

coming several weeks. The CDC's advice includes rescheduling elective and non-urgent admissions, and postponing routine dental and eye care visits. Additionally, the President and the White House Coronavirus Task Force have announced a program called "15 Days to Slow the Spread," a nationwide effort to slow the spread of COVID-19 in the United States through the implementation of social distancing at all levels of society.

Statement of Policy

It is not in the public interest at this time to maintain the requirement of an FAA medical examination, which is a nonemergency medical service, in order for pilots and flight engineers with expiring medical certificates to obtain new medical certificates. This is because of the burden that COVID-19 places on the U.S. healthcare system, and because these aviation medical examinations increase the risk of transmission of the virus through personal contact between the physician and the applicant for an airman medical certificate.

Accordingly, as an exercise of the FAA's enforcement discretion, through June 30, 2020, the FAA will not take legal enforcement action against any person serving as a required pilot flight crewmember or flight engineer based on noncompliance with medical certificate duration standards when expiration of the medical certificate occurs from March 31, 2020, through June 30, 2020. This discretionary accommodation does not apply to pilots or flight engineers who lacked an unexpired medical certificate as of March 31, 2020. Also, regardless of the date of expiration of a medical certificate, this accommodation does not commit to non-enforcement for noncompliance with medical certificate duration standards that occurs after June 30, 2020. This policy applies only to holders of an FAA-issued medical certificate serving as a required pilot flight crewmember or flight engineer within the United States. It does not apply to holders of an FAA-issued medical certificate serving as a required pilot flight crewmember or flight engineer outside the United States.

The FAA has determined that those persons subject to this temporary measure may operate beyond the validity period of their medical certificate during the effective period of this accommodation without creating a risk to aviation safety that is unacceptable under the extraordinary circumstances surrounding the COVID-19 pandemic. The FAA will reevaluate this decision as circumstances unfold, to determine whether an extension or

other action is needed to address this pandemic-related challenge.

The relief provided in this notification does not extend to the requirements of 14 CFR 61.53 and 63.19 regarding prohibition on operations during medical deficiency. These prohibitions remain critical for all pilots and flight engineers to observe, especially given the policy of emergency accommodation announced here and the health threat of COVID-19. Accordingly, the FAA emphasizes that under 14 CFR 61.53, no person who holds a medical certificate issued under 14 CFR part 67 may act as a required pilot flight crewmember while that person: (1) Knows or has reason to know of any medical condition that would make the person unable to meet the requirements for the medical certificate necessary for the pilot operation; or (2) is taking medication or receiving other treatment for a medical condition that results in the person being unable to meet the requirements for the medical certificate necessary for the pilot operation. Additionally, under 14 CFR 63.19, no person may serve as a flight engineer during a period of known physical deficiency, or increase in physical deficiency, that would make the flight engineer unable to meet the physical requirements for an unexpired medical certificate.

All required pilot flight crewmembers and flight engineers are to comply with all other applicable obligations under the FAA's regulations and other applicable laws. This notification creates no individual rights of action and establishes no precedent for future determinations.

Issued in Washington, DC, on March 26, 2020.

Naomi Tsuda,

*Assistant Chief Counsel for Enforcement,
Federal Aviation Administration.*

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CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2015-0029]

16 CFR Part 1232

Revisions to Safety Standard for Children's Folding Chairs and Stools

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: In December 2017, the U.S. Consumer Product Safety Commission (CPSC) issued a consumer product

safety standard for children's folding chairs and stools. The standard incorporated by reference the applicable ASTM voluntary standard. We are publishing this direct final rule revising the CPSC's mandatory standard for children's folding chairs and stools to incorporate by reference the most recent version of the applicable ASTM standard.

DATES: This direct final rule is effective on July 6, 2020, unless we receive significant adverse comment by May 1, 2020. If we receive timely significant adverse comments, we will publish a document in the **Federal Register**, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of July 6, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2015-0029, by any of the following methods:

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

Mail/hand delivery/courier Submissions: Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504-7479.

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: <https://www.regulations.gov>. Do not submit electronically confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information please submit it according to the instructions for written submissions.

Docket: For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, and insert the docket number, CPSC-2015-0029, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Keysha Walker, Compliance Officer,

Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814-4408; telephone: 301-504-6820; email: kwalker@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

1. Statutory Authority

Section 104(b)(1)(B) of the Consumer Product Safety Improvement Act (CPSIA), also known as the Danny Keysar Child Product Safety Notification Act, requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. The law requires these standards to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

The CPSIA also sets forth a process for updating CPSC’s durable infant or toddler standards when the voluntary standard upon which the CPSC standard was based is changed. Section 104(b)(4)(B) of the CPSIA provides that if an organization revises a standard that has been adopted, in whole or in part, as a consumer product safety standard under this subsection, it shall notify the Commission. In addition, the revised voluntary standard shall be considered to be a consumer product safety standard issued by the Commission under section 9 of the Consumer Product Safety Act (15 U.S.C. 2058), effective 180 days after the date on which the organization notifies the Commission (or such later date specified by the Commission in the **Federal Register**) unless, within 90 days after receiving that notice, the Commission notifies the organization that it has determined that the proposed revision does not improve the safety of the consumer product covered by the standard and that the Commission is retaining the existing consumer product safety standard.

2. The Children’s Folding Chair and Stool Standard

On December 15, 2017, the Commission published a final rule issuing a mandatory standard for children’s folding chairs and stools that incorporated by reference the standard in effect at that time, ASTM F2613-17a, *Standard Consumer Specification for Children’s Chairs and Stools*. 82 FR 59505. The ASTM standard for children’s folding chairs and stools,

ASTM F2613, *Standard Consumer Safety Specification for Children’s Chairs and Stools*, applies to children’s folding chairs and stools with a seat height of 15 inches or less, and equipped with or without a rocking base. These chairs are intended to be used by a single child who can get in and out of the product unassisted. The standard was codified in the Commission’s regulations at 16 CFR part 1232. Since publication of ASTM F2613-17a, the current mandatory standard, ASTM has published one revision to ASTM F2613. ASTM F2613-19 was approved and published in November 2019. ASTM officially notified the Commission of this revision on January 6, 2020. The rule is incorporating ASTM F2613-19 as the mandatory standard.

B. Revisions to the ASTM Standard

Under section 104(b)(4)(B) of the CPSIA, unless the Commission determines that ASTM’s revision of a voluntary standard that is a CPSC mandatory standard “does not improve the safety of the consumer product covered by the standard,” the revised voluntary standard becomes the new mandatory standard. As discussed below, the Commission determines that the changes made in ASTM F2613-19 are neutral or improve the safety of children’s folding chairs and stools. Therefore, the Commission will allow the revised voluntary standard to become effective as a mandatory consumer product safety standard under the statute, effective July 6, 2020.

Differences Between 16 CFR Part 1232 and ASTM F2613-19

In November 2019, ASTM revised ASTM F2613-17a. The resulting standard, ASTM F2613-19, includes the changes below:

Non-Substantive Changes

Several changes were minor and editorial and do not affect the safety of children’s folding chairs and stools. Specifically, sections 5.7 and 5.8 removed duplicative language such as “when folded” and “when being folded,” and clarified words to add “comply with” instead of “meet.” The Latching and Locking Mechanisms sections under section 5.8.1 were restructured to improve clarity and organization. All of these changes are explanatory or editorial in nature and non-substantive. The Commission finds that all of the non-substantive changes made in ASTM F2613-19 are neutral regarding safety and do not affect the safety of children’s folding chairs and stools.

Substantive Change

There is one substantive change in ASTM F2613-19 concerning the requirement that products without latching or locking mechanisms have adequate clearance to protect fingers, hands and toes from crushing, laceration or pinching hazards.

The original ASTM F2613-17a sections 5.8.2 and 5.8.2.1 provided that if products without latching or locking mechanisms had an accessible gap at the hinge line that could “admit a $\frac{3}{16}$ -in. (5-mm) diameter rod, it shall also admit a $\frac{1}{2}$ -in. (13-mm) diameter rod at all positions of the hinge.” In other words, products without locking or latching mechanisms could have gaps at the hinge line smaller than $\frac{3}{16}$ inch or larger than $\frac{1}{2}$ inch, but could not have gaps between $\frac{3}{16}$ and $\frac{1}{2}$ inch wide.

ASTM F2613-19 now simplifies this requirement by requiring that all products without latching and locking mechanisms must have a hinge gap greater than or equal to $\frac{1}{2}$ -inch. A minimum $\frac{1}{2}$ inch gap will require that all hinge clearances must be large enough to prevent injury should a child insert their finger in the hinge gap. Thus, section 5.8.2 now requires that products without latching and locking mechanisms “shall be constructed such that a $\frac{1}{2}$ -in (13-mm) diameter rod can be admitted at all positions between any adjacent moving parts and between any moving part and an adjacent stationary part along the entire length of the clearance. The entire length of the clearance shall be assessed during folding and unfolding of the product.” In section 6.2, *Locking Test Method*, testing for the latching or locking mechanism would apply a force of 10 lbf (45 N) to the latching or locking mechanism in the direction tending to release it. CPSC staff concludes that ASTM F2613-19 section 5.8.2 is a simpler requirement that enhances safety compared to the original ASTM F2613-17a. Instead of the original ASTM F2613-17a standard which allowed for hinge gaps less than or equal to $\frac{3}{16}$ -inch and greater than or equal to $\frac{1}{2}$ -inch, the new standard simply prohibits hinge gaps less than a $\frac{1}{2}$ -inch. The Commission considers these changes an improvement to safety.

C. Incorporation by Reference

The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to the final rule, ways 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 to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR's requirements, section A of this preamble summarizes the major provisions of the ASTM F2613–19 standard that the Commission incorporates by reference into 16 CFR part 1232. The standard is reasonably available to interested parties, and interested parties may purchase a copy of the standard from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; phone: 610–832–9585; www.astm.org. In addition, once the rule becomes effective, a read-only copy of the standard will be available for viewing on the ASTM website at <https://www.astm.org/READINGLIBRARY/>. A copy of the standard can also be inspected at CPSC's Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814, telephone 301–504–7923.

D. Certification

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, be certified as complying with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program, or, for children's products, on tests on a sufficient number of samples by a third party conformity assessment body accredited by the Commission to test according to the applicable requirements. As noted, standards issued under section 104(b)(1)(B) of the CPSIA are "consumer product safety standards." Thus, they are subject to the testing and certification requirements of section 14 of the CPSA.

Because children's folding chairs and stools are children's products, samples of these products must be tested by a third party conformity assessment body whose accreditation has been accepted by the Commission. These products also must comply with all other applicable CPSC requirements, such as the lead content requirements in section 101 of the CPSIA, the tracking label requirement in section 14(a)(5) of the CPSA, and the consumer registration form requirements in section 104(d) of the CPSIA.

E. Notice of Requirements

In accordance with section 14(a)(3)(B)(iv) of the CPSIA, the

Commission has previously published a notice of requirements (NOR) for accreditation of third party conformity assessment bodies for testing children's folding chairs and stools (82 FR 59505, December 15, 2017). The NOR provided the criteria and process for our acceptance of accreditation of third party conformity assessment bodies for testing children's folding chairs and stools to 16 CFR part 1232. The NORs for all mandatory standards for durable infant or toddler products are listed in the Commission's rule, "Requirements Pertaining to Third Party Conformity Assessment Bodies," codified at 16 CFR part 1112.

The section 5.8.2 revision in ASTM F2613–19 simplifies the minimum hinge gap size to 1/2-in. for all positions in a product without latching and locking mechanisms. This reduces the number of probes required to test compliance to the standard. Testing laboratories that are currently CPSC-accepted, have demonstrated competence for testing in accordance with ASTM F2613–17a, and will have the competence to conduct the testing to the new standard under the revised standard ASTM F2613–19. Therefore, the Commission considers the existing CPSC-accepted laboratories for testing to ASTM F2613–17a to be capable of testing to ASTM F2613–19 as well. Accordingly, the existing NOR for this standard will remain in place, and CPSC-accepted third party conformity assessment bodies are expected in the normal course of renewing their accreditation to update the scope of the testing laboratories' accreditation to reflect the revised standard.

F. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA) generally requires notice and comment rulemaking, section 553 of the APA provides an exception when the agency, for good cause, finds that notice and public procedure are "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. 553(b)(B). The Commission concludes that when the Commission updates a reference to an ASTM standard that the Commission has incorporated by reference under section 104(b) of the CPSIA, notice and comment are not necessary.

Under the process set out in section 104(b)(4)(B) of the CPSIA, when ASTM revises a standard that the Commission has previously incorporated by reference as a Commission standard for a durable infant or toddler product under section 104(b)(1)(b) of the CPSIA, that revision will become the new CPSC

standard, unless the Commission determines that ASTM's revision does not improve the safety of the product. Thus, unless the Commission makes such a determination, the ASTM revision becomes CPSC's standard by operation of law. The Commission is allowing ASTM F2613–19 to become CPSC's new standard. The purpose of this direct final rule is merely to update the reference in the Code of Federal Regulations (CFR) so that it reflects accurately the version of the standard that takes effect by statute. The rule updates the reference in the CFR, but under the terms of the CPSIA, ASTM F2613–19 takes effect as the new CPSC standard for children's folding chairs and stools, even if the Commission did not issue this rule. Thus, public comment will not impact the substantive changes to the standard or the effect of the revised standard as a consumer product safety standard under section 104(b) of the CPSIA. Under these circumstances, notice and comment are not necessary. In Recommendation 95–4, the Administrative Conference of the United States (ACUS) endorsed direct final rulemaking as an appropriate procedure to expedite promulgating rules that are noncontroversial and that are not expected to generate significant adverse comment. *See* 60 FR 43108 (August 18, 1995). ACUS recommended that agencies use the direct final rule process when they act under the "unnecessary" prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule because we do not expect any significant adverse comments.

Unless we receive a significant adverse comment within 30 days, the rule will become effective on July 6, 2020. In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be one where the commenter explains why the rule would be inappropriate, including an assertion challenging the rule's underlying premise or approach, or a claim that the rule would be ineffective or unacceptable without change. As noted, this rule merely updates a reference in the CFR to reflect a change that occurs by statute.

Should the Commission receive a significant adverse comment, the Commission would withdraw this direct final rule. Depending on the comments and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of

proposed rulemaking, providing an opportunity for public comment.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that agencies review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603 and 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As explained, the Commission has determined that notice and comment are not necessary for this direct final rule. Thus, the RFA does not apply. We also note the limited nature of this document, which merely updates the incorporation by reference to reflect the mandatory CPSC standard that takes effect under section 104 of the CPSIA.

H. Paperwork Reduction Act

The standard for children's folding chairs and stools contains information-collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The revisions made no changes to that section of the standard. Thus, the revisions will have no effect on the information-collection requirements related to the standard.

I. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement where they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

J. 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 CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA deems rules issued there under "consumer product safety rules." Therefore, once a rule issued under section 104 of the CPSIA takes effect, it

will preempt in accordance with section 26(a) of the CPSA.

K. Effective Date

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standard organization revises a standard upon which a consumer product safety standard was based, the revision becomes the CPSC standard within 180 days of notification to the Commission, unless the Commission determines that the revision does not improve the safety of the product, or the Commission sets a later date in the **Federal Register**. The statutory effective date of 180 days falls on July 4, 2020, a legal holiday and a weekend. Therefore, the Commission is setting the effective date of the rule on the next business day, July 6, 2020. As discussed in the preceding section, this is a direct final rule. Unless we receive a significant adverse comment within 30 days, the rule will become effective on July 6, 2020.

L. The Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that, before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The submission must indicate whether the rule is a "major rule." The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a "major rule." Pursuant to the CRA, this rule does not qualify as a "major rule," as defined in 5 U.S.C. 804(2). To comply with the CRA, the Office of the General Counsel will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1232

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

For the reasons stated above, the Commission amends Title 16 CFR chapter II as follows:

PART 1232—SAFETY STANDARD FOR CHILDREN'S FOLDING CHAIRS AND STOOLS

■ 1. Revise the authority citation for part 1232 to read as follows:

Authority: Sec. 104, Pub. L. 110–314, 122 Stat. 3016 (15 U.S.C. 2056a); Sec 3, Pub. L. 112–28, 125 Stat. 273.

■ 2. Revise § 1232.2 to read as follows:

§ 1232.2 Requirements for children's folding chairs and stools.

Each children's folding chair and stool shall comply with all applicable provisions of ASTM F2613–19, *Standard Consumer Safety Specification for Children's Chairs and Stools*, approved on November 1, 2019. 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 of this ASTM standard from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; phone: 610–832–9585; www.astm.org. A read-only copy of the standard is available for viewing on the ASTM website at <https://www.astm.org/READINGLIBRARY/>. You may inspect a copy at the Division of the Secretariat, 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, email fedreg.legal@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html.

Alberta E. Mills,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2020–06334 Filed 3–31–20; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 510, 520, 522, 524, 526, 556, and 558

[Docket No. FDA–2019–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsors' Name and Addresses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during October, November, and December 2019. FDA is informing the public of the availability