarily add to heading totals.

¹ (3 hosp.).

² (2 hosp.).

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 Web sites at: www.cpsc.gov or www.saferproducts.gov.

SOFT INFANT AND TODDLER CARRIER RECALL SUMMARY

[January 1, 1999 through June 17, 2010]

Manufacturer	Model	Year recalled	Units recalled	Reason	Incident reports	Injury reports
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 Re-pair).	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.

SOFT INFANT AND TODDLER CARRIER RECALL SUMMARY—Continued
[January 1, 1999 through June 17, 2010]

Manufacturer	Model	Year recalled	Units recalled	Reason	Incident reports	Injury reports
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 Noand 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 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.

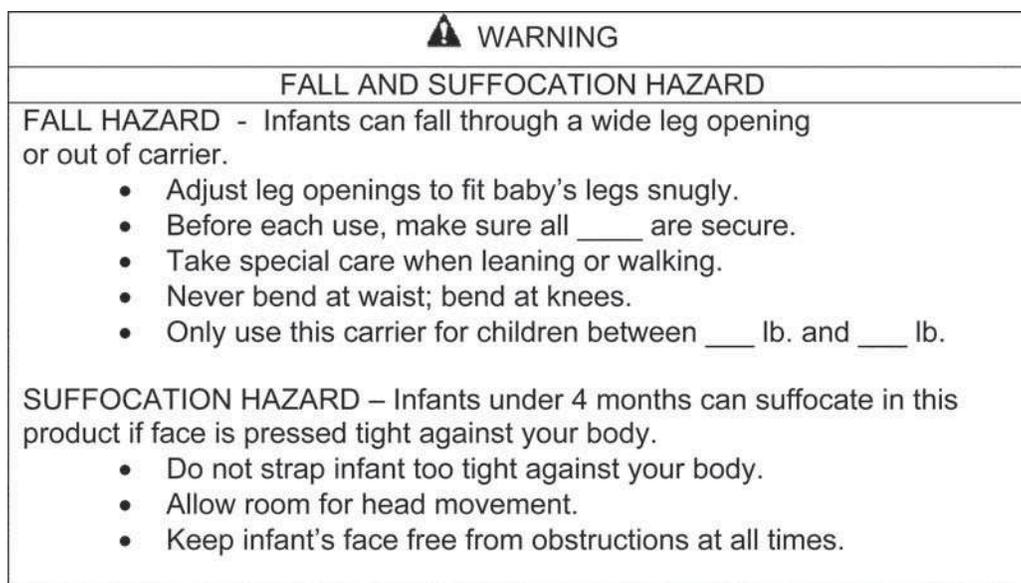


Figure 1. ASTM F2236-13 Example Warning label.

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 broadrange 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.²

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.³ Approximately 30 percent of soft infant and toddler carriers were handed down or purchased secondhand.⁴ 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).⁵

Many soft infant and toddler carriers have expanded their maximum weight

² Staff made these determinations using information from Dun & Bradstreet and Reference USAGov, as well as firm Web sites.

³ 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.

⁴ 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.

⁵ 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.

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. 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 JPA 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 × 39 firms × 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 × 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 May 6, 2013, 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 FR 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 Web site at: 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?

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(b) * * *

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(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.

(b) Reserved

Dated: March 29, 2013.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2013–07687 Filed 4–4–13; 8:45 am]

BILLING CODE 6355–01–P

EXHIBIT 16

EXHIBIT 16

- (iv) Task 57-29-03-270-801-A-01, Gear Rib Forward Lug Attachment for the Main Gear Before Modification 32025J2211, of Subject 57-29-03, Inspection of the Gear Rib Forward and Aft Lug Attachment for the Main Gear, of Chapter 57, Wings, of the Airbus A318/A319/A320/A321 Nondestructive Testing Manual, Revision 89, dated August 1, 2011.
- (v) Task 57-29-04-270-801-A-01, Gear Rib Forward Lug Attachment for the Main Gear Before Modification 32025J2211, of Subject 57-29-04, Inspection of the Gear Rib Forward and Aft Lug Attachment for the Main Gear, of Chapter 57, Wings, of the Airbus A318/A319/A320/A321 Nondestructive Testing Manual, Revision 89, dated August 1, 2011.

(4) The following service information was approved for IBR on May 19, 2008 (73 FR 19975, April 14, 2008):

(i) Airbus Service Bulletin A320-57-1138, Revision 01, dated October 27, 2006.

(ii) Reserved.

(5) For Airbus service information identified in this AD, contact Airbus, Airworthiness Office—ELAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email: account.airworth-eas@airbus.com; Internet <http://www.airbus.com>.

(6) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

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

Issued in Renton, Washington, on December 26, 2013.

John P. Piccola,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014-04954 Filed 3-27-14; 8:45 am]

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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: 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, CPSC, or we) to promulgate consumer product safety standards for durable infant or toddler products. Durable infant and toddler standards must 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 issuing this final rule establishing a safety standard for soft infant and toddler carriers in response to the direction under section 104(b) of the CPSIA.

DATES: The rule will become effective September 29, 2014 and apply to product manufactured or imported on or after that date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of September 29, 2014.

FOR FURTHER INFORMATION CONTACT: Julio A. Alvarado, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-7418; email: jalvarado@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub L. 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. Durable infant and toddler standards must 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.” Section 104(f)(2)(H) of the CPSIA specifically identifies “infant carriers” 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, hand-held infant carriers, slings, and soft infant and toddler carriers.

On April 5, 2013, the Commission issued a notice of proposed rulemaking (NPR) for soft infant and toddler carriers. 78 FR 20511. The NPR proposed to adopt as a mandatory standard the current voluntary standard for soft infant and toddler carriers, ASTM F2236-13, “Standard Consumer Safety Specification for Soft Infant and Toddler Carriers” (ASTM F2236-13), without alteration.

The Commission is issuing a final mandatory safety standard for soft infant and toddler carriers. Pursuant to section 104(b)(1)(A) of the CPSIA, the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public to develop this standard, largely through the ASTM process. After publication of the NPR, ASTM approved two revised versions of F2236-13, F2236-13a, on November 1, 2013, and F2236-14, on January 1, 2014. The revisions included in ASTM F2236-14 clarify several issues raised in the comments received on the NPR. Furthermore, the Commission finds that the revisions included in ASTM F2236-14 adequately address the comments received on the NPR. Section V of the preamble below discusses clarifying changes to the standard. The final rule for soft infant and toddler carriers incorporates ASTM F2236-14, by reference, without alteration.

II. Product Description

A. Definition of a Soft Infant and Toddler Carrier

ASTM F2236-14 defines a “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 F2236-14 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.

In the United States, soft infant and toddler carriers are available in two broad classes: Structured and nonstructured. Structured soft infant and toddler carriers contain straps and waist belts that connect to the seat area and other carrier components with buckles, straps, and 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 consist of a flat, textile center with waist straps and very long upper straps (5 to 6 feet) that wrap around the caregiver and are secured by tying the ends of the straps, such as the mei-tai design. ASTM F2236-14 does not distinguish between products based on whether they are structured or nonstructured; therefore, requirements apply equally to all types of soft infant and toddler carriers.

ASTM F2236-14's definition of a "soft infant and toddler carrier" distinguishes soft infant and toddler carriers from other types of infant carriers that are also worn by a caregiver but that are not covered under ASTM F-2236-14, 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. However, 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 that a sling 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 covered by 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. However, framed backpack carriers are distinguishable from soft infant and toddler carriers because typically, backpack carriers are constructed of sewn fabric over a rigid frame and are intended solely for carrying a child on the caregiver's back.

III. Incident Data

The preamble to the NPR summarized incident data involving soft infant and toddler carriers reported to the Commission from January 1, 1999 to September 10, 2012. 78 FR 20513 (April 5, 2013). CPSC's Directorate for Epidemiology, Division of Hazard Analysis updated this information for

the final rule to include soft infant and toddler carrier-related incident data reported to the Commission from September 11, 2012 through July 15, 2013. During the September 11, 2012 to July 15, 2013 time frame, CPSC received 31 new incident reports related to soft infant and toddler carriers. Two of the incidents were fatal, and 29 were nonfatal. Twenty-four of the 29 nonfatal incidents involved injuries. The total count of reported incidents includes emergency department-treated injuries (*i.e.*, injuries reported through the National Electronic Injury Surveillance System (NEISS)).¹ CPSC staff cannot present national emergency department-treated injury estimates for the final rule due to insufficient numbers of NEISS incidents reported during the time period. The number of incidents occurring in 2012 and 2013 is subject to change because the CPSC continues to collect information about such incidents.

A. Fatalities

Both reported fatalities involved suffocation. One suffocation fatality occurred in 2010. The decedent was a 17-day-old infant who was being carried in a soft infant and toddler carrier—facing the mother—while the mother ran errands. The mother reportedly breast fed the victim while walking. The report is unclear about whether the victim was out of the carrier or in the carrier while being fed. The mother found the child nonresponsive in the carrier. The child was placed on life support, which was later removed due to the child's poor prognosis. The second suffocation fatality occurred in 2011. The decedent, a 4-month-old female, was placed prone to sleep on a bed while still in a soft infant carrier.²

B. Nonfatalities

Twenty-nine soft infant and toddler carrier-related nonfatal incidents were reported to the CPSC from September 11, 2012 to July 15, 2013. The incident reports demonstrate that an injury occurred in 24 of the 29 incidents. The children's age was unreported or

unknown in four of the 29 nonfatal incidents. For the remaining 25 incidents, the ages provided in the reports ranged from 1 month to 18 months, with 64 percent of the total reports involving children 6 months of age or younger.

Among the 24 nonfatal injuries reported, four incidents required hospitalization. Two of the four injuries requiring hospitalization, a skull fracture and a leg fracture, resulted from infants falling out of a soft infant and toddler carrier. The other two injuries that required hospitalization were head injuries to the infant resulting from the caregiver falling. Other injuries included contusions, abrasions, and lacerations, mostly of the head and face. Fourteen of the injuries resulted from falls, either from the caregiver falling while wearing the carrier or from the infant falling out of the carrier.

The remaining five incident reports stated problems with the product but indicated that either no injury had occurred or the report failed to provide information about any injury.

C. Hazard Pattern Identification

CPSC identified hazard patterns among the 31 new incident reports that were similar to the hazard patterns identified among the incidents considered for the NPR. The primary hazard associated with use of a soft infant and toddler carrier continues to be 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. Hazard patterns are grouped into the following categories in order of frequency of incident reports:

- Caregiver falls (11)³;
- structure, fit, and position issues (7);
- design and finish-related issues⁴ (2), (which are also among the 7 in the previous category);
- strap issues (2);
- issues with stitching/seams (1); and
- other issues (10).

Caregiver Falls: Eleven of the 31 incidents (35 percent) reported injuries to the infant in the carrier, when the caregiver slipped or tripped and fell. All of these were emergency department-treated injury (NEISS data) reports.

Structure, fit, and position issues: Seven of the 31 incidents (23 percent) were related to aspects of the leg- and torso-opening design, how the carrier held the infant, and where the soft

¹ CPSC's NEISS database is a national probability sample of hospitals in the United States and its territories. Patient information is collected from each NEISS hospital for every emergency visit involving an injury associated with consumer products. From this sample, the total number of product-related injuries treated in hospital emergency rooms nationwide can be estimated.

² According to CPSC Human Factors staff, this scenario represents an unsafe sleep environment. The prone sleep position is a known risk factor for SIDS, and placing an infant to sleep face down on top of a bed may increase the risk of suffocation. Sleeping in the prone position on a bed with an infant still inside a carrier may further increase the suffocation risk.

³ All of the fall incidents were emergency department-treated injury (NEISS data) reports.

⁴ Finish-related issues concern items such as material smoothness and lead content.

infant and toddler carrier was positioned on the caregiver. Examples of scenarios reported include: an infant slipping far down into the carrier and suffering an injury when the caregiver bent over; an infant falling out of the carrier when the caregiver bent forward; and leg circulation-related injuries to the infant. Three injuries were reported in this category, including one hospitalization.

Design-related issues: Two of the reports included in the structure, fit, and position category above stated complaints about how the carrier fit on the caregiver and that the infant got too hot when the carrier was used with the carrier insert. A carrier insert is available with some soft infant and toddler carriers to help support a young infant's head and neck. No one reported injuries in this category.

Strap issues: Two of the 31 incidents (six percent) reported issues with straps, mostly regarding the adjuster breaking or slipping. Both incidents resulted in injuries, including one hospitalization for a skull fracture stemming from a fall when the strap came undone.

Issues with stitching/seams: One incident report (three percent) stated that stitching on a carrier component came undone. However, the infant sustained no injury.

Other issues: Ten incident reports (32 percent) involved non-product-related issues or provided insufficient information for CPSC staff to determine definitively how the product contributed to the incident. The two fatalities are included in this category—one case of an infant suffering respiratory distress while being carried facing inward, and the other case involved an infant put to sleep in a prone position on a bed while still in a soft infant and toddler carrier. In each case, CPSC staff concluded that insufficient information was reported to determine a predominant factor about the product that contributed to the death. Five reports were of incidental injuries sustained by infants while being carried around in a soft infant and toddler carrier. Examples of such incidents include an infant who hit a pole after a bus in which the child was riding suddenly accelerated and an infant who got hurt while being put into a carrier. The remaining three reports involved infants who fell out of the carrier, with no additional information specified.

D. NEISS Data

The soft infant and toddler carrier NPR presented a separate national injury estimate for the 13-year period from January 1999 through December

2011. However, insufficient emergency department-treated injuries associated with soft infant and toddler carriers in 2012 prevent derivation of reportable national estimates.⁵ In addition, until NEISS data for 2013 are finalized in spring 2014, partial estimates for 2013 are not available. Hence, injury estimates are not presented separately in this final rule. However, the emergency department-treated injuries are included in the total count of reported incidents presented in section III.C above.

IV. Response to Comments

CPSC received five comments regarding the NPR, including comments from industry, consumer groups, trade associations, and consumers. The comments address eight separate issues related to fastener strength testing requirements, warning label revisions, and the effective date of the final rule. Two commenters generally supported the rule. Comments submitted in response to the NPR are available at: www.regulations.gov, by searching under the docket number of the rulemaking, CPSC–2013–0014. The Commission finds that revisions made to the ASTM voluntary standard, which are incorporated into ASTM F2236–14, approved on January 1, 2014, and published in January 2014, adequately address comments received on the NPR. Accordingly, the Commission will incorporate by reference the most recent version of the voluntary standard, ASTM F2236–14, as the mandatory standard for soft infant and toddler carriers.

We summarize the comments received on the NPR and CPSC's responses below. To make identification of the comments and our responses easier, we placed the word "Comment," in parentheses, before the comment's description, and the word "Response," in parentheses, before our response. Additionally, we have numbered each comment to help distinguish among comments. The number assigned to each comment is for organizational purposes only and does not signify the comment's value or importance, or the order in which we received the comment.

A. Fastener Strength

(Comment 1) Two commenters stated that the specified fastener strength test load of 80 pounds in section 7.7.2 of ASTM F2236–13 is too high for soft infant and toddler carriers whose manufacturer-recommended maximum occupant weight for the product is less

than 45 pounds. The commenters suggested using a sliding scale for the test load that would adjust the test load by 1 pound for every pound the carrier is rated above or below 45 pounds. For example, for soft infant and toddler carriers designed for a maximum occupant weight of 25 pounds, commenters recommended a fastener test load of 60 pounds (80 pounds minus 20 pounds) instead of an 80-pound force. One commenter stated that for carriers designed for very small occupants, it would be difficult for every load-bearing fastener to be designed to meet the 80-pound test load because such fasteners tend to be large and difficult to handle gently when close to a small infant.

(Response 1) The Commission disagrees with the commenters and declines to modify the final rule based on this comment. ASTM F2236–13 added requirements for fastener strength testing. Each unique load-bearing fastener, except load-bearing fasteners used for a leg opening adjustment, must not break or disengage when subjected to a tensile load of 80-pound force for 5 seconds. The force is applied to the straps or soft goods on either side of the fastener. Leg opening adjustment fasteners are tested to a 45-pound force.

As noted in the NPR, CPSC staff tested fasteners on 14 different soft infant and toddler carriers, including recalled carriers. The manufacturer's recommended maximum occupant weight of the carriers tested ranged from 20 pounds to 45 pounds. CPSC staff found that most of the tested fasteners failed at loads well above the 80-pound force used in the test, while some of the fasteners on recalled products (which were rated at 26-pound maximum occupant weight) failed at 22 pounds to 55 pounds. The Commission agrees with CPSC staff that lowering the test load to a 60-pound force on a carrier rated at 25 pounds does not provide a sufficient safety factor, considering that fasteners from some recalled carriers failed at 55 pounds during testing. Based on the test results, the Commission finds that an 80-pound test load is appropriate, even for carriers with maximum occupant weights below 45 pounds.

All of the buckle and strap fasteners on the 14 carriers that CPSC staff tested were made from plastic. CPSC staff concluded that the characteristics of the plastic used for the fasteners dictated the fastener's ability to withstand the test load. The plastic material on the fasteners that fractured at a lower load was much less ductile, resulting in the fastener fracturing instead of deforming. Accordingly, CPSC staff found that smaller fasteners were as capable as

⁵ 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.

larger fasteners at meeting the 80-pound test load. Staff concluded that fastener strength was not necessarily proportional to fastener size.

CPSC staff states that the 80-pound test load for the fastener pull test is not directly related to the maximum carrier weight rating. Rather, the 80-pound test load was established based on testing the strength of fasteners on carriers already on the market. Fasteners that meet the required test load are robust enough for expected use during the life of the product. Moreover, CPSC staff believes that it is reasonably foreseeable that some caregivers may use soft infant and toddler carriers with infants whose weight exceeds the manufacturer's recommended occupant weight.

For the reasons discussed, the Commission declines to modify the final rule based on this comment.

B. Fasteners That Support the Head

(Comment 2) Two commenters stated that fasteners that support the head should be exempt from load testing. Non-load-bearing fasteners intended to retain items such as, but not limited to, hoods, bibs, and toy rings are exempt from load testing in ASTM F2236–13. One of the commenters stated: “head support for new born babies is critical,” but to achieve a good, adjustable head support requires fasteners that are slim and easy to use. The commenter designs head support fasteners to carry a certain load; however, the commenter stated that these fasteners are not load bearing and should be exempt from load testing in section 6.4 of the standard.

(Response 2) ASTM balloted and approved two clarifying changes to Note 1 in section 6.4 of the standard, which have been incorporated into ASTM F2236–14. These changes address the commenters' concern. Note 1 exempts non-load-bearing fasteners from the fastener strength tests in section 6.4 and lists examples of non-load-bearing fasteners that are exempt. We note that the list in Note 1 is not exhaustive, but merely illustrative, and that other features attached to a soft infant and toddler carrier by a non-load-bearing fastener are also exempt from the fastener strength tests in section 6.4.

ASTM F2236–13, the proposed standard for adoption in the NPR, stated that fasteners intended to retain items such as “hoods, bibs and toy rings” were exempt from testing. The ASTM subcommittee for soft infant and toddler carriers was aware of a feature called a “sleeping hood” that is attached to a soft infant and toddler carrier by non-load bearing fasteners. The “sleeping hood” feature was intended to be captured in ASTM F2236–13 Note 1

with the phrase “hoods.” To clarify that non-load-bearing fasteners used to retain “sleeping hoods” are exempt from testing, ASTM changed the word “hoods” in Note 1 to “sleeping hoods.” This revision was approved and published in ASTM F2236–13a.

Subsequently, based on a manufacturer's concern that Note 1 was still unclear about whether head adjustment fasteners that were non-load bearing had to be tested, ASTM balloted and approved another modification to Note 1. The second modification was incorporated into ASTM F2236–14 and added “head adjustment fasteners” to the list of examples of fasteners exempt from testing in Note 1. The Commission agrees with the clarification and believes that these revisions to the voluntary standard address the commenters' concern.

To the extent that commenters are suggesting that any potential load-bearing fastener that supports the head should be excluded from the fastener strength test in section 6.4 of the standard, the Commission disagrees. CPSC found that on the 14 carriers tested, the uppermost fastener generally supports the infant's upper torso and shoulders, as well as the head, and therefore, the fastener is critical to securing the infant in the carrier. Load-bearing fasteners that support the head, upper torso, and shoulders are not exempt from fastener-load testing requirements. The commenter apparently does not intend to exempt this type of fastener from testing.

C. Fastener Strap Slip During Load Testing

(Comment 3) One commenter stated that the strap slippage requirement as articulated in the standard (ASTM F2236–13, paragraphs 6.4.1 and 6.4.2) can result in a technical failure of an otherwise safe product. The commenter found that during product testing, certain straps can slip more than 1 inch but in a direction that makes the straps become tighter, not looser. The commenter asserted that this does not compromise safety. The commenter suggested that the language in paragraph 6.4.1 should be changed from “. . . adjustable elements in straps shall not slip more than 1 in. (2.5 cm) when tested . . .” to “. . . adjustable elements in straps shall not loosen more than 1 in. (2.5 cm) when tested . . .”

(Response 3) The strap slippage requirement in section 6.4.1 of ASTM F2236–13, the standard referenced in the NPR, prevents the fastener straps from slipping an appreciable amount through the buckles during fastener strength testing. Significant slippage can

result in a minimal load being held by the fastener/strap and could result in the strap pulling out of the fastener or loosening to the point that the infant could fall out of the carrier. The commenter seeks to clarify that straps that tighten during the test do not constitute a test failure.

The Commission agrees that straps that tighten during testing should not fail the strap retention requirement in the standard. However, based on the CPSC staff's assessment, the Commission finds that use of the word “slip” in the standard is more accurate than “loosen.” The amount of strap “slip” through a fastener can be measured; whereas, CPSC staff is uncertain how to measure strap “loosening.” Additionally, the requirement for support/shoulder strap slippage during the dynamic and static load testing in paragraph 6.2 uses the same wording, which states: “adjustable sections of the support/shoulder straps shall not slip more than 1 in. (25 mm) per strap from their original adjusted position . . .” Therefore, the Commission will not replace the word “slip” with “loosen” in the final rule, as suggested by the commenter.

After publication of the NPR, ASTM balloted and approved a modification to the voluntary standard that addresses the commenter's concern about straps that tighten during testing. ASTM F2236–14 incorporates a revision to sections 6.2.2, 6.4.1, and 6.4.2 of the voluntary standard to state: “straps shall not slip, *in a manner that loosens the strap*, by more than 1 inch.” This modification was included in the voluntary standard, beginning with revision ASTM F2236–13a.

The Commission finds that the revisions now incorporated into sections 6.2.2, 6.4.1, and 6.4.2 of ASTM F2236–14 addresses the commenter's concern and clarifies when fasteners pass the fastener strength test requirement without substantively altering the test method.

D. Warning Text Format

(Comment 4) One commenter noted that in ASTM F2236–13, the text height requirement for the warnings provided with product instructions specified in section 9.2.2 needs to be modified to match the text height requirement for warning labels in section 8.3.1. The commenter stated that if this modification is not made, section 9.2.2 would require every letter of warning text to be at least 0.1” high, instead of only the upper case letters, as is the case in section 8.3.1.

(Response 4) The Commission agrees that the text height requirement for

warnings should be consistent throughout the standard. To address the

commenter's concern, ASTM balloted and approved the following modified

text in section 9.2.2, as follows (additions are shown by *italics*):

9.2.2 In warning statements, the symbol “” and the word WARNING shall be at least 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case is at least 0.1 in. (2.5 mm) high.

Section 9.2.2 of the voluntary standard incorporates this revision, beginning with ASTM F2236–13a. The Commission believes that the revised language addresses the commenter's concern.

E. Suffocation Warning

(*Comment 5*) One commenter stated that the required warning statement should read: “Infants, especially those under four months, can suffocate in this product if face is pressed tight against your body,” rather than the warning statement in the proposed rule, as provided in the ASTM standard:

“Suffocation Hazard—Infants under 4 months can suffocate in this product if face is pressed tight against your body.” The commenter said that this warning language does not adequately warn the user of the risk of suffocation for infants over four months and that the suggested warning statement will alert parents and other caregivers to a risk to older babies as well.

(*Response 5*) The Commission disagrees that the proposed suffocation warning, as provided in the ASTM voluntary standard, does not adequately warn users of the risk of suffocation. The primary mechanism for suffocation in a soft infant and toddler carrier is the infant's face being pressed tightly against a caretaker's body, obstructing the nose and mouth and keeping the infant's head from moving. Infants younger than 4 months old are mostly at risk because they do not have the head control or the muscle strength to move their head away if their airway becomes obstructed. By 4 months of age, infants have increased neck strength and can hold their heads up and explore their surroundings while the caretaker is walking. Infants who are 4 months old can be carried in the outward-facing position in soft infant and toddler carriers that allow this carry position. At around age 6 months, infants begin to sit upright unassisted. Caretakers can carry infants of this age in a soft infant and toddler carrier on the hip or on the caregiver's back, depending on the caretaker's level of comfort. As children reach toddlerhood, caregivers can carry

children in this age group in a carrier on the hip or back depending on the carrier type. Given that infants from age 4 months and older have developed head control and muscular strength and can be placed in outward facing, hip, and back carry positions, their face is less likely to become pressed tightly into a caretaker's body. Therefore, the risk of suffocation for these children is low. The Commission has not received data indicating that a risk of suffocation exists for children 4 months and older.

Identifying explicitly children who are most at risk does not suggest that others are not at risk. However, guidelines for warning labels recommend focusing on the most likely and most serious risks (Laughery and Hammond, 1999; Wogalter, 2006). Warnings about low-probability events (*i.e.*, older infants suffocating in soft infant carriers) may reduce the believability or arousal strength of warnings that caution of more likely risks (*i.e.*, infants under 4 months suffocating in soft infant carriers). The Commission finds that the current ASTM warning label about the suffocation hazard is sufficient without modification.

F. Stability Warning

(*Comment 6*) One commenter stated: “we are concerned that raising the upper weight limits, for the purpose of ensuring that all soft infant and toddler carriers on the market are covered by the rule, brings in carriers that might have a greater risk of instability and falls due to the extra weight load relative to the weight and strength of the caregiver. We would urge the Commission to include an adequate alert to this risk in the required warnings and instructions.”

(*Response 6*) During the rulemaking, CPSC staff identified soft infant and toddler carriers on the market that have a manufacturer-recommended upper weight limit of 45 pounds. The Commission believes that expanding the scope of the standard to increase the upper weight limit from 25 pounds to 45 pounds is necessary for the standard to cover all products on the market.

However, for the Commission to include a warning statement about the greater risk of instability and falls involving products with higher weight limits, data must be available to demonstrate that carrying heavier children in soft infant and toddler carriers presents a greater risk of instability and falls. At this time, the available data do not support this position. Furthermore, the commenter did not provide data demonstrating that products with higher weight limits present a greater risk of instability and falls than carriers with a lower weight limit. Therefore, at this time, the Commission declines to modify the warning label as suggested by the commenter.

G. Product Marking

(*Comment 7*) One commenter recommended that the CPSC require that products manufactured after the effective date of the final rule be marked as compliant, so that consumers can identify clearly products that meet the new mandatory standard for soft infant and toddler carriers.

(*Response 7*) The Commission finds that sufficient incentive exists for compliant producers to label their products as compliant with the final standard for soft infant and toddler carriers. A final rule implementing testing, certification, and labeling of children's products in section 14 of the CPSA, as amended by the CPSIA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107 (the 1107 rule), became effective on February 13, 2013. Under the 1107 rule, a manufacturer or importer may label a certified compliant product as “Meets CPSC Safety Requirements.” Because producers are already allowed to label compliant products as such under the 1107 rule, adding this option to the soft infant and toddler carrier standard would be redundant. The Commission declines to change to the final rule based on this comment.

H. Effective Date

(*Comment 8*) Two commenters address the 6-month effective date proposed in the NPR. One commenter,

representing several advocacy groups, expressed support for the 6-month effective date. Another commenter, a soft infant and toddler carrier manufacturer, recommended a 12-month effective date, stating that the manufacturing process can take up to 6 months, and the product may be stocked in a warehouse for additional months, depending on sales.

(Response 8) The final standard will not be applied retroactively to products manufactured prior to the effective date of the final rule. Thus, any products warehoused before the effective date will not be affected by the standard. Manufacturers should be able to comply with the mandatory standard within 6 months of the final rule's publication. Manufacturers whose products do not comply with the standard will require some product modification. However, product modification is expected to involve minor changes, such as adding or changing straps or fasteners. Moreover, ASTM F2236–13 was adopted by ASTM in March 2013, and became effective in September 2013. Although the Commission is adopting ASTM F2236–14 as the mandatory standard, no substantive changes have been made to the voluntary standard since ASTM F2236–13. Manufacturers that comply with ASTM F2236–13 have already made, or have begun to make, the necessary modifications. The Commission declines to change the effective date of the final rule based on this comment.

V. Summary of ASTM F2236–14

The Commission is issuing this final rule for soft infant and toddler carriers that incorporates by reference the most recent voluntary standard for soft infant and toddler carriers, ASTM F2236–14. Together with the changes made in ASTM F2236–12, ASTM F2236–13, and ASTM F2236–13a, ASTM F2236–14 reflects the most significant revisions to the standard to date. Revisions to the voluntary standard 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. After the comment period for the NPR closed, the ASTM F15.21 Soft Infant and Toddler Carrier subcommittee held a teleconference on August 12, 2013, to discuss comments submitted on the NPR. The subcommittee discussed the basis for each comment and reached a consensus on revisions to be submitted for ballot. The subcommittee chair balloted the proposed revisions to ASTM F2236–13 for concurrent ASTM Main Committee F15 and Subcommittee

F15.21 consideration on August 23, 2013, with a 1-month comment period. The August 23, 2013 ballot contained three revisions to the voluntary soft infant and toddler carrier standard:

- Revisions to sections 6.2.2, 6.4.1, and 6.4.2 to clarify that during the dynamic load, static load, and fastener strength tests, straps shall not slip, in a manner that loosens the strap, more than 1 inch.
- A revision to Note 1 in section 6.4 to clarify that “sleeping hoods” are an example of non-load-bearing fasteners that are exempt from fastener strength testing.
- A revision to section 9.2.2 to clarify that the text height requirements for the warnings included with instructions in section 9.2.2 are the same as the text height requirements for warnings required in section 8.3.1 of the voluntary standard.

ASTM did not receive any negative votes on the balloted revisions to ASTM F2236–13. ASTM approved the balloted revisions on November 1, 2013, and subsequently published ASTM F2236–13a in November 2013.

On September 26, 2013, the ASTM F15.21 Soft Infant and Toddler Carrier subcommittee met to discuss results of the items balloted on August 23, 2013. One manufacturer wanted the voluntary standard to further clarify that fasteners used for adjusting the head portion of the carrier were exempt from fastener strength testing because such fasteners are not load bearing. As a result, the subcommittee chair developed a draft ballot item that proposed to add “head adjustment fasteners” to the list of examples of fasteners that are exempt from load testing listed in Note 1 of section 6.4. The subcommittee chair balloted the proposed revision to ASTM F2236–13a for concurrent ASTM Main Committee F15 and Subcommittee F15.21 consideration on November 6, 2013, with a 1-month comment period. ASTM did not receive any negative votes on the balloted revision, and approved the revised standard, ASTM F2236–14, on January 1, 2014. ASTM published ASTM F2236–14 in January 2014.

We summarize the provisions of ASTM F2236–14 below. Each revision to ASTM F2236–13 discussed above is described below in more detail in the relevant section of the standard where the change appears. ASTM F2236–14 includes the following key provisions: scope, terminology, general requirements, performance requirements, test methods, marking and labeling, and instructional literature.

Scope. The scope of the voluntary standard was broadened in December 2012 to include soft infant and toddler carriers with an upper weight limit of up to 45 pounds. Previously, it was unclear whether carriers with upper weight limits over 25 pounds fell within the standard. Expanding the scope of the standard clarifies that all soft infant and toddler carrier products currently on the market fall within the standard. The name of the standard was changed in 2012 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. The scope provides 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 the standard does not apply to infant slings.

Terminology. Section 3.1 of the standard includes 14 definitions to help explain general requirements 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 F2236–14, 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.” Beginning in 2012, the standard included a new definition for “carrying position” to clarify methods for dynamic and static load testing in section 7 of the standard. Finally, in 2013, the standard was updated to include a new definition for “fastener” to aid in a new test for fastener strength and strap retention.

General Requirements. ASTM F2236–14 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, beginning with 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). Adopting the wearing apparel flammability requirement in the soft infant and toddler standard makes it 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 F2236–14 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-pound 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-pound shot bag, or a shot bag equal to the manufacturer's maximum occupant weight limit, whichever is heavier. Additionally, the static load test was revised—from requiring a 75-pound weight for testing—to requiring a 75-pound 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. Such revisions to the dynamic and static load tests strengthen the test requirements, by requiring that products with a maximum recommended weight of 45 pounds be tested to a 135-pound weight instead of 75 pounds, which represents an 80 percent increase in the severity of the requirement.

ASTM F2236–14 requires that testing conducted 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, the standard provides that 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.

Section 6.2.2 of the standard on Support/Shoulder Strap Slippage was modified beginning with ASTM F2236–13a. The modification clarifies what constitutes passing or failing the strap slippage test. Section 6.2.2 was amended to state: “Adjustable sections of support/shoulder straps shall not slip, *in a manner that loosens the strap*, more than 1 in. (25 mm) per strap from their original adjusted position after dynamic and static load testing is performed in accordance with 7.2.1 and 7.2.2, respectively.” The amendment allows straps to tighten during testing but not loosen more than 1 inch, which is the intent of the testing.

Fastener Strength and Strap Retention—ASTM F2236–14 includes a new component-level performance requirement that was added to the standard in 2013 to evaluate the strength of fasteners and strap retention to help prevent falls from a carrier. Previously, soft infant and toddler carriers were recalled due to an occupant fall hazard caused by broken fasteners that passed the static and dynamic performance requirements in the then existing standard, ASTM F2236–10. Accordingly, the performance requirement in section 6.4 of ASTM F2236–14 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. ASTM F2236–14 requires that when tested, fasteners must not break or disengage, and adjustable elements must not slip more than 1 inch.

Similar to the strap slip requirement in the static and dynamic load testing section of the standard, ASTM also clarified the strap slip section of the fastener strength test section in ASTM F2236–13a. Sections 6.4.1 and 6.4.2 were amended to state: “Each unique fastener, except for leg opening adjustment fasteners as tested per 6.4.2, shall not break or disengage, and adjustable elements in straps shall not slip, *in a manner that loosens the strap*, more than 1 in. (2.5 cm)” This amendment allows straps to tighten during testing but not to loosen more than 1 inch, which is the intent of the testing.

Additionally, Note 1 to section 6.4 of the standard provides that the fastener

strength and strap retention testing apply only to load-bearing fasteners. ASTM F2236–13 stated: “Fasteners intended to retain items such as, but not limited to, hoods, bibs and toy rings, are exempt from these requirements.” ASTM approved two changes to the language in Note 1 to clarify that several non-load-bearing features, “sleeping hoods” and “head adjustment fasteners,” are included in the list of examples exempted from fastener strength testing when such features are non-load-bearing. Note 1 in section 6.4 of ASTM F2236–14 now provides that: “Fasteners intended to retain items such as, but not limited to, *sleeping hoods, head adjustment fasteners*, bibs and toy rings, are exempt from these requirements.”

Unbounded Leg Opening—The voluntary standard was updated in 2013 to clarify the unbounded leg opening test procedure to improve test repeatability. ASTM F2236–14 requires that 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 standard requires a test cone to be pulled through the leg opening with a 5-pound force for 1 minute.

Marking, Labeling, and Instructional Literature. ASTM F2236–14 requires that each product and its retail package be marked or labeled with certain information and warnings. The warning label requirement was updated in 2013 to address fall and suffocation hazards. ASTM F2236–14 requires that the warning label provide a fall hazard statement addressing that infants can fall through wide leg openings or out of the carrier. The standard requires the following fall-related precautionary statements 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, ASTM F2236–14 requires that a suffocation hazard statement must address the fact 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 standard requires that the warning label must also address the following suffocation-related precautionary statements: 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. All products are required to come with instructional literature on assembly, use, maintenance, cleaning, and required warnings.

ASTM F2236-14 includes an example warning label that identifies more clearly the hazards, the consequences of

ignoring the warning, and how to avoid the hazards. The label format was designed to communicate more effectively these warnings to the caregiver (Fig. 1). Manufacturers may alter the rectangular shape of the label to fit on shoulder straps, if the

manufacturer chooses not to place label in the occupant space. However, the standard requires that the label be placed in a prominent and conspicuous location, where the caregiver will see the label when placing the soft infant and toddler carrier on their body.

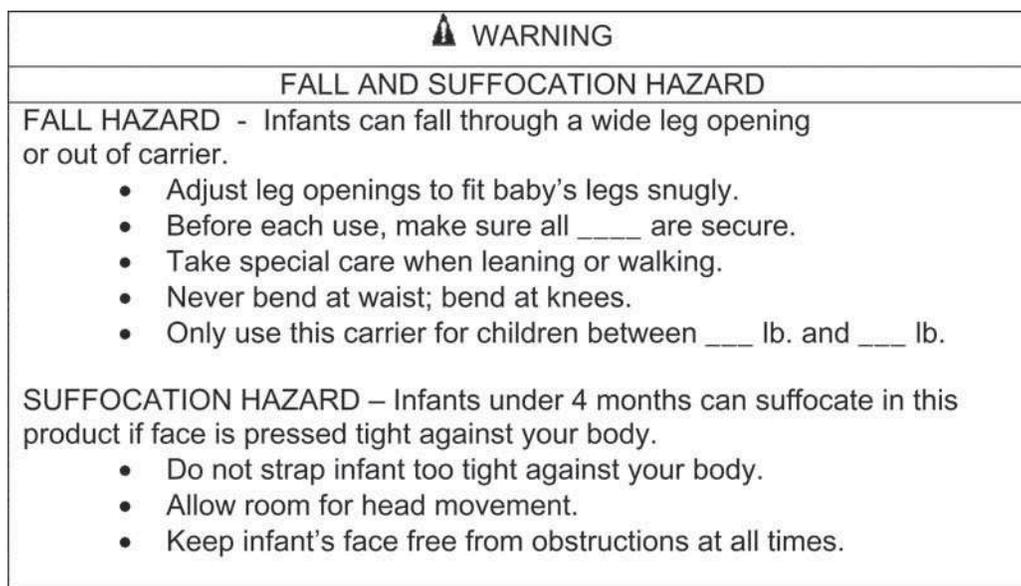


Figure 1. ASTM F2236-14 Example Warning Label.

ASTM F2236-14 includes a 2013 revision to section 9.2.2 of the standard on Instructional Literature. Section 9.2.2 of the standard describes how the warning label is to be conveyed in the instructional literature. The text height requirements in this section should match the text height requirements for the on-product warning label in section 8.3.1, which was overlooked when publishing ASTM F2236-13. To correct this issue, ASTM F2236-14 includes the following revision to section 9.2.2, so that it is the same as 8.3.1: “In warning statements, the symbol “” and the word WARNING shall be at least 0.2 in. (5 mm) high. The remainder of the text shall be in characters whose upper case is at least 0.1 in. (2.5 mm) high.”

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). The NPR proposed that the final rule would become effective 6 months after publication of a final rule

in the **Federal Register**. Although we received one comment requesting a 12-month effective date (comment 8 in section IV.H), the Commission finds that a 6-month effective date is sufficient time to allow manufacturers to come into compliance. Manufacturers whose products are not compliant with the

standard will require some product modification; however, any necessary product modification is expected to involve minor changes, such as adding or changing straps or fasteners. Moreover, ASTM F2236-13 was adopted by ASTM in March 2013, and became effective in September 2013.

Although the Commission is adopting ASTM F2236–14, this version of the voluntary standard is substantially the same as ASTM F2236–13. Manufacturers that are compliant with ASTM F2236–13 have already made or have begun to make the necessary modifications.

VII. Regulatory Flexibility Act

A. Introduction

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that CPSC prepare a final regulatory flexibility analysis (FRFA) when the Commission promulgates a final rule. The FRFA must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the FRFA must contain:

- A succinct statement of the objectives of, and legal basis for, the rule;
- a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

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 primarily produce soft infant and toddler carriers, as well as substitute

products, such as slings. CPSC Economic Analysis (EC) staff believes that there are at least 54 suppliers of soft infant and toddler carriers to the U.S. market.⁶ Thirty-nine domestic firms supply soft infant and toddler carriers to the U.S. market: 23 are domestic manufacturers; eight are domestic importers; and eight firms have unknown supply sources. In addition, 12 foreign firms supply soft infant and toddler carriers to the U.S. market. CPSC has insufficient information available to categorize the remaining three firms.⁷

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.⁸ Approximately 30 percent of soft infant and toddler carriers are handed down or purchased secondhand.⁹ Thus, about 70 percent of soft infant and toddler carriers are acquired new. This estimate suggests that approximately 1.5 million soft infant and toddler carriers are sold to households annually ($0.51 \times 0.70 \times 4.1$ million births per year).¹⁰

Many soft infant and toddler carriers have expanded their maximum weight limits in recent years to accommodate older children. However, from the lack of incident data involving children older than 2 years, CPSC staff believes that most caregivers would not be comfortable carrying older, heavier children in soft infant and toddler carriers. Based on the incident data, it appears that soft infant and toddler carriers are used during a child's first year, with some caregivers continuing to

⁶ Staff conducted research to identify manufacturers and importers of soft carriers. From the time of the NPR to the final rule, several firms entered the market, raising the number of suppliers from 39 in the NPR to 54 presently.

⁷ CPSC staff made these determinations using information from Dun & Bradstreet and ReferenceUSA.gov, as well as the firms' Web sites.

⁸ 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, the information may not reflect the current market.

⁹ 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.

¹⁰ 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. The number of live births in 2009 is rounded from 4,130,665.

use these products into the second year. While we do not know the proportion of caregivers who continue to use these products into the second year, we estimated the numbers of soft infant and toddler carriers in use by assuming that a portion of caregivers, e.g., 25–50 percent, will continue to use carriers in the child's second year. Based on data from the *2006 Baby Products Tracking Study*, approximately 2.1 million soft infant and toddler carriers are owned by new mothers. Assuming that 25–50 percent of caregivers continue to use soft infant and toddler carriers in the second year, approximately 2.6 million ($2.1 \text{ million} \times 0.25 \times 2.1 \text{ million}$) to 3.2 million ($2.1 \text{ million} \times 0.50 \times 2.1 \text{ million}$) households have soft infant and toddler carriers available for use annually. Based on Directorate for Epidemiology staff's estimate of 1,400 injuries treated nationally in emergency departments from 1999 to 2011, an average of about 108 emergency department-treated injuries involve soft infant and toddler carriers annually.¹¹ 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.

C. Reason for Agency Action and Legal Basis for the Final Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards for nursery products that are substantially the same as, or more stringent than, the voluntary standard. Staff recommends adopting the voluntary standard (ASTM F2236–14), without modification.

D. Requirements of the Final Rule

The requirements of the final rule are set forth above in section V of this preamble, which describes ASTM F2236–14.

E. Issues Raised by Public Comments

Section IV of this preamble contains a summary of the five comments received and the issues raised by the comments.

¹¹ Memorandum from Risana Chowdhury, Directorate for Epidemiology, dated March 11, 2013, Subject: Soft Infant and Toddler Carrier-Related Deaths, Injuries, and Potential Injuries, and NEISS Injury Estimates: 1999–September 10, 2012. CPSC staff cannot present national emergency department-treated injury estimates for 2012 due to insufficient numbers of NEISS incidents reported during the time period, and 2013 data is not yet available. Memorandum from Risana Chowdhury, Directorate for Epidemiology, dated September 23, 2013, Subject: Soft Infant and Toddler Carrier-Related Deaths, Injuries, and Potential Injuries between September 11, 2012 and July 15, 2013.

F. Other Federal Rules

Two federal rules interact with the soft infant and toddler carrier mandatory standard: (1) *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107); and (2) *Requirements Pertaining to Third Party Conformity Assessment Bodies* (16 CFR part 1112). The regulation at 16 CFR part 1107 requires every manufacturer of a children's product that is subject to a children's product safety rule to certify, based on third party testing, that the product complies with all applicable safety rules. Because soft infant and toddler carriers will be subject to a mandatory children's product safety rule, they will also be subject to the third party testing requirements of 16 CFR part 1107 when the soft infant and toddler carrier mandatory standard becomes effective.

In addition, 16 CFR part 1107 requires the third party testing of children's products to be conducted by CPSC-accredited laboratories. Section 14(a)(3) of the CPSA required the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (*i.e.*, testing laboratories) to test for conformance with each children's product safety rule. The NORs for existing rules are set forth in 16 CFR part 1112. The Commission is finalizing an amendment to 16 CFR part 1112 that establishes the requirements for the accreditation of testing laboratories to test for compliance with the soft infant and toddler carrier final rule.

G. Impact on Small Businesses

The FRFA is limited to the 39 domestic firms known to be marketing soft infant and toddler carriers in the United States because U.S. Small Business Administration (SBA) guidelines and definitions pertain to U.S.-based entities. Under 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, 32 of the 39 domestic firms supplying soft infant and toddler carriers to the U.S. market are small firms—18 manufacturers, six importers, and eight firms—whose supply source is unknown. Additional unknown small soft infant and toddler carrier suppliers may also operate in the U.S. market.

One purpose of the regulatory flexibility analysis is to evaluate the impact of a regulatory action and determine whether the impact is economically significant. While the SBA gives considerable flexibility in defining

“economically significant,” CPSC staff typically uses one percent of gross revenue as the threshold for determining “economic significance.” CPSC staff considers any impact that is one percent or more of gross revenue is considered economically significant. SBA has accepted the one percent of gross revenue threshold and this threshold is also commonly used by agencies in determining economic significance.¹²

Small Manufacturers: The expected impact of the final rule on small manufacturers will differ, based on whether manufacturers' soft infant and toddler carriers are already compliant with F2236–13. Although F2236–14 was published in January 2014, firms are still likely to be testing to F2236–13. However, because ASTM F2236–13, ASTM F2236–13a, and ASTM F2236–14 do not contain material differences, manufacturers in compliance with ASTM F2236–13 are likely to continue to comply with the voluntary standard.

The Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers, has certified several soft infant and toddler carriers as compliant with the voluntary standard, and other manufacturers have claimed compliance with the voluntary standard. Based on this information, 11 of 18 domestic manufacturers comply with ASTM F2236–13. These 11 firms should not require any modifications to their products and, as such, the firms should not be impacted by incorporation of ASTM F2236–14 as the final rule.

Meeting ASTM F2236–14's requirements could require some modifications for seven of the 18 domestic manufacturers who are believed not to be currently compliant with ASTM F2236–13. Based upon past discussions with firms and Engineering Sciences staff, necessary modifications would likely involve adding or changing straps, fasteners, or fabrics and generally would be less expensive to accomplish than a complete product redesign. Therefore, in most cases, the impact of the final rule is not expected to have a significant effect on products that do not comply with ASTM F2236–13.

Under section 14 of the CPSA, soft infant and toddler carriers are also subject to third party testing and certification requirements. Once the

new soft infant and toddler requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107). Third party testing will pertain to any physical and mechanical test requirements specified in the soft infant and toddler carrier final rule; lead and phthalates testing is already required. Third party testing costs are in addition to the direct costs of meeting the soft infant and toddler standard.

Based on information from the durable nursery product industry and confidential business information supplied for the development of the third party testing rule, CPSC staff estimates that testing to a single ASTM voluntary standard could cost around \$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 to the requirements in the soft infant and toddler standard is conducted every year on a single sample for each model, third party testing costs associated for each manufacturer would be about \$1,000–\$1,200 annually. Based on an examination of estimates of firms' revenues from recent Dun & Bradstreet reports, the impact of third party testing is not likely to be economically significant if only one sample per model is required. However, if more than one sample is needed to meet the testing requirements, third party testing costs could have an economically significant impact on some small manufacturers (*i.e.*, testing costs could be one percent or more of gross revenue). CPSC staff does not know exactly how many samples each manufacturer will need to test to meet the “high degree of assurance” criterion required by 16 CFR part 1107.

Small Importers: Most importers will not experience significant impacts as a result of the final rule. CPSC staff believes that four of the six small importers are compliant with the voluntary standard. The remaining importers may need to find an alternate source of soft infant and toddler carriers if their existing suppliers do not come into compliance with the requirements of the final rule. Alternatively, the firms may discontinue importing soft infant and toddler carriers altogether and perhaps substitute another juvenile product.

As is the case with manufacturers, all importers will be subject to third party

¹² U.S. Small Business Administration, Office of Advocacy. A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act and Implementing the President's Small Business Agenda and Executive Order 13272. May 2012, pgs. 18–20. http://www.sba.gov/sites/default/files/rfaguide_0512_0.pdf.

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 potentially have a significant impact on a few small importers that must perform the testing themselves, particularly if more than one sample per model is required.

Eight small firms have unknown supply sources, three of which appear to be compliant with ASTM F2236–13 and should not be impacted by the incorporation of ASTM F2236–14 as the mandatory final rule. The remaining five firms may need to make small changes to their products to be compliant with ASTM F2236–14. Due to the nature of the product, the modifications should be limited to changes in straps or fasteners and should not have a significant impact.

H. Alternatives

One alternative would be to set an effective date for the final rule later than the staff-recommended 6 months, which

is generally considered sufficient time for suppliers to come into compliance with a 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. However, given that the changes to meet the standard are not substantial, CPSC staff believes that 6 months is sufficient.

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,” the rule will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The final rule for soft infant and toddler carriers falls within the categorical exemption.

IX. Paperwork Reduction Act

This 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. 3501–3520). The preamble to the proposed rule (78 FR at 20520 through 20521) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. OMB has assigned control number 3041–0162 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 54 manufacturers rather than the 39 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
1226	54	2	108	1	108

Our estimate is based on the following:

Section 8.1 of ASTM F2236–14 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 54 firms that supply soft infant and toddler carriers in the U.S. market. For PRA purposes, we assume that all 54 firms use labels on their products and on their packaging already. However, firms might 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 54 firms supplies an average of two different models of soft infant and toddler carriers. Therefore, we estimate the burden hours associated with labels to be 108 hours annually (1 hour × 54 firms × 2 models per firm = 108 hours annually).

We estimate the hourly compensation for the time required to create and update labels is \$27.71 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” September 2013, 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 \$2,992.68 (\$27.71 per hour × 108 hours = \$2,992.68). 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.

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 applies to final durable infant and toddler product final rules. Therefore, the final rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when the final rule becomes effective.

XI. Certification and Notice of Requirements

Section 14(a) of the CPSA requires 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 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 final rule for 16 CFR part 1226, "Safety Standard for Soft Infant and Toddler Carriers," is a children's product safety rule that requires the issuance of a NOR.

Effective June 10, 2013, the Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 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 final rule amends 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. The final NOR is based on the CPSC's 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 this standard.

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 are 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, the laboratory can apply to the CPSC to have 16 CFR part 1226, *Safety Standard for Soft Infant and Toddler Carriers*, included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC Web site at: www.cpsc.gov/labsearch.

A FRFA was conducted as part of the promulgation of the original 16 CFR part 1112 (78 FR 15836, 15855–15858), as required by the Regulatory Flexibility Act. 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 expected to provide such services are those that anticipate 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 soft infant and toddler carrier 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 soft infant and toddler carrier standard. Most of these laboratories have already 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 certifies that the NOR for the soft infant and toddler carrier 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, 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 amends 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. No. 110–314, section 3, 122 Stat. 3016, 3017 (2008)

■ 2. In § 1112.15 add paragraph (b)(37) 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) * * *

(37) 16 CFR part 1226, Safety Standard for Soft Infant and Toddler Carriers.

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■ 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, Sec. 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 F2236–14, Standard Consumer Safety Specification for Soft Infant and Toddler Carriers, approved on January 1, 2014. 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.

(b) [Reserved]

Dated: March 24, 2014.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

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