

Supporting Statement
Information Collection Requirements for Sound Levels for Toy Caps

A. Justification

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

In 1970, the Food and Drug Administration (FDA) issued a rule, now codified at 16 C.F.R. 1500.18 (a)(5), banning toy caps which produce peak sound pressure levels of 138 decibels (dB) or greater when measured from a distance of 25 centimeters (approximately 10 inches). This rule had the effect of banning all toy caps then on the market, although FDA had not intended this result.

In 1971, FDA convened an advisory panel to consider sound pressure levels produced by toy caps. This panel concluded that toy caps producing sound levels of 138 dB have potential for causing hearing loss; and toy caps producing levels between 138 dB and 158 dB were in a gray area requiring labeling and further study.

After considering the findings of the advisory panel, FDA issued an exemption to the banning rule in 1971. It is codified now at 16 C.F.R. 1500.86 (a)(6) and permits the distribution of toy caps producing sound levels between 138 dB and 158 dB if:

- (a) the packages are labeled with appropriate warnings;
- (b) firms intending to distribute such caps notify the enforcing agency before beginning distribution;
- (c) firms distributing such caps participate in a program to reduce sound levels produced by such caps to 138 dB or less; and
- (d) firms distributing such caps submit quarterly reports on the status of the program to reduce sound levels.

In 1973, enforcement of the rule was transferred to the U.S. Consumer Product Safety Commission (CPSC). In 1986, the Commission reviewed all provisions of the rule exempting caps producing sound levels between 138 and 158 dB to determine if the rule should be revoked, amended, or continued in effect. During this review, the Commission considered information about the number of firms manufacturing or importing toy caps; the absence of any reports of injuries associated with toy caps; and results of testing conducted by the Commission's engineering laboratory. At the conclusion of the review, the Commission decided to continue the rule without change.

2. *Use and sharing of collected information, and impact on privacy.*

The information is used to monitor industry efforts to reduce the sound levels of toy caps. It also provides a mechanism for ascertaining which firms currently manufacture or import 138-158 dB toy caps.

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

The records required to be maintained by this standard may be in any appropriate form or format that clearly provides the required information. Where records are kept on computer disk or other retrievable media, the records shall be made available to the Commission on paper copies or via electronic mail in the same format as paper copies, upon request.

4. *Efforts to identify duplication.*

CPSC staff has reviewed the reporting requirements to assure that they do not collect information that is already collected for any other purpose by CPSC, by another government agency, or by others.

5. *Impact on small businesses.*

Not applicable.

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

If reports were required to be submitted less frequently, the Commission's ability to monitor new developments would be limited and could hamper enforcement or regulatory action could be hampered.

7. *Special circumstances requiring respondents to report information more often than quarterly or to prepare responses in fewer than 30 days.*

None.

8. *Agency Federal Register Notice and related information.*

First FR Notice published on July 3, 2008. No comments were received. Second FR Notice published September 24, 2008.

9. *Decision to provide payment or gift.*

Not applicable.

10. *Assurance of confidentiality.*

Any information required to be maintained by the Commission's standard which the manufacturer or importer claims to be confidential is subject to procedures for

withholding confidential information from public disclosure set forth at 16 C.F.R. Part 1015, subpart B.

11. *Questions of a sensitive nature.*

There are no questions of a sensitive nature.

12. *Estimate of hour burden to respondents.*

The Commission estimates that approximately 10 firms are manufacturing or importing toy caps. Staff further estimates that the average report preparation time is approximately one hour. It might take several hours to prepare a report, if significant developments occurred during a three-month period, however, most reports simply state that no changes have occurred since the previous report. Since four reports are required each year, the total estimate per firm is four hours and the total annual industry burden is estimated at 40 hours.

13. *Estimate of total annual cost burden to respondents.*

We estimate that the total annualized cost/burden to respondents would be about 40 hours. The estimated annualized cost to respondents is approximately \$1,002 based on a mean hourly wage of \$25.04 for a first line office manager within NAICS 339000 Miscellaneous manufacturing. (Bureau of Labor Statistics, May 2007)

14. *Estimate of annualized costs to federal government.*

The estimated annual cost of the information collection requirements to the Federal government is approximately \$10,321, which includes one staff month to examine and evaluate the reported information. The Commission is unable to estimate the total dollar cost that would have been incurred by the industry to conduct or participate in programs to develop toy caps that produce sound levels of not more than 138 dB.

15. *Program changes or adjustments.*

Not applicable.

16. *Plans for tabulation and publication.*

Not applicable.

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

Not applicable.

18. *Exception to the certification statement.*

Not applicable.

A. Statistical Methods - The reporting requirements do not employ statistical methods.