

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Parts 1112 and 1233

[Docket No. CPSC–2015–0016]

#### Safety Standard for Portable Hook-On Chairs

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (“CPSIA”), requires the United States Consumer Product Safety Commission (“Commission” or “CPSC”) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards, or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is issuing a safety standard for portable hook-on chairs (“hook-on chairs”) in response to the direction of section 104(b) of the CPSIA. In addition, the Commission is amending its regulations regarding third party conformity assessment bodies to include the mandatory standard for hook-on chairs in the list of Notices of Requirements (“NOR”) issued by the Commission.

**DATES:** This rule will become effective September 28, 2016. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of September 28, 2016.

**FOR FURTHER INFORMATION CONTACT:** Keysha Walker, Compliance Officer, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301–504–6820; email: [kwalker@cpsc.gov](mailto:kwalker@cpsc.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background and Statutory Authority

The CPSIA 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. Standards issued under section 104 are to be “substantially the same as” the applicable voluntary standards or more stringent than the voluntary standard if the Commission 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)(C) of the CPSIA specifically identifies “hook-on chairs” as a durable infant or toddler product.

On July 2, 2015, the Commission issued a notice of proposed rulemaking (“NPR”) for hook-on chairs. 80 FR 38041. The NPR proposed to incorporate by reference the voluntary standard, ASTM F1235–15, *Standard Consumer Safety Specification for Portable Hook-On Chairs*, without modification. In this document, the Commission is issuing a mandatory safety standard for hook-on chairs. As required by section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and the public to develop this proposed standard, largely through the ASTM process. The rule incorporates by reference the most recent voluntary standard, developed by ASTM International, ASTM F1235–15.

In addition, the final rule amends the list of NORs issued by the Commission in 16 CFR part 1112 to include the standard for hook-on chairs. Under section 14 of the Consumer Product Safety Act (“CPSA”), the Commission promulgated 16 CFR part 1112 to establish requirements for accreditation of third party conformity assessment bodies (or testing laboratories) to test for conformity with a children’s product safety rule. Amending part 1112 adds a NOR for the hook-on chair standard to the list of children’s product safety rules.

##### II. Product Description

The scope section of ASTM F1235–15 defines a “portable hook-on chair” as “[u]sually a legless seat constructed to locate the occupant at a table in such a position and elevation so that the surface of the table can be used as the feeding surface for the occupant . . . [s]upported solely by the table on which it is mounted.” The ASTM standard specifies the appropriate ages and weights for children using portable

hook-on chairs as “between the ages of six months and three years and who weigh no more than 37 lb (16.8 kg) (95th percentile male at three years).” Typical hook-on chairs consist of fabric over a lightweight frame, with a device to mount the seat to a support surface, such as a table or counter. Some hook-on chairs fold for easy storage or transport, and some include a removable tray that can be used in conjunction with a table.

##### III. Market Description

CPSC staff has identified 10 firms supplying hook-on chairs to the U.S. market, typically priced at \$40 to \$80 each. These 10 firms specialize in the manufacture and/or distribution of durable nursery products and represent only a small segment of the juvenile products industry. Nine of the 10 known firms are domestic (including 3 manufacturers and 6 importers). The remaining firm is a foreign manufacturer. Hook-on chairs represent only a small proportion of each firm’s overall product line; on average, each firm supplies one hook-on chair model to the U.S. market annually.

Staff expects that the hook-on chairs of nine of the 10 firms are compliant with ASTM F1235 because they are either: (1) Certified by the Juvenile Products Manufacturers Association (“JPMA”) (three firms); or (2) the supplier claims compliance with the voluntary standard (six firms). It is unknown whether the hook-on chairs supplied by the remaining firm, a foreign manufacturer, comply with the ASTM voluntary standard.

##### IV. Incident Data

The preamble to the NPR summarized the hook-on chair incident data—covering the period between January 1, 2000 and October 31, 2014—reported to the Commission. 80 FR 38041. In the NPR, CPSC’s Directorate for Epidemiology, Division of Hazard Analysis, identified 89 portable hook-on chair-related incidents reported to the CPSC that occurred during the covered time period, including 50 incidents involving injury, 38 non-injury incidents, and one fatality. Since the publication of the NPR, CPSC staff has received 11 new reports (seven nonfatal injuries and four incidents without injury) that were determined to involve portable hook-on chairs. The seven new injuries all involved children between the ages of 6 and 12 months. Among the 11 new incidents, no ages were reported outside the ASTM-recommended user range of 6 months to 3 years. The hazards identified in the new incidents are consistent with the hazard patterns

identified among the incidents present in the NPR briefing package.

## V. Overview of ASTM F1235

The voluntary standard for hook-on chairs was first approved and published in 1989, as ASTM F1235–89, *Standard Consumer Safety Specification for Portable Hook-On Chairs*. ASTM has revised the voluntary standard seven times since initial publication of the standard. The current version, ASTM F1235–15, was approved on May 1, 2015. In the NPR, the Commission proposed to incorporate ASTM F1235–15, which addresses the hazard patterns identified for hook-on chairs, without modification.

## VI. Response to Comments

The Commission received two comments in response to the NPR. A summary of each comment and a response is provided below.

### A. General Support of Standard Adoption

*Comment:* A comment from representatives of Kids In Danger, Consumer Federation of America, and Consumers Union urged the Commission to adopt the proposed rule and agreed with staff's recommendations.

*Response:* The Commission is issuing a final rule that is identical to the NPR.

### B. Hook-On Chair Injuries

*Comment:* The second commenter discussed infant fall data, head injuries, severed body parts, and installation considerations for hook-on chairs. In addition, the commenter questioned why “so many injuries, and even on[e] fatality” occurred before anyone took action to implement stringent standards. Additionally, the commenter opined that hook-on chairs never should have been released to the market, or that they should have been removed immediately after compromised attachment incidents surfaced. Lastly, the commenter opined that even if injuries and fatalities decrease after implementing this new rule, the chances are high that more infants will be killed.

*Response:* Section 104 of the CPSIA requires the Commission to promulgate consumer product safety standards for durable infant or toddler products, including hook-on chairs (specifically identified by section 104(f)(2)(C) of the CPSIA). Furthermore, section 104 of the CPSIA lays out a broad timeline for promulgation of such durable infant and toddler product safety standards. These standards must be “substantially the same as” or more stringent than the relevant voluntary standard.

Accordingly, through section 104 of the CPSIA, Congress has directed the Commission to promulgate safety standards relating to hook-on chairs rather than ban their use.

The current ASTM standard, ASTM F1235–15, incorporates numerous changes implemented after hazard patterns emerged under the previous version of the standard, ASTM F1235–08. For example, the one fatal incident involved an older hook-on chair that did not have a passive crotch restraint. Passive crotch restraints are used to prevent “submarining” deaths and are specified in other similar juvenile standards, such as the juvenile standard for high chairs. Had the hook-on chair involved in the fatal incident contained a passive crotch restraint, the death would not have occurred. In 2014, ASTM added a performance requirement for passive-crotch restraints to ASTM F1235. During the ensuing 7 years between adoption of ASTM F1235–08 and ASTM F1235–15, the hazard patterns identified in the NPR were all addressed, and corresponding requirements were incorporated into the 2015 version of the standard. The Commission is confident that these changes in the standard (including changes addressing scissoring/shearing, openings, and labeling/markings) will reduce injuries associated with hook-on chairs.

## VII. Final Rule

### A. Final Rule for Part 1233 and Incorporation by Reference

Section 1233.2(a) of the final rule provides that hook-on chairs must comply with ASTM F1235–15.

The Office of the Federal Register (“OFR”) has regulations concerning incorporation by reference. 1 CFR part 51. These regulations require that, for a final rule, agencies must discuss in the preamble of the rule the way that the materials the agency incorporates by reference are reasonably available to interested persons and how interested parties can obtain the materials. In addition, the preamble of the rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR's requirements, the discussion in this section summarizes the provisions of ASTM F1235–15. Interested persons may purchase a copy of ASTM F1235–15 from ASTM, either through ASTM's Web site or by mail at the address provided in the rule. A copy of the standard may also be inspected at the CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, or at NARA, as discussed above. We note that the Commission and ASTM

arranged for commenters to have “read only” access to ASTM F1235–15 during the NPR's comment period.

ASTM F1235–15 contains requirements covering:

- Sharp points;
- Small parts;
- Lead in paint;
- Wood parts;
- Latching and locking mechanisms;
- Scissoring, shearing, and pinching (including during detachment from table support surface);
- Exposed coil springs;
- Openings;
- Labeling; and
- Protective components.

The standard additionally contains test methods that must be used to assess conformity with these requirements.

### B. Amendment to 16 CFR Part 1112 To Include NOR for Hook-On Chairs Standard

The final rule amends part 1112 to add a new § 1112.15(b)(40) that lists 16 CFR part 1233, *Safety Consumer Safety Specification for Portable Hook-On Chairs*, as a children's products safety rule for which the Commission has issued an NOR. Section XIII of the preamble provides additional background information regarding certification of hook-on chairs and issuance of an NOR.

## VIII. 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). The safety standard for hook-on chairs and the corresponding changes to part 1112 regarding requirements for third party conformity assessment bodies will become effective 6 months after publication of the final rule in the **Federal Register**.

Without evidence to the contrary, CPSC generally considers 6 months to be sufficient time for suppliers to come into compliance with a new standard, and a 6-month effective date is typical for other CPSIA section 104 rules. Six months is also the period that JPMA typically allows for products in the JPMA certification program to transition to a new standard once that standard is published. The Commission proposed a 6-month effective date in the NPR and did not receive any comments regarding the effective date.

## IX. Regulatory Flexibility Act

### A. Introduction

The Regulatory Flexibility Act (“RFA”), 5 U.S.C. 601–612, requires that agencies review a proposed rule and a

final rule for the rule's potential economic impact on small entities, including small businesses. Section 604 of the RFA generally requires that agencies prepare a final regulatory flexibility analysis ("FRFA") when promulgating final rules, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

#### *B. Impact on Small Businesses*

Approximately 10 firms currently market portable hook-on chairs in the United States, nine of which are domestic firms. Under U.S. Small Business Administration ("SBA") guidelines, a manufacturer of hook-on chairs is small if it has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees.

In the NPR briefing package, the Commission certified that the proposed hook-on chair rule would not have a significant economic impact on a substantial number of small entities. That conclusion has not changed. All of the domestic hook-on chairs appear to conform to the current voluntary standard and are expected to continue to do so. Consequently, costs of compliance, if any, are expected to be negligible. Third party testing costs are expected to be small and economically insignificant (*i.e.*, less than 1 percent of gross revenues for the affected firms). Furthermore, we received no comments questioning or challenging the certification that the rule would not have a significant economic impact on a substantial number of small entities.

#### **X. Environmental Considerations**

The Commission's regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, a rule that has "little or no potential for affecting the human environment," is categorically exempt from this requirement. 16 CFR 1021.5(c)(1). The final rule falls within the categorical exemption.

#### **XI. 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. 3501–3521). The preamble to the proposed rule discussed the information collection burden of the proposed rule. Sections 8 and 9 of ASTM F1235–15 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 3041–0170 to this information collection. The Commission did not receive any comments regarding the information collection burden of this proposal.

#### **XII. Preemption**

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSA 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.

#### **XIII. Amendment to 16 CFR Part 1112 To Include Notice of Requirements (NOR) for Hook-On Chair Standard**

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 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 *Standard Consumer Safety Specification for Hook-On Chairs*, to be codified at 16 CFR part 1233, is a children's product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third-Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which is codified at 16 CFR part 1112 (referred to here as part 1112). This rule became effective 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. Part 1112 also codifies a list of all of the NORs that the CPSC had published at the time part 1112 was issued. All NORs issued after the Commission published part 1112, such as the standard for hook-on chairs, require the Commission to amend part 1112. Accordingly, the Commission is now amending part 1112 to include the standard for hook-on chairs in the list of other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third-party conformity assessment body to test to the new standard for hook-on chairs would be required to meet the third-party conformity assessment body accreditation requirements in 16 CFR part 1112, *Requirements Pertaining to Third-Party Conformity Assessment Bodies*. When a laboratory meets the requirements as a CPSC-accepted third-party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1233, *Standard Consumer Safety Specification for Hook-on Chairs*, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC Web site at: [www.cpsc.gov/labsearch](http://www.cpsc.gov/labsearch).

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

Based on similar reasoning, amending 16 CFR part 1112 to include the NOR for the hook-on chairs standard will not have a significant adverse impact on small test laboratories. Moreover, based upon the number of test laboratories in the United States that have applied for CPSC acceptance of accreditation to test for conformance to other mandatory juvenile product standards, we expect that only a few test laboratories will

seek CPSC acceptance of their accreditation to test for conformance with the hook-on chair standard. Most of these test laboratories will have already been accredited to test for conformity to other mandatory juvenile product standards, and the only costs to them would be the cost of adding the hook-on chairs standard to their scope of accreditation. For these reasons, the Commission certifies that the NOR amending 16 CFR part 1112 to include the hook-on chairs 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 1233

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

For the reasons discussed in the preamble, the Commission amends title 16 of the Code of Federal Regulations as follows:

#### PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

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

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

■ 2. Amend § 1112.15 by adding and reserving paragraph (b)(39) and adding paragraph (b)(40) to read as follows:

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

\* \* \* \* \*

(b) \* \* \*

(40) 16 CFR part 1233, Safety Standard for Portable Hook-On Chairs.

\* \* \* \* \*

■ 3. Add part 1233 to read as follows:

#### PART 1233—SAFETY STANDARD FOR PORTABLE HOOK-ON CHAIRS

Sec.

1233.1 Scope.

1233.2 Requirements for portable hook-on chairs.

**Authority:** Sec. 104, Pub. L. 110–314, 122 Stat. 3016 (August 14, 2008); Pub. L. 112–28, 125 Stat. 273 (August 12, 2011).

##### § 1233.1 Scope.

This part establishes a consumer product safety standard for portable hook-on chairs.

##### § 1233.2 Requirements for portable hook-on chairs.

Each portable hook-on chair must comply with all applicable provisions of ASTM F1235–15, Standard Consumer Safety Specification for Portable Hook-On Chairs, approved on May 1, 2015. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: [http://www.archives.gov/federal-register/code-of-federal-regulations/ibr\\_locations.html](http://www.archives.gov/federal-register/code-of-federal-regulations/ibr_locations.html).

Dated: March 22, 2016.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

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#### COMMODITY FUTURES TRADING COMMISSION

##### 17 CFR Part 10

##### Rules of Practice

##### CFR Correction

In Title 17 of the Code of Federal Regulations, Parts 1 to 40, revised as of April 1, 2015, on page 386, in § 10.12, paragraph (a)(2)(v) is reinstated to read as follows:

##### § 10.12 Service and filing of documents; form and execution.

(a) \* \* \*

(2) \* \* \*

(v) Service shall be complete at the time of personal service; upon deposit in the mail or with a similar commercial package delivery service of a properly addressed document for which all postage or delivery service fees have been paid; or upon transmission by fax or email. Where a party effects service by mail or similar package delivery service (but not by fax or email), the time within which the party being

served may respond shall be extended by five (5) days. Service by fax or email shall be permitted at the discretion of the Presiding Officer, with the parties' consent. Signed documents that are served by email must be in PDF or other non-alterable form.

\* \* \* \* \*

[FR Doc. 2016–07017 Filed 3–25–16; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

##### 21 CFR Parts 312 and 320

[Docket No. FDA–2016–N–0011]

##### Investigational New Drug Applications for Biological Products; Bioequivalence Regulations; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is amending its regulations to update the address for applicants to submit investigational new drug applications (INDs) for biological products regulated by the Center for Drug Evaluation and Research (CDER). FDA is also amending its regulations on the criteria and evidence to assess actual and potential bioequivalence problems (bioequivalence regulations) to correct a typographical error. FDA is taking this action to ensure accuracy and clarity in the Agency's regulations.

**DATES:** This rule is effective March 28, 2016.

**FOR FURTHER INFORMATION CONTACT:** Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

**SUPPLEMENTARY INFORMATION:** FDA is amending 21 CFR 312.140(a)(2) to update the address for applicants to submit INDs for biological products regulated by CDER. FDA is amending 21 CFR 320.33(f)(3) of its bioequivalence regulations to correct a typographical error by removing the phrase “(first-class metabolism)” and adding in its place “(first-pass metabolism).”

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that