

September 15, 2011 is amended as follows:

Paragraph 6002 Class E airspace designated as surface areas.

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ANM MT E2 Lewistown, MT [Modified]

Lewistown Municipal Airport, MT
(Lat. 47°02'57"N., long. 109°28'00"W.)

Within a 6.8-mile radius of the Lewistown Municipal Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

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ANM MT E5 Lewistown, MT [Modified]

Lewistown Municipal Airport, MT
(Lat. 47°02'57"N., long. 109°28'00"W.)

That airspace extending upward from 700 feet above the surface within 9.3-mile radius of the Lewistown Municipal Airport, and within 4.5 miles each side of the Lewistown Municipal Airport 269° bearing extending from the 9.3-mile radius to 14.5 miles west of the airport, and within 2.5 miles south and 4 miles north of the Lewistown Municipal Airport 258° bearing extending from the 9.3-mile radius to 20.5 miles west of the airport; that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 47°21'00"N., long. 110°33'00"W.; to lat. 47°30'00"N., long. 110°00'00"W.; to lat. 47°16'00"N., long. 109°44'00"W.; to lat. 47°11'33"N., long. 108°46'00"W.; to lat. 46°43'40"N., long. 108°48'22"W.; to lat. 46°43'40"N., long. 109°32'14"W.; to lat. 46°32'19"N., long. 109°32'14"W.; to lat. 46°32'19"N., long. 110°06'30"W.; thence to the point of origin.

Issued in Seattle, Washington, on August 17, 2012.

John Warner,

Manager, Operations Support Group, Western Service Center.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1221

[CPSC Docket No. CPSC-2011-0064]

RIN 3041-AC92

Safety Standard for Play Yards

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), also known as the

“Danny Keysar Child Product Safety Notification Act,” requires the United States Consumer Product Safety Commission (Commission, CPSC, us, or we) 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. In this rule, we are issuing a safety standard for play yards in response to the CPSIA.¹

DATES: This rule is effective on February 28, 2013 and will apply to all play yards 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 February 28, 2013.

FOR FURTHER INFORMATION CONTACT: Justin Jirgl, Compliance Officer, Office of Compliance and Field Investigations, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; email: jjirgl@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background: Section 104(b) of the Consumer Product Safety Improvement Act

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 requires the Commission to 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. Play yards are one of the products specifically identified in section 104(f)(2)(F) as a durable infant or toddler product.

¹ The Commission voted 4-0 to approve publication of this rule. Chairman Inez M. Tenenbaum filed a statement concerning this action which may be viewed on the Commission's Web site at <http://www.cpsc.gov/library/foia/ballot/ballot12/playyards.pdf> or obtained from the Commission's Office of the Secretary.

In the **Federal Register** of September 20, 2011 (76 FR 58167), we published a notice of proposed rulemaking (NPR) for play yards, incorporating by reference ASTM F406-11, “Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards,” with three clarifications. ASTM F406 is the safety standard for both non-full-size cribs and play yards. In the proposed rule for play yards, we indicated which sections of the ASTM standard apply to play yards, and we excluded the provisions of ASTM F406 that apply to non-full-size cribs.

The ASTM subcommittee on play yards developed a newer edition of this standard, ASTM F406-12a, which includes the three clarifications we proposed in the NPR. ASTM F406-12a also contains two clarifications that were suggested in comments we received from the public in response to the NPR. Those two clarifications: (1) Added a preload to the mattress vertical displacement test; and (2) exempted from the top rail configuration requirement play yards with upward-folding top rails.

In this document, we are issuing a safety standard for play yards, which incorporates by reference ASTM F406-12a and provides a 6-month (from the date of publication) effective date for the mandatory play yard standard.

B. The Product

ASTM F406-12a defines a “play yard” as a “framed enclosure that includes a floor and has mesh or fabric sided panels primarily intended to provide a play or sleeping environment for children. It may fold for storage or travel.” Play yards are intended for children who are less than 35 inches tall, who cannot climb out of the product. Some play yards include accessory items that attach to the product, including mobiles, toy bars, canopies, bassinets, and changing tables.

C. Incident Data

The preamble to the NPR (76 FR 58168) summarized the data for incidents related to play yards reported to us from early November 2007 through early April 2011. The final rule is based on the data provided in the NPR, as well as updated data on incidents related to play yards reported to us from April 2011 through December 31, 2011.

From April 10, 2011, through December 31, 2011, we received information on 41 play yard-related incidents. Fifteen of the 41 incidents were fatal. Of the remaining 26 incidents, eight resulted in injuries to the child.

Eleven of the 15 fatal incidents are attributable to an unsafe sleep environment, such as the presence of soft bedding. For one fatality, very little information was supplied to us and, we were unable to determine the cause of the death. Three of the 15 fatalities were play yard related. One child died when the bassinet accessory being used as a sleep environment was assembled without key structural elements, which resulted in a dangerous tilt of the sleep surface. The child slid into the corner of the bassinet and suffocated. In another incident, a child was attempting to climb out of a play yard and, while holding onto a separate bassinet nearby, the canopy of the bassinet fell forward and caught him on the back of the neck, suffocating him. A third child suffocated when he got his head stuck in a torn opening between the floor and the mesh side of the play yard.

The recent incidents have hazard patterns similar to those reported in the NPR, and include:

- Eleven incidents, all resulting in fatalities, were the result of unsafe sleep environments and unsafe sleep practices.

- Ten incidents were caused by broken or detached component parts, such as loose wheels and loose hardware, which resulted in the instability or collapse of the product. There were three injuries reported in this category.

- Five incidents were related to the mesh or fabric sides of the play yard, such as stitching that unraveled, tears in the fabric, and mesh holes that were too large. There were two injuries and one fatality reported in this category.

- Four incidents were caused by hazardous accessories, such as broken or detached components from a mobile or a tent accessory. There was one injury reported in this category.

- Three incidents were related to the mattress pad or floor of the play yard, including reports that the fasteners designed to keep the floor board in place failed. There were no injuries reported in this category.

- Three incidents were due to the side rail of the play yard collapsing. There were no injuries in this category.

- Two incidents were the result of the child being able to climb out of the play yard. There was one injury and one fatality reported in this category.

- One incident, which resulted in a fatality, can be attributed to assembly issues in the bassinet accessory of a play yard. In this incident, the bassinet was missing key structural elements meant to support the accessory. The sleep surface of the bassinet tilted, and the

child slid into the corner and suffocated.

- One incident was the result of a child nearly choking on a sticker that was a component of the play yard.

- For one reported fatality associated with a play yard, there was insufficient information to determine the cause.

D. Response to Comments on the Proposed Rule

The preamble to the NPR invited comments concerning all aspects of the proposed rule. We received comments from 23 individuals or organizations. Many of the comments contained more than one issue. Thus, we organized our responses by issue, rather than responding to each individual commenter. Each comment and response is numbered below to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance, or the order in which it was received. All of the comments can be viewed on: www.regulations.gov, by searching under the docket number for this rulemaking, CPSC–2011–0064.

1. Generally Unsupportive of Regulations

(*Comment 1*)—One commenter does not support government regulation of this, or any, consumer product and asserts that the free market will “weed out those manufacturers of unsafe products.”

(*Response 1*)—The CPSIA requires that we promulgate mandatory regulations for durable infant or toddler products, including play yards. This final rule fulfills a statutory obligation given to us by Congress. Accordingly, issuance of a play yard mandatory standard is consistent with the statutory requirements of the CPSIA.

2. The Definition of “Play Yard”

(*Comment 2*)—One commenter notes a possible loophole in the ASTM F406 definition of “play yard” because materials other than mesh or fabric could be used to form the walls. According to the commenter, this would allow a manufacturer to circumvent the mandatory play yard rule.

(*Response 2*)—Play yards with sides made of materials that are not flexible would be considered rigid-sided products. These products would be classified as full-size- or non-full-size cribs, subject to more severe requirements under 16 CFR part 1219 (full-size cribs) or 16 CFR part 1220 (non-full-size cribs). It would be less burdensome to produce a mesh- or

fabric-sided product. Accordingly, we do not believe that a play yard manufacturer would attempt to evade the play yard standard requirements by making a rigid-sided product.

3. ASTM Voluntary Standard as the Basis for the Mandatory Standard

(*Comment 3*)—Three commenters note that the ASTM standard might not be the best basis for the mandatory play yard rule. Each commenter asserts that because we do not have data to indicate whether the fatalities and injuries were caused by play yards not in compliance with the current ASTM standard, we cannot be sure that incorporating by reference the ASTM standard will result in safer play yards.

(*Response 3*)—The CPSIA requires that we base our mandatory standard for play yards on a voluntary standard. We chose the ASTM standard because it is the most widely used play yard standard in the United States. The ASTM committees that produce the durable infant and toddler product standards represent a cross-section of stakeholders, including manufacturers, retailers, testing laboratories, independent consultants, representatives from consumer advocacy groups, representatives from Health Canada, as well as CPSC staff. The creation of an ASTM standard involves analyzing CPSC incident data in detail, assessing other standards (including international standards), and testing products. The ASTM standard upon which we are basing the mandatory regulation addresses the known hazards of play yards and it is the most stringent standard available. Therefore, we believe that it is an appropriate standard upon which to base the play yard mandatory rule.

4. Injury Rates

(*Comment 4*)—One commenter indicates that “the extremely low incidence of injury puts into question the need for regulation at all, outside of the CPSIA mandate, as there probably is no heinous market failure.”

(*Response 4*)—The standard is based on careful analysis of incidents, injuries, and fatalities associated with play yards. Injury rates, when available, are an important part of that analysis. In this case, however, even if we agreed with the commenter that the injury rate is too low, that does not negate the requirement for the issuance of a play yard mandatory standard, which fulfills a statutory obligation given to us by Congress. However, we disagree with the commenter and believe that the incidents, injuries, and fatalities justify

the issuance of a play yard mandatory standard.

5. American Baby Group Data

(*Comment 5*)—One commenter says that the “record demonstrates that the Commission relies solely upon information provided by a 2005 survey by American Baby Group for all market data,” and that “affected parties may challenge the rule by claiming that the Commission’s actions are based on old, inaccurate data.”

(*Response 5*)—The commenter is incorrect in assuming that the 2005 American Baby Group survey (2006 *Baby Products Tracking Study*) was the sole source of market information we considered in the rulemaking process. The *Baby Products Tracking Study* was used to provide an estimate of the magnitude of the play yard market. The initial regulatory flexibility analysis recognized the limitations of this data, both for its age and potentially biased sampling methods.

However, we also used market research—conducted independently—to perform the regulatory flexibility analysis. This research provided information on the number of firms supplying play yards to the U.S. market, their type, their size, and their location. We also researched, independently, the number of products supplied by each firm, each firm’s compliance with the voluntary standard, as well as details about accessories sold with each play yard. It is this information, along with input from our staff and play yard manufacturers, which led to the conclusions of the initial regulatory flexibility analysis.

6. Small Business Impact

(*Comment 6*)—One commenter expresses concerns about how effectively the CPSC complied with the requirements of the Regulatory Flexibility Act (RFA). The commenter asserts that the proposed rule will have a significant impact on all small firms.

(*Response 6*)—The economic impact of the mandatory play yard standard proposed in the NPR would not be significant for play yard suppliers who already are in compliance with the ASTM play yard standard. Many play yard manufacturers and importers have a history of making adjustments to their play yards to remain in compliance with the ASTM standard, and they likely would continue to comply in the absence of a mandatory standard. Firms with a history of voluntary compliance would have few, if any, costs associated with the proposed rule, regardless of their size.

The initial regulatory flexibility analysis recognized that the impact on firms that supply noncompliant play yards to the U.S. market potentially could be significant. However, because the CPSIA requires that we promulgate a mandatory standard that is substantially the same as, or more stringent than, the voluntary standard, the CPSC is limited in how it can minimize the economic impact on small firms that are not in compliance with the standard.

7. International Standards

(*Comment 7*)—We received two comments regarding international play yard standards. One commenter expresses the concern that our play yard mandatory standard could impact trade agreements and emphasizes the importance of standards harmonization as a way to avoid this. Another commenter states that international harmonization should be a priority.

(*Response 7*)—When drafting the NPR for play yards, we reviewed, compared, and considered a variety of play yard standards, including the Canadian standard, the European standard, and the Australian/New Zealand standard. There are differences among all of the international standards. Thus, even if we adopt part, or all, of one of the standards listed here, we still would not have complete international harmonization. We are aware of the utility of having harmonized standards in a global marketplace, and we will continue to strive to achieve this harmonization, whenever possible.

8. Adequacy of Testing

(*Comment 8*)—One commenter states that the proposed test methods for play yards, which do not include any cyclic tests (tests that involve hundreds or thousands of testing cycles in order to evaluate a product’s durability), are insufficient because play yards are set up and taken down more often than cribs.

(*Response 8*)—Cyclic testing is time-consuming and expensive. For play yards, we have found that using very heavy loads applied for one testing cycle (instead of cyclic testing that would require relatively lighter loads and testing cycles that are repeated hundreds or thousands of times) can simulate a lifetime of use. The tests found in the play yard standard were developed over time, and they have been found to be reliable indicators of when a play yard could present a hazard.

9. Quality Control

(*Comment 9*)—One commenter states that the CPSC should establish a mandatory set of production and manufacturing inspection standards for the industry.

(*Response 9*)—The CPSC’s role is to monitor the results of the manufacturing process, not participate in the process itself. We monitor the manufacturing process in several ways. First, we are able to act preventatively by issuing mandatory standards and requiring children’s products be third party tested by an accredited laboratory. Second, we have the ability to act if the manufacturing process fails and a product is sold that does not meet a mandatory standard or is defective and presents a substantial risk of injury to the public.

10. Effective Date

(*Comment 10*)—Several commenters weigh in on the appropriate effective date for the proposed rule. One commenter, representing numerous juvenile product manufacturers, supports the proposed 6-month effective date. One manufacturer says: “from an industrial point of view, 6 months of fulfilling a new legislation is very short” and, therefore, suggests a 12-month effective date. Two other commenters also feel that the effective date should be longer. One suggests that it is “doubtful that a six month grace period would provide sufficient protection for the small businesses that the RFA intends to protect,” while the other says that an effective date “6 months after publication of the final rule” is “seemingly arbitrary” and that other alternatives “may encourage more compliance.”

One commenter, representing several consumer advocacy groups, recommends: “an effective date of 90 days after publication in the **Federal Register**.” Their rationale is twofold. First, “the changes to the voluntary standard proposed by CPSC are minor,” the commenter opines. Second, the commenter adds: “it affects only product manufactured after that date, not sold by that date,” and “manufacturers and retailers have large inventories of children’s products and will be able to sell noncompliant product for years after the effective date. The sooner new products meet the standard, the better for the infants and toddlers who will be using them.”

(*Response 10*)—We consider 6 months sufficient time for suppliers to come into compliance with the proposed rule. Although a longer effective date would allow small entities to spread their costs

out over a longer period of time, 6 months is common in the industry. For example, 6 months is the amount of time the Juvenile Products Manufacturers Association allows for products in their certification program to shift to a new standard. On the other hand, a shorter effective date could put a substantial burden on firms, particularly those whose play yards currently do not meet the requirements of the voluntary ASTM standard.

We share concerns about noncompliant products being available for years beyond the effective date. However, the number and severity of play yard incidents does not seem to warrant a shorter effective date than that used for other durable infant products, particularly given that ongoing compliance activities would continue to be used to pull unsafe play yards from the market.

11. Bassinet and Cradle Accessory Misassembly

(Comment 11)—One commenter states that incidents arise from products that appear to be set up correctly but are actually misassembled. The commenter recommends that we add language to the mandatory play yard standard to address this hazard, by requiring products with consumer-assembled components be designed to prevent misassembly. If that is not possible, the commenter suggests that clear visual indicators be included to alert consumers that the accessory has not been assembled correctly.

(Response 11)—Many play yards are sold with accessories that attach to the product, such as bassinets, changing tables, and mobiles. Bassinet accessories are unique among play yard accessories because bassinet accessories are intended to be used as a sleeping environment, and infants are meant to be left unsupervised in them for extended periods of time. Serious injuries or fatalities can result if a play yard bassinet accessory has been assembled without key structural elements, such as rods, tubes, bars, and hooks, which keep the sleep surface flat and level. A tilt in the sleeping surface of the bassinet can result in an infant getting into a position where he or she is unable to breathe and is at risk of suffocation.

It is possible that the omission of key structural elements initially may not be visually evident to the consumer. If the misassembled accessory supports an infant without a catastrophic and obvious change to the sleep surface, then a consumer may continue to use the accessory and place a child in danger inadvertently.

We considered adding a provision to the play yard final rule to address the hazards associated with play yard bassinet accessories that can be assembled while missing key structural elements. However, we have chosen, instead, to publish an NPR in today's issue of the **Federal Register**, in which we propose a requirement and a test method to address bassinet accessory misassembly in play yards.

12. Play Yards With Upward Folding Side Rails

(Comment 12)—One commenter, a play yard manufacturer, states that play yards with side rails that fold upward should be excluded from the top rail configuration requirement. The commenter notes that most play yards form a dangerous V-shape if the side rail latch mechanisms are not locked properly. The commenter states that his firm's play yards are designed differently than the "typical" play yard, in that the top rail folds upward, which forms a non-dangerous upside down V-shape. If a child were to put their weight on the top rail by leaning on it, their weight would actually lock the top side rail further, rather than unlock it. The commenter requests that the play yard standard exempt play yards that fold upward from the top rail configuration requirement because they will not expose a child to a dangerous V-shape.

(Response 12)—We agree with the commenter. The top rail configuration requirements, found in section 7.10 of ASTM F406–12a, are intended to address entrapment hazards associated with side rails folding and creating a V-shape. If a child's neck is caught in the V-shape, the child could suffocate. The exemption for play yards with upward folding side rails has already been added to ASTM F406–12a. By incorporating by reference ASTM F406–12a, we support the inclusion of this clarification in the play yard mandatory standard.

13. Unsafe Sleep Environment

(Comment 13)—Five commenters raise concerns about the addition of soft bedding, such as blankets, pillows, and quilted covers, which can create an unsafe sleep environment for an infant. Some commenters suggest methods to educate the public about this issue, including: Publishing a safety guide, providing public outreach through traditional and social media, and offering information on the Web site: www.saferproducts.gov, in addition to: www.cpsc.gov.

(Response 13)—We agree that this is an extremely serious issue, and we are dedicated to public outreach and

education campaigns that could prevent infant fatalities caused by unsafe sleep environments and practices. Safety guides, blogs, and videos addressing safe sleep are already available on the agency's Web site at: www.cpsc.gov. Additionally, we use traditional media channels, as well as popular social media outlets, such as Twitter, YouTube and Flickr, to disseminate information to the public about unsafe sleep environments and practices.

(Comment 14)—One commenter recommends that graphics or pictograms depicting the dangers of unsafe sleep environments be added to the existing warnings in the play yard standard in order to enhance their effectiveness.

(Response 14)—We believe that graphics depicted on warnings are useful and potentially can enhance the effectiveness of warnings. However, the development of an effective pictogram warning takes considerable testing to ensure that the graphic is not confusing or counterintuitive or does not lessen the effectiveness of current warnings. We continue to evaluate warnings on play yards and other children's products and will revise such warnings, as necessary.

14. Clearance Around Play Yards

(Comment 15)—One commenter is concerned about outside objects, such as window blind cords and computer cords, which can fall into the play yard and potentially strangle a child. The commenter feels that requiring a minimum clearance of 24 inches around a play yard would prevent children from reaching out and pulling window blind cords or other hazardous objects into the play yard.

(Response 15)—For children who are too young to climb out of the play yard, a minimum clearance of about 3 feet usually would suffice. However, once a child can climb out of the play yard, this minimum clearance has limited utility. For this reason, we feel that the existing required warning on play yards, advising parents to stop using the product once the child can climb out, is the most effective way to prevent these incidents. The ASTM standard also includes warnings that address the hazards of strings, cords, and window blind cords that may fall into the play yard.

15. Play Yard Covers

(Comment 16)—One commenter is concerned about fatalities that have occurred when caregivers place improvised covers on the play yard in an attempt to keep children in the product. In some instances, children were killed when attempting to climb

out of the play yard because they became trapped between the cover and the play yard side rail. The commenter feels that perhaps, there is a "market failure in providing adequate, and adequately priced, covers." The commenter also suggests that play yard covers could be subject to mandatory regulations.

(*Response 16*)—Before a child can stand and reach a cover, the cover likely presents little risk. Once the child can reach it, the cover itself becomes a hazard. We are aware of two fatal incidents associated with covers and tents that can be affixed on top of play yards and cribs. In one incident, a child was able to tear the tent fabric and strangle in the loose strands. In the other incident, the child was able to deform the tent poles and become trapped beneath the mattress and the inverted poles. Because of these incidents, we recommend that consumers avoid using tents and covers on play yards and cribs. We believe that the following existing warning in section 9.4.2.6 of ASTM F406–12a is sufficient to address this hazard: "Child can become entrapped and die when improvised netting or covers are placed on top of product. Never add such items to confine child in product."

16. Risks Associated With Children Climbing Out of a Play Yard

(*Comment 17*)—One commenter feels that the CPSC has "unnecessarily disregarded the idea to make the play yard walls higher" as a way to prevent children from climbing out of the product.

(*Response 17*)—A designer of a play yard faces limited options for preventing children from climbing out of the product. The play yard is essentially a lidless box. Play yards that prevent climbing out would require either higher sides or lids to be effective. Both designs could introduce other problems that potentially are of more concern than the problem of climbing out of the play yard. For instance, making the sides higher increases the difficulty caregivers have placing their children, especially the youngest ones, into the play yard. This could increase the use of alternative sleeping arrangements, such as allowing children to sleep in adult beds, which can have serious hazards associated with them. Introducing a lid or some other kind of cover to a play yard creates more movable parts and the potential for mechanical failures that could lead to entrapment, entanglement, or strangulation.

We have been unable to identify a performance requirement for inclusion

in the play yard standard that would effectively reduce incidents of children climbing out of play yards without simultaneously introducing other potential hazards. The current ASTM standard contains a warning advising parents to stop using the product once a child can climb out of the play yard. We feel that this is the most effective way to prevent injuries associated with children being able to climb out of play yards.

17. Standing/Choking Deaths

(*Comment 18*)—In the NPR, we reported that two toddlers were killed in separate incidents while standing up in a play yard. It is believed that they leaned forward against the side rail (perhaps to reach an object that the child had thrown outside the play yard), lost consciousness, or suffocated when the pressure from the side rail compressed their airway. One commenter asks that we continue to investigate these deaths and address this hazard.

(*Response 18*)—We are very concerned about these deaths. At this time, we are unable to explain how these children died; and thus, we are unable to comment on whether there are changes that could be made to play yard designs that would prevent fatalities like this from occurring. We have reached out to medical professionals and are continuing to collect information that might assist us in understanding the deaths and determining whether there is an engineering solution that could prevent them.

18. Hazards Related to Accessories

(*Comment 19*)—One commenter notes that the accessories that come with play yards can be dangerous. Specifically, the commenter feels that changing table attachments should come with restraints.

(*Response 19*)—There are strong arguments against changing table attachments having restraints, including the concern that the presence of restraints will give the consumer a false sense of security about the accessory. Restraints might lead to the caregiver walking away while the infant is left on the table. More troubling is the concern that parents mistakenly will use changing tables as a sleep environment, which is not the intended use of the product and can be very dangerous. Thus, we cannot recommend that changing tables have restraints.

(*Comment 20*)—One commenter requests that play yard accessories, such as changing tables and bassinets, be banned completely. Failing this, the

commenter asks that these products be required to lock in place so that they cannot be manipulated by infants and toddlers. The commenter's 13-month-old daughter died when her head became trapped between a non-locking changing table attachment and side rail of a play yard.

(*Response 20*)—The current ASTM standard includes a requirement to address this hazard. It can be found in section 5.15 of ASTM F406–12a, titled, *Entrapment in Accessories*. The requirement was added in 2005. The standard requires that accessories not separate from a play yard when an infant-size head probe is pushed against the attachment from inside the play yard with 25 pounds of force. The pushing direction is varied to evaluate the security of the attachment to the play yard better. We feel that this test is adequate to address the hazard the commenter mentions, and we are not recommending any further action.

(*Comment 21*)—One commenter states that the cyclic testing required for rigid-sided products, contained in section 8.5 of ASTM F406–12a, should be required for mesh-sided products, such as play yards. The commenter states that a cyclic test would better assess the integrity of play yard accessory attachment points used to secure bassinets and changing tables to the side rails of play yards. The commenter recommends that the cyclic testing in section 8.5 of the ASTM standard be repeated with and without the attachments installed. The commenter states that it appears that many incidents reported to the CPSC occur when the accessory became unattached at one or more attachment points and that additional durability testing will ensure that the attachment points will hold through a lifetime of use.

(*Response 21*)—The purpose of the cyclic testing requirement, found in section 8.5, is to evaluate the attachment security of threaded fasteners, such as screws, used in rigid-sided products, specifically full- and non-full-size cribs. Of the accessories mentioned by the commenter, bassinet play yard accessories are of the greatest concern because they are intended to be used while an infant is sleeping unsupervised. The majority of play yard bassinet accessories are structureless, fabric shells that attach to the top rails of play yards. Because they have no structure of their own they will be substantially unaffected by this kind of cyclic testing. The attachment components in play yards typically consist of plastic clips, hook-and-loop (Velcro) straps, or snaps sewn into soft material around the inner perimeter of

the play yard. These attachment means are substantially different than the threaded fasteners this test is intended to evaluate. Thus, we feel that cyclic testing would not adequately test the durability of attachment points in play yard accessories.

We identified five incidents where the attachment points of a play yard bassinet accessory failed. None of the incidents resulted in an injury to the child. Three incidents were caused by weak fabric or poor stitching. These hazards are addressed in the ASTM standard for play yards at sections 7.7 and 7.8, which address the durability of fabric and the strength of seams. The other two incidents were caused by separated hook-and-loop (Velcro) closures. On one, the closure failed to secure during the consumer's first use of the product and permitted the sleep surface to tilt slightly. The consumer noticed the problem immediately. We have evaluated the incident and determined that it can be attributed, most likely, to poor quality control in the manufacturing process. In the other incident, the hook-and-loop closure, used as a back-up means of attachment, wore out over time. The concern is that if the primary attachment were to fail, the worn hook-and-loop closure might permit the sleep surface to tilt. However, in this case, because the hook-and-loop closure was a secondary means of attachment, the product did not cause an injury or incident.

We share the commenter's concern about the robustness of bassinet and cradle attachments, but we do not agree that requiring cyclic testing for the attachment points will address those concerns. At this point, we cannot recommend a performance requirement and test method that would reduce the risk of injury associated with this hazard. Incoming data will be monitored to ensure that any emerging trends are identified.

19. Mattress Vertical Displacement Test Repeatability

(Comment 22)—One commenter feels that the consistency of the mattress vertical displacement test could be improved by adding a provision that accounts for slack in the mattress.

(Response 22)—The change the commenter suggests will improve testing consistency for vertical mattress displacement by ensuring that free movement of fabric is taken up before establishing the initial clamp position reference point. It has already been approved by ASTM members and was published in ASTM F406–12. It is also contained in F406–12a. By incorporating by reference ASTM F406–

12a, we support the inclusion of this clarification in the play yard mandatory standard.

20. Impact on Play Yard

(Comment 23)—One commenter states that small children have “wobbly legs and can fall down” and sustain an injury because the play yard is not secured firmly to the floor, or it might be placed on an unlevel floor. The commenter suggests securing play yards to the surface of hard floors with suction cups.

(Response 23)—Our incident data suggest that most children who are injured by falling in a play yard simply lose their balance. Thus, we disagree that children fall in play yards because the products are not secured firmly to the floor. However, even if that were the case, we disagree that suction cups will provide an improved attachment to hard surfaces. The length of time for which the suction effect can be maintained depends significantly on the porosity, flatness, and cleanliness of the floor surface. Furthermore, play yards typically are set up and taken down multiple times and are used on a multitude of indoor surfaces, including carpet, hardwood, and tile, as well as outdoor surfaces, such as grass or dirt. A consumer would not only have to inspect the suction cups for cleanliness and physical deformation before each use, but also remember to remove and install the suction cups, as needed, depending upon the floor surface. Therefore, we feel that requiring suction cups is not an adequate means of preventing injuries to children who fall in play yards.

21. Warnings Statements

(Comment 24)—One commenter notes that the ASTM standard does not require multilingual warnings, and they ask us to consider requiring them. The commenter argues that the use of multilingual warnings reasonably could be expected to reduce play yard injuries by educating caregivers who do not speak or read English.

(Response 24)—We are not opposed to the use of multilingual labels. Many manufacturers already use multilingual warnings, although currently, they are not required. We feel that play yard manufacturers are in the best position to determine who uses their product and decide when to create labels and instructional materials in other languages.

(Comment 25)—One commenter feels that the warning label on play yards requiring adult supervision while the child uses the product is unreasonable because you cannot reasonably expect a

parent to supervise a child who is sleeping in a play yard.

(Response 25)—The warning label that this commenter refers to can be found in section 9.4.2.11 of ASTM F406–12a, and it advises caregivers: “(a)lways provide the supervision necessary for the continued safety of your child. When used for playing, never leave child unattended.” This warning is intended to address the use of play yards as a play environment, not as a sleep environment. We agree with the commenter that a caregiver is not expected to continuously supervise a child who is sleeping in a play yard. This warning is intended for caregivers who are using the product as a play environment.

22. Package and Product Marking To Indicate Compliance With the Mandatory Rule

(Comment 26)—One commenter recommends that products be marked clearly to enable a consumer to determine if the product was manufactured after the play yard mandatory standard became effective. This would enable consumers to discern easily which products comply with the mandatory rule, and which were manufactured before the standard became effective.

(Response 26)—A date code is already required to be on the product, under section 9.1.1.2 of ASTM F406–12a. In addition, future changes to the standard may come into effect. Because it is not practicable to delineate every change to the standard through a new mark on the product, we decline to take action.

E. Summary of ASTM F406–12a and Description of the Final Rule

For the play yard final rule, we are incorporating by reference ASTM F406–12a. The final rule excludes sections of ASTM F406–12a that apply to non-full-size cribs exclusively. In this section, we: (1) summarize the requirements of ASTM F406–12a; and (2) describe the final rule, listing the excluded provisions of ASTM F406–12a that only apply to non-full-size cribs.

1. Summary of ASTM F406–12a

In the NPR (76 FR 58169 through 58170), we described, in detail, the key provisions of ASTM F406–11 that apply to play yards. ASTM F406–12a differs from ASTM F406–11 in the following ways:

- It includes the three changes to the play yard standard we proposed in the NPR, specifically two clarifications to the testing method used to measure the strength of the play yard floor, and one change to the Top Rail to Corner Post

Attachment Test that would allow testers to choose the shape and area of the clamping surface, within a specified range. We reviewed the language that ASTM adopted and, while not exactly the same as the wording we proposed in the NPR, we believe it provides better clarity than what we proposed. By incorporating by reference ASTM F406–12a, we support the inclusion of these clarifications in the play yard mandatory standard.

- On its own initiative, the ASTM committee clarified the Top Rail to Corner Post Attachment Test, as well as the accompanying explanatory graphics. By incorporating by reference ASTM F406–12a, we support the inclusion of these clarifications in the play yard mandatory standard.

- A preload was added to the Mattress Vertical Displacement Test in order to improve testing consistency by ensuring that free movement of fabric is taken up before establishing the initial clamp position reference point. We also received a comment to the NPR suggesting this change. By incorporating by reference ASTM F406–12a, we support the inclusion of this clarification in the play yard mandatory standard.

- An exemption was included in the Top Rail Configuration requirement to exclude play yards with side rails that fold upward. The side rails of most play yards move downward vertically. If the side rail latch mechanisms are not locked properly, they can form a dangerous V-shape. If the child's neck is caught in the V-shape, the child could suffocate. Play yards with side rails that fold upward, however, do not create this risk. We also received a comment to the NPR suggesting this change. By incorporating by reference of ASTM F406–12a, we support the inclusion of this clarification in the play yard mandatory standard.

2. Description of the Final Rule

The final play yard rule incorporates by reference ASTM F406–12a, with several exclusions for provisions that apply to non-full-size cribs only. In the **Federal Register** of December 28, 2010 (75 FR 81766), we issued a final rule on safety standards for non-full-size cribs. Thus, the final rule excludes provisions of ASTM F406–12a that apply to non-full-size cribs, including the following:

- Section 5.17 of ASTM F406–12a, containing the requirements for mattresses in rigid-sided products;
- Section 5.19 of ASTM F406–12a, containing a provision to prevent misassembly in non-full-size cribs;

- Section 5.20 of ASTM F406–12a, containing record keeping requirements for non-full-size cribs;

- The entirety of section 6 of ASTM F406–12a, containing the performance requirements for rigid-sided products;

- Sections 8.1 through 8.10.5 of ASTM F406–12a, containing the test methods for rigid-sided products;

- A portion of section 9.4.2.10 of ASTM F406–12a, containing warning label requirements for nonrectangular cribs; and

- Section 10.1.1.1 of ASTM F406–12a, containing instructional literature requirements for non-full-size cribs.

F. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d).

We are providing a 6-month effective date, as proposed in the NPR. This will give suppliers sufficient time to come into compliance with the mandatory standard.

G. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–605, requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that we prepare a final regulatory flexibility analysis when promulgating final rules. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

1. A succinct statement of the need for, and objectives of, the rule;
2. A summary of the significant issues raised by the 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;
3. A description of, and an estimate of, the number of small entities to which the rule will apply, or an explanation of why no such estimate is available;
4. A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement, and the type of professional skills necessary for preparation of the report or record; and
5. A description of the steps that the agency has taken to minimize 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 final rule, and why each one of the other significant alternatives to the rule considered by the agency that affect the impact on small entities was rejected.

2. The Market

There are 21 domestic firms known to be producing or selling play yards in the United States. Ten are domestic manufacturers, and 11 are domestic importers. Under the U.S. Small Business Administration (SBA) guidelines, a manufacturer of play yards is small if it has 500 or fewer employees, and an importer is considered small if it has 100 or fewer employees. Based on these guidelines, nine domestic manufacturers and 10 domestic importers known to supply play yards to the U.S. market are small businesses. The remaining domestic entities are one large manufacturer and one large importer. There are also three foreign firms supplying play yards to the U.S. market. There may be additional unknown small manufacturers and importers operating in the U.S. market.

The Juvenile Products Manufacturers Association (JPMA) runs a voluntary certification program for juvenile products. Certification under the JPMA program is based on the most recent ASTM voluntary play yard standard, typically with a 6-month delay. Six of the nine small manufacturers produce play yards that are certified as compliant with the ASTM voluntary play yard standard by the JPMA. Of the importers, three import play yards that have been certified as compliant with the ASTM voluntary standard. One additional importer claims compliance with the ASTM standard but is not JPMA certified.

3. Impact of the Standard on Small Businesses

a. Costs of Complying With the Voluntary Standard

The extent to which each firm will be impacted by the play yard mandatory standard depends upon whether the firm's play yards currently comply with the ASTM voluntary standard. Small firms whose play yards already comply with the voluntary standard will not incur any new costs. 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. Thus, it is

likely that most of the firms that already comply with the ASTM standard would continue to do so, even in the absence of a mandatory regulation.

b. Small Domestic Manufacturers

Six of the small manufacturers produce play yards known to comply with the voluntary standard. Small firms whose play yards already comply with the voluntary standard will not incur any new costs. For the three manufacturing firms whose play yards may not be compliant with the voluntary standard, the costs could be more significant. Meeting the existing voluntary standard could require manufacturers to redesign their product. The impact on manufacturers who produce noncompliant play yards may be mitigated if the costs are treated as new product expenses and amortized over time.

This scenario also assumes that the three firms whose play yards are not JPMA certified do not meet the voluntary standard. In fact, we have identified many instances in which a juvenile product not certified by the JPMA complies with the ASTM voluntary standard. To the extent that these firms already may supply play yards that meet the ASTM voluntary standard, the costs incurred would be lower.

c. Small Domestic Importers

Four of the 10 small importers produce play yards known to comply with the voluntary standard. Three are certified by the JPMA, and one additional firm claims compliance with the ASTM standard. Small firms whose play yards already comply with the voluntary standard will not incur any new costs.

The costs to the six importers whose play yards may not be compliant with the voluntary standard could be more significant. Importers of play yards would need to find an alternate source if their existing supplier does not come into compliance with the standard. Purchasing compliant, higher quality play yards could increase the cost of the product.

This will not be an option for two of the noncompliant play yard importers because they specialize in the importation of play yards from a specific foreign company. Thus, finding an alternative supply source is probably not an option for them. These firms could respond to the rule by discontinuing the import of play yards. The impact of this decision could be mitigated by replacing play yards with a different infant or toddler product. Deciding to import an alternative infant or toddler product would be a reasonable and realistic way to offset any lost revenue.

As with manufacturers, to the extent that some of the firms believed to supply noncompliant play yards actually may supply play yards that meet the ASTM voluntary standard, the costs incurred would be lower.

4. Alternatives

An alternative that could minimize the economic impact on small business is providing an effective date longer than 6 months. However, the JPMA, which represents many play yard manufacturers, felt that a 6-month effective date was adequate to allow suppliers to come into compliance with the mandatory standard. We agree. Therefore, we have chosen a 6-month effective date for the play yard mandatory standard.

5. Issues Raised by Public Comment

We received several comments from the public in response to the initial regulatory flexibility analysis, including comments regarding the use of market data, the impact on small businesses, and the appropriate effective date. A summary of those comments and our responses can be found in part D of this preamble, titled, "Response to Comments on the Proposed Rule."

6. Conclusion of the Final Regulatory Flexibility Analysis

The impact of the final play yard rule on firms supplying non-ASTM-compliant play yards could be significant. However, the requirements of the final rule address known play yard hazard patterns and will help

reduce injuries and deaths. We are providing a 6-month effective date as proposed in the NPR. This will give suppliers sufficient time to come into compliance with the mandatory standard and spread the costs over a longer period of time.

H. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. Our rules generally have "little or no potential for affecting the human environment," and therefore, are exempt from any requirement to prepare an environmental assessment or impact statement. 16 CFR 1021.5(c)(1). This rule falls within the categorical exemption.

I. 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. The preamble to the proposed rule (76 FR 58173 through 58174) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. Briefly, sections 9 and 10 of ASTM F406–12a 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).

OMB has assigned control number 3041–0152 to this information collection. We did not receive any comments regarding the information collection burden of this proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated suppliers subject to the information collection burden is now estimated to be 24 firms rather than the nine firms 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
1221.2(a)	24	3	72	1	72

There are 24 known firms supplying play yards to the U.S. market. All 24

firms are assumed to use labels already on both their products and their

packaging, 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 entity supplies an average of three different models of play yards; therefore, the estimated burden associated with labels is 1 hour per model $\times$ 24 entities $\times$ 3 models per entity = 72 hours. We estimate the hourly compensation for the time required to create and update labels is \$28.36 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," September 2011, 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 \$2,041.92 (\$28.36 per hour $\times$ 72 hours = \$2,041.92). There are no operating, maintenance, or capital costs associated with the collection.

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.

J. Preemption

Section 26(a) of the Consumer Product Safety Act (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 establish or continue in effect a requirement dealing with the same risk of injury, unless the state's 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 the rule becomes effective.

K. Certification

Once in effect, the final rule on play yards will make it unlawful for anyone to manufacture, distribute, or import a play yard into the United States that is not in conformity with the standard. 15 U.S.C. 2068(1). Pursuant to section 14(a)(2) of the CPSA, play yards must be certified by the manufacturer to the final standard based on testing conducted by a CPSC-accepted third party conformity assessment body. The third party testing and certification requirement for play yards will not be in effect until we issue

a final notice of requirements (NOR). The final NOR establishes requirements for how third party conformity assessment bodies can become accepted by us to test play yards to the final rule. A proposed NOR for play yards was published in the **Federal Register** on May 24, 2012, as part of an NPR titled, "Requirements Pertaining to Third Party Conformity Assessment Bodies." 77 FR 31086. When the final rule is effective and the NOR is final, third party conformity assessment bodies can apply to us for acceptance of their accreditation to test play yards. Play yard manufacturers will be required to certify products to the final play yard rule based on third party testing once we have accepted the accreditation of such laboratories.

List of Subjects in 16 CFR Part 1221

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

Therefore, the Commission amends Title 16 of the Code of Federal Regulations by adding part 1221 to read as follows:

PART 1221—SAFETY STANDARD FOR PLAY YARDS

Sec.

1221.1 Scope.

1221.2 Requirements for play yards.

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, section 104, 122 Stat. 3016 (August 14, 2008).

§ 1221.1 Scope.

This part establishes a consumer product safety standard for play yards manufactured or imported on or after February 28, 2013.

§ 1221.2 Requirements for play yards.

(a) Except as provided in paragraph (b) of this section, each play yard must comply with all applicable provisions of ASTM F406-12a, Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards, approved on May 1, 2012. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org>. You may inspect a copy at the 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) Comply with the ASTM F406-12a standard with the following exclusions:

(1) Do not comply with section 5.17 of ASTM F406-12a.

(2) Do not comply with section 5.19 of ASTM F406-12a.

(3) Do not comply with section 5.20 of ASTM F406-12a.

(4) Do not comply with section 6, Performance Requirements for Rigid-Sided Products, of ASTM F406-12a, in its entirety.

(5) Do not comply with sections 8.1 through 8.10.5 of ASTM F406-12a.

(6) Instead of complying with section 9.4.2.10 of ASTM F406-12a, comply with only the following:

(i) 9.4.2.10 For products that have a separate mattress that is not permanently fixed in place: Use ONLY mattress/pad provided by manufacturer.

(ii) [Reserved].

(7) Do not comply with section 10.1.1.1 of ASTM F406-12a.

Dated: August 23, 2012.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2009-F-0570]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D₂ Bakers Yeast

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of vitamin D₂ bakers yeast as a source of vitamin D₂ and as a leavening agent in yeast-leavened baked products at levels not to exceed 400 International Units (IU) of vitamin D₂ per 100 grams (g) in the finished food. This action is in response to a petition filed by Lallemand, Inc. (Lallemand).

DATES: This rule is effective August 29, 2012. Submit either electronic or written objections and requests for a hearing by September 28, 2012. See section VII of this document for information on filing objections.