Information Collection Request (ICR) Safety Standard for Infant Sleep Products Supporting Statement

A. Justification

1. Information to be collected and circumstances that make the collection of information necessary

Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (CPSIA), Public Law 110-314, 122 Stat. 3016 (August 14, 2008), requires the 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.

As directed by this statutory requirement, the Commission is promulgating a safety standard for infant sleep products. The final rule defines an "infant sleep product" as a product marketed or intended to provide a sleeping accommodation for an infant up to 5 months of age, and that is not already subject to one of the mandatory CPSC sleep standards: full-size cribs, non-full-size cribs, play yards, bassinets and cradles, or bed-side sleepers. The infant sleep products covered by this rule include inclined and flat sleep products, such as inclined sleepers, play yard infant sleep accessories, baby nests and pods, in-bed sleepers, baby hammocks, compact or travel bassinets without a stand or legs, and baby tents. This final rule for infant sleep products incorporates by reference the voluntary standard for infant inclined sleep products issued by ASTM International, ASTM F3118-17a, *Standard Consumer Safety Specification for Infant Inclined Sleep Products*, with modifications to further reduce the risk of injury associated with infant sleep products. The final rule sets a safety floor for all infant sleep surface angle of 10 degrees or less from horizontal, and to meet the requirements of 16 CFR part 1218, Safety Standard for Bassinets and Cradles, including conforming to the definition of a bassinet/cradle.

Part 1218 incorporates by reference the performance and labeling requirements of ASTM F2194-13, with modifications to make the standard more stringent. Part 1218 is substantially similar to ASTM F2194-16ɛ1. Accordingly, we discuss sections 8 and 9 of ASTM F2194-16ɛ1 in this supporting statement, which 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).

2. Use and sharing of collected information

These information collection requirements apply to manufacturers and importers of infant sleep products. The information collected is intended to address safety issues that might arise with the product.

The information required in section 8 of ASTM F2194 is intended to help the CPSC and the consumer identify the firm and the product, should a safety issue arise. This information includes clear labeling that indicates the name of the manufacturer, distributor, or seller of the product and either their place of business, or telephone number. This information also requires that each product shall have prescribed warning statements.

The instructional literature required by section 9 of ASTM F2194 is meant to prevent safety problems with products sold by providing information to consumers that is easy to read and understand. Instructions for assembly, maintenance, cleaning, operating, and adjustment, where applicable, for infant sleep products are required.

3. Use of information technology (IT) in information collection

The use of information technology will not be required but may be used. In the final rule, manufacturers are required to provide labeling, marking, and instructional literature according to ASTM F2194. This disclosure is provided with the purchase of the product. However, suppliers may make the information available digitally as well.

4. Efforts to identify duplication

Information being disclosed is manufacturer and product specific. To the extent that firms do not already comply with the voluntary standard, information provided by these requirements is not available through any other agency, organization, or individual.

5. Impact on small businesses

Infant sleep products covered by this rule may be purchased at general retailers, online retailers, mattress and bedding stores, and baby specialty stores. At least 60 small U.S.-based manufacturers and importers are in this market, as well as five large domestic companies, and dozens of foreign companies, some that ship these items directly to customers in the United States via online marketplaces. More than a thousand home-based manufacturers, hundreds based in the United States, sell soft-sided baby nests and pods, in-bed sleepers, and infant hammocks directly to consumers via online marketplaces and as third-party sellers via major retailers' websites.

The Final Regulatory Flexibility Analysis included in the final rule and published to the Federal Register on June 23, 2021, provides an analysis of the impact on small business of the rule. Based on the staff's analysis, the Commission anticipates there is a possible significant economic impact associated with this rule for twelve small importers and nine small domestic manufacturers that supply infant sleep products to the U.S. market, as well as for hundreds of

home-based small businesses that ship from the U.S. However, the burden associated with this information collection is smaller and will not apply to all small entities equally.

CPSC has attempted to minimize the impact of the collection burden on small entities by defining the scope of the rule to only include infant sleep products that are not within the scope of another standard; marketed or intended for infant sleep, including napping; and marketed and intended for use by children up to 5 months old. These requirements provide small businesses the opportunity to remove their products from the scope of this standard by marketing them as not intended for sleep, or only intended for use by older children, or for pets.

CPSC published an SNPR in 2019 (84 FR 60949), which means firms have been aware of this rulemaking effort and have had several years to prepare for implementation of the final rule. Furthermore, CPSC has established a 12-month effective date for this rule which allows firms to plan for costs that may be incurred or associated with the information collection, and to spread costs out, before needing to comply.

6. Consequences to federal program or policy activities if collection is not conducted or is conducted less frequently

The purpose of the Safety Standard for Infant Sleep Products is to reduce deaths associated with known infant sleep hazards. Without marking, labeling, and instructional literature requirements, the level of noncompliance and consumer misuse of products intended for infant sleep could result in product-related injuries and/or deaths. Furthermore, the lack of proper marking and labeling could complicate CPSC efforts to locate and recall noncomplying products and result in additional product-related injuries and/or deaths.

7. Paperwork Reduction Act Guidelines

This collection of information does not require collection to be conducted in a manner inconsistent with the guidelines delineated in 5 CFR 1320.5(d)(2).

8. Consultation outside the agency

The CPSC meets with ASTM International, an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of consumer products, including products designed for infant sleep. At meetings, members of industry are able to provide comments and concerns to CPSC and express their views on many topics related to safety standards including the burden of information collection. ASTM actively engages in developing appropriate marking and labeling requirements. This collection adopts ASTM's requirements for Bassinets and Cradles.

The CPSC consulted several manufacturers to obtain their views on the information collection burden associated with the marking and label requirements. Additionally, the preamble to the proposed rule published on April 7, 2017 (82 FR 16963) discusses the information collection burden and invites public comment on the CPSC's estimates.

On November 12, 2019, the CPSC published a Supplemental Notice of Proposed Rulemaking (84 FR 60949). The preamble to the 2019 SNPR discussed the information collection burden of the supplemental proposed rule and specifically requested comments on the accuracy of our estimates. On January 28, 2020, the CPSC published an Extension of Comment Period (85 FR 4918) for the supplemental notice. The period for public comments closed on Feb 26, 2020 for the Supplemental Notice of Proposed Rulemaking for Infant Sleep Products, and the comment period extension. We did not receive any comment regarding the information collection burden of the proposal in the 2019 SNPR.

9. Decision to provide payment or gift

There is no payment or gift provided to respondents.

10. Assurance of confidentiality

There is no assurance of confidentiality. Marking and labeling information, and instructional literature is not confidential.

11. Questions of a sensitive nature

There are no questions of a sensitive nature.

12. Estimate of hour burden to respondents

Burden is estimated for entities who manufacture or import infant sleep products. We estimate the burden of this collection of information as follows:

Burden Type	Type of Supplier	Number of Firms	Number of Models (Frequency)	Total Annual Reponses	Hours per Response	Annual Burden (hours)
Labeling	Home-based manufacturer	1,200	1	1,200	7	8,400
	Other suppliers	125	2	250	1	250
Total Labeling						8,650
Instructional Literature	Home-based manufacturer	1,200	1	1,200	50	60,000
Total Hourly Burden						68,650

Table 1.	. Estimated	Annual	Rei	norting	Burden
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ASTM F2194 (section 8) requires that the name and mailing address (including city, state, and zip code) or telephone number, or both, of the manufacturer, distributor, or seller be marked clearly and legibly on each product and its retail carton. Section 8 of ASTM F2194

further requires a code mark or other means that identifies the date (month and year, as a minimum) of manufacture.

Two groups of quantifiable entities supply infant sleep products to the U.S. market that will likely need to make some modifications to their existing warning labels to meet the requirements for warnings. The first group consists of very small home-based manufacturers, which may not currently have warning labels on their infant sleep products. Similar rulemakings (such as that for sling carriers) assumed that it would take home-based manufacturers approximately 15 hours to develop a new label. Given that some home-based manufacturers supply infant sleep products with warning labels already, we have estimated approximately 7 hours per response for this group of suppliers. Therefore, the total burden hours for very small home-based manufacturers is 7 hours per model x 1200 entities x 1 models per entity = 8400 hours.

The second group of quantifiable entities supplying infant sleep products to the U.S. market that will need to make some modifications to their existing warning labels are non-home-based manufacturers and importers. These firms do not operate at the low production volume of the home-based firms. All of the firms in this second group have existing warning labels on their products, but not necessarily labels that are compliant with the requirements of ASTM F2194, as specified in 16 CFR part 1218, and would therefore, have to make label modifications. Given that these firms are used to working with warning labels, we estimate that the time required to make any modifications now or in the future would be about 1 hour per model. Based on an evaluation of supplier product lines, each entity supplies an average of 2 models of infant sleep products; therefore, the estimated burden associated with labels for this second group is 1 hours per model x 125 entities x 2 models per entity = 250 hours.

The total burden hours attributable to warning labels is the sum of the burden hours for both entity groups: very small home-based manufacturers (8,400 burden hours) + non-home-based manufacturers and importers (250 burden hours) = 8,650 burden hours. We estimate the hourly compensation for the time required to create and update labels is \$33.71 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," December 2020, Supplementary table 1, total compensation for all sales and office workers in goods-producing private industries: https://www.bls.gov/web/ecec/ecsuptc.pdf.) Therefore, the estimated annual cost to industry associated with the labeling requirements is \$291,591.50 (\$33.71 per hour x 8,650 hours = \$291,591.50). No operating, maintenance, or capital costs are associated with the collection.

ASTM F2194 (section 9) requires instructions to be supplied with the product. As already noted, the proposed Safety Standard for Infant Sleep Products requires infant sleep products to meet these requirements. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the "normal course of their activities" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary."

We are unaware of infant sleep products that generally require use instructions but lack such instructions. However, it is possible that the 1,200 home-based manufacturers of infant hammocks, baby nests, and in-bed sleepers may not supply instruction manuals as part of their "normal course of activities." Based on information collected for the infant slings rulemaking, staff tentatively estimates that each small entity supplying homemade infant hammocks, baby nests, or in-bed sleepers might require 50 hours to develop an instruction manual to accompany their products. These firms typically supply only one infant sleep product model. Therefore, using the U.S. Bureau of Labor Statistics estimated wage rate, the costs of designing an instruction manual for these firms could be as high as \$2,022,600 (50 hours per model x 1 model per entity x 1200 entities x 33.71 per hour = 2,022,600. However, this cost estimate may overestimate the annual cost to industry because many home-based firms might not pay average U.S. domestic wage rates. Not all firms would incur these costs every year, but new firms that enter the market would incur these costs, and this is a highly fluctuating market. Other firms are estimated to have no burden hours associated with instruction manuals because any burden associated with supplying instructions with infant sleep products would be "usual and customary" and not within the definition of "burden" under the OMB's regulations.

Based on this analysis, CPSC staff estimates that the final rule for infant sleep products would impose a burden to industry of 68,650 hours at a cost of \$2,314,191.50 annually.

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents beyond those presented in Section A.12. There are no other operating, maintenance, or capital costs associated with the collection.

14. Estimate of annualized costs to the federal government

The estimated annual cost of the information collection requirements to the federal government is approximately \$4,166, which includes 60 staff hours to examine and evaluate the information as needed for Compliance activities. This is based on a GS-12 level salaried employee. The average hourly wage rate for a mid-level salaried GS-12 employee in the Washington, DC metropolitan area (effective as of January 2021) is \$47.35 (GS-12, step 5). This represents 68.2 percent of total compensation (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," December 2020, Table 2, percentage of wages and salaries for all civilian management, professional, and related employees: https://www.bls.gov/news.release/eccc.t02.htm). Adding an additional 31.8 percent for benefits brings average annual compensation for a mid-level salaried GS-12 employee to \$69.43 per

hour. Assuming that approximately 60 hours will be required annually, this results in an annual cost of \$4,166 (\$69.43 per hour \times 60 hours = \$4,165.80).

15. Program changes or adjustments

The Supplemental NPR published to the Federal Register on November 12, 2019 (84 FR 60949) proposed to incorporate by reference the most recent version of the voluntary standard, ASTM F3118, for marking and labeling requirements. The 2019 SNPR proposed to incorporate

by reference ASTM F2194, *Standard Consumer Safety Specification for Bassinets and Cradles*, and this incorporation is finalized in the Final Rule.

16. Plans for tabulation and publication

Not applicable.

17. Rationale for not displaying the expiration date for OMB approval

Not applicable.

B. Collection of Information Employing Statistical Methods

Not applicable.