

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?

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(b) * * *

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

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- 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.

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.

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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