firm of the choking incident. A retailer or distributor may have no information other than the name and a sample of the product, its own distribution information, and the choking complaint. The rule has been modified to make it clear a retailer or distributor is not under any obligation to seek additional information from its supplier to complete a report. Section 1117.5(c). A manufacturer (including an importer) may have more information about the design iterations of the product and any corrective action taken.

Several commenters stated that if their product was not involved in the choking incident it would be pointless to submit some of the information such as corrective action measures. Firms have no obligation to report on design changes or corrective action measures if none were undertaken. Therefore, these provisions pose no burden on firms.

A trade association expressed uncertainty about the obligation in section 1117.5(b)(7) to report changes made in the design of the product and whether changes made before or after the incident need be reported. The Commission intentionally made this provision broad to include all changes made to address choking incidents similar to the one reported, whether made before or after the reported choking occurred.

Several commenters expressed concern that the 24 hour reporting obligation would make supplemental reports necessary. They suggested that some timeframe be supplied for supplemental reports. The Commission agrees and has added language to subsection (c) of 1117.5 requiring supplemental reports be submitted within ten days. Firms do not have to file a supplemental report if they have already provided all the information required by subsection (b) of section 1117.5.

Section 1117.6 of the proposed rule explains this reporting provision is in addition to, but is not a substitute for, the reporting requirements of section 15(b) of the CPSA (15 U.S.C. 2064(b)). Even if a report of a choking hazard is not required by the proposed rule, a report may be necessary under section 15(b) of the CPSA (15 U.S.C. 2064(b)) and 16 CFR Part 1115. Several consumer groups said the agency should vigorously enforce the section 15(b) reporting obligation. The Commission plans to do so.

The remaining provisions of the regulation set forth the confidentiality, liability and penalty provisions that would apply to reporting in accordance with the proposed regulation published

below. These provisions were not controversial.

### C. Impact on Small Businesses

In accordance with section 3(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that this regulation will not have a significant economic impact upon a substantial number of small entities if issued on a final basis. Any obligations imposed upon such entities arise under the express provisions of section 102 of the Child Protection Safety Act, Pub. L. 103-267, June 17, 1994. The regulation simply implements the obligations imposed by that law. The regulation itself will not have a significant economic impact or small businesses, either beneficial or negative, beyond that which results from the statutory provisions.

# D. Environmental Considerations

The rule falls within the provisions of 16 CFR 1021.5(c), which designates categories of actions conducted by the Consumer Product Safety Commission that normally have little or no potential for affecting the human environment. The Commission does not believe that the rule contains any unusual aspects which may produce effects on the human environment, nor can the Commission foresee any circumstance in which the rule issued below may produce such effects. For this reason, neither an environmental assessment nor an environmental impact statement is required.

# E. Effective Date

This regulation will become effective 30 days after publication of the final regulation in the Federal Register. Subject firms should be aware, however, that the Child Safety Protection Act required reporting as of June 17, 1994.

List of Subjects in 16 CFR Part 1117

Administrative practice and procedure, Business and industry, Consumer protection, Toy safety, Penalties, Reporting and recordkeeping requirements, Small parts.

#### Conclusion

Therefore, pursuant to the authority of the Child Safety Protection Act (Pub. L. 103–267), section 16(b) of the CPSA (15 U.S.C. 2065(b)) and 5 U.S.C. 553, the CPSC amends Title 16 of the Code of Federal Regulations, Chapter II, Subchapter B by adding a new Part 1117 to read as follows:

## PART 1117—REPORTING OF CHOKING INCIDENTS INVOLVING MARBLES, SMALL BALLS, LATEX BALLOONS AND OTHER SMALL PARTS

1117.1 Purpose.

1117.2 Definitions.

1117.3 Reportable information.

1117.4 Time for filing a report.

1117.5 Information that must be reported and to whom.

1117.6 Relation to section 15(b) of the CPSA.

1117.7 Confidentiality of reports.

1117.8 Effect of reports on liability.

1117.9 Prohibited acts and sanctions.

Authority: Section 102 of the Child Safety Protection Act (Pub. L. No. 103–267), section 16(b), 15 U.S.C. 2065(b) and 5 U.S.C. 553.

#### §1117.1 Purpose.

The purpose of this part is to set forth the Commission's interpretative regulations for reporting of choking incidents required by the Child Safety Protection Act. The statute requires that each manufacturer, distributor, retailer, and importer of a marble, small ball, or latex balloon, or a toy or a game that contains a marble, small ball, latex balloon, or other small part, shall report to the Commission any information obtained by such manufacturer, distributor, retailer, or importer which reasonably supports the conclusion that an incident occurred in which a child (regardless of age) choked on such a marble, small ball, or latex balloon or on a marble, small ball, latex balloon, or other small part contained in such toy or game and, as a result of that incident the child died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional.

### §1117.2 Definitions.

(a) Small part means any component of a toy or game which, when tested in accordance with the procedures in 16 CFR 1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR part 1501.

(b) *Small ball* means any ball that under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (4.445 cm) in a rigid template .25 inches (6 mm.) thick. For purposes of this designation, the term "ball" includes any spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, or bounced, and is either not permanently attached to another toy or article, or is attached to such a toy or article by means of a string, elastic cord, or similar tether. The term "ball" includes any multi-sided object formed by connecting planes into a generally