CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1107 and 1109

[Docket No. CPSC–2020–0019]

Regulatory Flexibility Act Section 610 Review of the Testing and Labeling Regulations Pertaining to Product Certification of Children's Products, Including Reliance on Component Part Testing

AGENCY: Consumer Product Safety Commission.

ACTION: Notification of section 610 review and request for comments.

SUMMARY: The Consumer Product Safety Commission (Commission or CPSC) is conducting a review of the regulations for third party testing and certification to demonstrate compliance with safety standards for children's products, under section 610 of the Regulatory Flexibility Act (RFA). That section requires the CPSC to review within 10 years after their issuance regulations that have a significant economic impact on a substantial number of small entities. The testing and component part regulations were promulgated in 2011. The CPSC seeks comment to determine whether, consistent with the CPSC's statutory obligations, these regulations should be maintained without change, or modified to minimize the significant impact of the rules on a substantial number of small entities.

DATES: Written comments should be submitted by October 23, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2020–0019, 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 Written 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; email: *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number for this notice. CPSC may post all comments received 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–2020–0019, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Susan Proper, Directorate for Economic Analysis, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7628; email: *sproper@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. The Current Regulations in 16 CFR Parts 1107 and 1109

Section 14 of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA) and Public Law 112–28 (2011), establishes requirements for the testing and certification of products subject to consumer product safety rules under the CPSA, or similar rules, bans, standards, or regulations, under any other Act enforced by the Commission. The domestic manufacturer or the importer of the product must issue a certificate that the product complies with applicable safety standards. Under section 14(a)(2) of the CPSA, the certification of children's products must be based on testing conducted by an accredited third party conformity assessment body (a third party testing laboratory). Section 14(i)(2) of the CPSA directed the Commission to publish a regulation that would ''initiate a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements'' and to establish protocols and standards for:

- Ensuring that a children's product is subject to testing periodically and when there has been a material change in the product's design or manufacturing process, and
- The testing of representative samples to ensure continued compliance, and
- Verifying that a children's product tested by a conformity assessment body complies with applicable children's product safety rules, and
- Safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler.

In 2011, in response to the statutory direction, the Commission issued two regulations related to testing: 16 CFR part 1107, ''Testing and Labeling Pertaining to Product Certification'' (testing regulation or part 1107) and 16 CFR part 1109, ''Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Certification, to Meet Testing and Certification Requirements'' (component part regulation or part 1109). Part 1107 implements the above statutory provisions and specifies the records that must be kept to document the required testing and test results. Part 1109 specifies how manufacturers can use third party testing of component parts of products to certify the compliance of a finished product. The intent of the component part regulation was, in part, to provide flexibility to manufacturers and importers and to reduce the costs and other burdens of testing finished products. The regulation has specific requirements that apply to component part testing for lead, paint, and phthalates requirements. The component part regulation also sets forth requirements for importers and other suppliers for relying upon third party testing and certificates provided by their own suppliers. Finally, this part also specifies record-keeping requirements for the testing of the component parts, and requirements to provide traceability of how the component parts were used in finished products.

When parts 1107 and 1109 were promulgated in 2011, the final regulatory flexibility analysis found that the third party testing requirements in part 1107 would have a significant economic impact on a substantial number of small entities. In contrast, the final regulatory flexibility analysis for the component part regulation in part 1109 found that the regulation would not likely have a significant impact on a substantial number of small entities because component part testing is not mandatory. Thus, the only companies expected to engage in component part testing are companies that believe it will be advantageous to do so. However, OMB determined that both 1107 and 1109 were considered major rules under the Congressional Review Act (CRA).[1]

[1] The CRA defines a ''major rule'' as one that has resulted in or is likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers,

Accordingly, CPSC is conducting a 610 rule review for both regulations.

B. Efforts To Reduce Burden Generally and on Small Businesses

The Commission has undertaken several burden-reduction efforts since promulgation of the testing and component part regulations. In August 2011, after the proposed testing and component part regulations had been published in the **Federal Register**, but before issuance of the final regulations, Congress passed Public Law 112–28 (August 12, 2011), ''An Act to Provide the Consumer Product Safety Commission with Greater Authority and Discretion in Enforcing the Consumer Product Safety Laws, and for Other Purposes,'' which amended various sections of the CPSIA. Among other things, Public Law 112–28 directed the CPSC to seek comment on ''opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation.'' Public Law 112–28 also authorized the Commission to issue new or revised third party testing regulations if the Commission determines ''that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.'' *Id.* 2063(d)(3)(B).

In response to the statutory charge to pursue burden reduction in Public Law 112–28, the Commission has issued several regulations that make determinations that certain specified materials do not contain prohibited elements or chemicals in excess of the regulated limits, and therefore, component parts made from these materials do not require third party testing for certification. These include the following regulations for materials determinations:

- That most fabrics used in apparel will not contain lead in excess of the regulated limits (16 CFR 1500.91 ''Hazardous Substances and Articles: Administration and Enforcement Regulations'');
- That unfinished and untreated wood will not contain the heavy elements regulated by the mandatory toy standard ASTM F963 (16 CFR part 1251 ''Toys: Determinations Regarding Heavy Elements Limits for Certain Materials'');
- That some manufactured wood will not contain lead, the chemicals regulated by the mandatory toy standard ASTM F963 and the prohibited phthalates (16 CFR part 1252 ''Children's Products, Children's Toys, and Child Care Articles: Determinations Regarding Lead, ASTM F963 Elements, and Phthalates for Engineered Wood Products'');
- That some unfinished manufactured fibers will not contain the chemicals regulated by the toy standard and the prohibited phthalates (16 CFR part 1253 ''Children's Toys and Child Care Articles: Determinations Regarding ASTM F963 Elements and Phthalates for Unfinished Manufactured Fibers''); and
- That certain plastics will not contain the prohibited phthalates (16 CFR part 1308 ''Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics'').

Although CPSC did not issue the above regulations only to address the impact of the testing regulations on small businesses, small businesses have benefitted from the determinations, often even more than their larger counterparts.

In addition to the materials determinations regulations discussed above, the Commission has taken other steps to reduce the testing burdens imposed by 16 CFR part 1107 since promulgation of the regulation. In June 2017, the Commission issued a Request for Information (RFI), ''Request for Information on Potentially Reducing Regulatory Burdens without Harming Consumers.'' The RFI solicited stakeholder input regarding how to reduce burdens broadly, to include burdens from third party testing. CPSC has implemented several of the recommendations in the RFI regarding reducing third party testing burdens. CPSC has provided sample conformity certificates for use by manufactures and importers; developed a ''regulatory robot'' on the CPSC website to help small businesses determine the regulatory requirements that apply to their products; and provided additional outreach documents and plain language instructions for small manufacturers on how to comply with CPSC regulations. The Commission continues to explore opportunities to reduce unnecessary burdens related to third party testing requirements while assuring compliance with applicable children's product safety rules.

C. Review Under Section 610 of the Regulatory Flexibility Act

Section 610(a) of the RFA requires agencies to review regulations within ten years after promulgation if they are expected to have a significant impact on a substantial number of small entities. Because the testing and component part regulations were issued in 2011, the Commission now requests comments to obtain additional information to inform its section 610 review of the testing regulations. 5 U.S.C. 610(a). The purpose of the review is to determine whether such rules should be continued without change, or should be amended, consistent with the stated objectives of applicable statutes, to minimize any significant impact of the rules on a substantial number of small entities. The RFA lists several factors that the agency shall consider when reviewing rules under section 610. These factors are:

- The continued need for the rule;
- The nature of complaints or comments received concerning the rule from the public;
- The complexity of the rule;
- The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with state and local governmental rules; and
- The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

5 U.S.C. 610(b).

The statute continues to require third party testing and certification of children's products under section 14 of the CPSA, thus establishing the need for the testing and component part regulations. However, the Commission seeks comment to evaluate the other factors and to determine whether the ongoing impact of the testing and component part regulations are significant for a substantial number of small entities. An important step in the review process involves gathering and analyzing information from affected persons about their experience with the rules and any material changes in circumstances since issuance of the rules. The Commission requests written comments on the adequacy or inadequacy of the testing and component part regulations, their small business impacts, and other relevant issues. The purpose of these questions is to assist commenters in their responses and not to limit the format or substance of their comments. Comments are requested on all issues raised by Section 610 of the RFA.

individual industries, federal, state, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. 5 U.S.C. 804(2).

Safety and Effectiveness

• Are there any sections of the testing and component part regulations that could be revised to be made less burdensome while still being consistent with assuring compliance? How would these suggested changes affect the burden on manufacturers and importers of children's products, specifically small businesses? Explain your response and provide supporting data, if possible.

Costs and Impacts—Manufacturers and Importers of Children's Products

• Are there any requirements of the testing and component part regulations that are especially or unnecessarily costly and/or burdensome, particularly to small suppliers of children's products? Please explain your response, and provide supporting data.

• Which requirements in the testing and component part regulations have the greatest impact on testing costs? Which requirements have the lowest impact on testing costs? We are especially interested in any differential impact of the testing requirements on small businesses. Explain your response, and provide supporting data if possible.

• The testing regulation provides general guidelines on what constitutes a sufficient number of samples to provide ''a high degree of assurance that the tests conducted for certification purposes accurately demonstrate the ability of the children's product to meet all applicable children's product safety rules.'' Is the current flexibility provided in the testing regulation for determining sample size helpful or burdensome to small businesses? Would more specific requirements on what constitutes an appropriate sample size reduce the burden on small businesses?

• The testing regulation provides several options to meet the periodic testing requirements, including options to test whenever there is a material change, every year, every two years, or every three years. Given model lifecycles for children's products that would lead to material changes, are these options sufficiently flexible for small businesses? Are there different options for ''periodic testing'' that could reduce the burden on small businesses and be consistent with assuring compliance with the applicable safety rules?

• Do testing and component part regulations cause delays in bringing new products to market? Do these impacts particularly affect small businesses? Are there actions CPSC could take to reduce any delay caused by the testing and component part regulations that would still be consistent with assuring compliance with all applicable safety rules?

• Are there particular types of children's products or small businesses that are substantially impacted by the testing and component part regulations? How could the regulations be revised to address these specific products or types of small businesses? Please provide data and specific examples to support your answer.

Recordkeeping Requirements

• Are the recordkeeping requirements in the testing and component part regulations inadequate, or overly burdensome for small businesses?

• Could the recordkeeping requirements in the testing and component part regulations be changed in a way that would reduce the recordkeeping costs for small businesses and still be consistent with assuring compliance with all applicable safety rules? Please explain your response.

Component Part Testing

• Have manufacturers, importers, and private labelers, particularly small businesses, been using the flexibilities provided in the component part testing rule (16 CFR part 1109) to reduce their third party testing costs (*e.g.,* relying upon third party testing provided by a supplier to certify products or relying on third party testing of a component part used in more than one model for certification purposes)? If so, in what way? Can you provide estimates of the cost savings provided by the component part regulation?

• Are there particular requirements in the component part regulation that are especially burdensome to small businesses and that limit the ability of small businesses to take advantage of the opportunities for burden reduction that could be offered by the rule? If so, how could we revise the requirements to reduce the burden on small businesses while still assuring compliance with all applicable safety rules?

• Have small businesses had difficulty identifying providers of certified component parts, such as paint, varnishes, fasteners, small parts, and fabrics? If so, are there ways CPSC could make it easier for small businesses to identify available providers of certified component parts?

• The component part regulation has specific requirements for component part testing for lead, phthalates, and paint. Are these requirements clear? If not, how could we make them clearer to small businesses while still assuring compliance with all applicable safety rules?

Labeling Requirements in 16 CFR 1107

The testing regulation includes a subpart on labeling. The regulations specify that manufacturers and private labelers of consumer products may provide a label that the product ''meets CPSC safety requirements.'' Such a label is permitted but not required.

• Are the labeling requirements clear? Could the testing regulation be revised to reduce the burden on small businesses or to increase the ability of small businesses to take advantage of the opportunity to label their products as being compliant with the CPSC safety requirements?

Changes in Market Conditions Since 2011

• How have market conditions for children's products changed since 2011 for small businesses? Should the testing and component part regulations change to address these market changes? If so, how?

• Could the testing and component part regulations be changed to address advances in testing technology that have occurred since 2011 that would reduce the burden on small businesses?

• Are there new categories of children's products that have entered the market since 2011 for which the testing and component part regulations are particularly burdensome on small businesses?

Outreach and Advocacy

• Are the requirements in CPSC's testing and component part regulations well understood by businesses that manufacture or import children's products, particularly small businesses and businesses that build or import children's products infrequently or in small lots? How could the requirements of the testing and component part regulations be more effectively communicated to such businesses?

• CPSC has provided a small business ''regulatory robot'' and sample Children's Product Certificates and General Certificates of Conformity, among other tools. We conduct periodic free webinars for small businesses. Our website has a list of all the accredited testing labs, which has been updated to make it more easily searchable. Are there other documents, instructional videos, or information of the above nature we could provide that would help small firms comply with the testing and component part regulations?

Overall Burden of the Testing and Component Part Regulations on Small Businesses

• To what extent, if any, have children's product manufacturers increased their use of third party testing in response to the third party testing requirements in section 14 of the CPSA and 16 CFR parts 1107 and 1109? Did third party testing replace other types of testing or quality assurance activities that the manufacturers or importers had been using to ensure that their products complied with the applicable product safety rules?

• Is it possible to estimate the overall burden of the testing and component part regulations, perhaps as a percentage of revenue, over and above what businesses would have spent to ensure compliance with the applicable product safety rules in the absence of the testing and component part regulation?

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2020–16441 Filed 8–21–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2019–C–1782]

CooperVision, Inc.; Withdrawal of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; withdrawal of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 9C0315) proposing that the color additive regulations be amended to provide for the safe use of disperse orange 3 methacrylamide as a color additive in contact lenses.

DATES: The color additive petition was withdrawn on June 15, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this document into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1075.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 8, 2019 (84 FR 20060), we announced that we had filed a color additive petition (CAP 9C0315), submitted by CooperVision, 5870 Stoneridge Dr., Suite 1, Pleasanton, CA 94588. The petition proposed to amend the color additive regulations in 21 CFR part 73, *Listing of Color Additives Exempt from Certification,* to provide for the safe use of disperse orange 3 methacrylamide (CAS Reg. 58142–15–7; CAS name 2-propenamide, 2-methyl-*N*-[4-[2-(4-nitrophenyl)diazenyl]phenyl]-) as a color additive in silicone-based hydrogel contact lenses. The color additive was intended to copolymerize with various monomers in the contact lens formulation to produce colored contact lenses. Through this notice, we are announcing that CooperVision has withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: July 31, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17195 Filed 8–21–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 7

[FAR Case 2019–001, Docket No. FAR–2019–0020, Sequence No. 1]

RIN 9000–AN84

Federal Acquisition Regulation: Analysis for Equipment Acquisitions

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement a section of the FAA Reauthorization Act of 2018, which requires, when acquiring equipment, a case-by-case analysis of cost and other factors associated with certain methods of acquisition, including purchase, short-term rental or lease, long-term rental or lease, interagency acquisition, and, if applicable, acquisition agreements with a State or local government.

DATES: Interested parties should submit written comments at the address shown below on or before October 23, 2020 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAR Case 2019–001 to *Regulations.gov*: *http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for ''FAR Case 2019–001''. Select the link ''Comment Now'' that corresponds with FAR Case 2019–001. Follow the instructions provided at the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2019–001'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite ''FAR case 2019–001'' in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Michael O. Jackson, Procurement Analyst, at 202–208–4949, or by email at *michaelo.jackson@gsa.gov,* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAR case 2019–001.

SUPPLEMENTARY INFORMATION:

I. Background

On July 16, 2013, DoD, GSA, and NASA published a Request for Information (RFI) in the **Federal Register** (78 FR 42524) to determine whether there is a distinction between renting and leasing that is useful for the purposes of FAR subpart 7.4. The public comment period closed in September 2013 and 13 respondents provided comments in response to the RFI. A review of the public comments identified that there are differences between renting and leasing in many industries, but there are no standard differences between renting and leasing that span across all industries. As a result of the review, FAR case 2017–017 was opened to clarify the term ''lease'', as used in the FAR and a proposed rule