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 part, component, or piece 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 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 tov 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 spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball.
- (c) Choked means suffered an obstruction of the airways.
- (d) A *latex balloon* is a toy or decorative item consisting of a latex bag that is designed to be inflated by air or gas. The term does not include inflatable children's toys that are used in aquatic activities, such as rafts, water wings, life rings, etc.
- (e) A *marble* is a ball made of a hard material, such as glass, agate, marble or plastic, that is used in various chil-

dren's games, generally as a playing piece or marker.

- (f) Serious injury includes not only the concept of "grievous bodily injury" defined in the Commission's rule for Substantial Hazard Reports at 16 CFR 1115.12(d), but also any other significant injury. Injuries necessitating hospitalization which require actual medical or surgical treatment and injuries necessitating absence from school or work of more than one day are examples of situations in which the Commission shall presume that such a serious injury has occurred.
- (g) Subject firm means any manufacturer, distributor, retailer or importer of marbles, small balls, latex balloons, or a toy or game that contains a marble, small ball, latex balloon, or other small part.
- (h)  $\bar{T}oy$  or game includes any toy or game, including those exempt under 16 CFR 1501.3 from the small parts banning provisions of 16 CFR 1500.18(a)(9).

[60 FR 10493, Feb. 27, 1995, as amended at 60 FR 41801, Aug. 14, 1995]

## §1117.3 Reportable information.

A subject firm shall report any information it obtains which reasonably supports the conclusion that a reportable incident occurred. Generally, firms should report any information provided to the company, orally or in writing, which states that a child choked on a marble, small ball, latex balloon, or on a marble, small ball, latex balloon or other small part contained in a 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. Subject firms must not wait until they have investigated the incident or conclusively resolved whether the information is accurate or whether their product was involved in the incident. Firms shall not wait to determine conclusively the cause of the death, injury, cessation of breathing or necessity for treatment. An allegation that such a result followed the choking incident is sufficient to require a report.

## $\S 1117.4$ Time for filing a report.

(a) A subject firm must report within 24 hours of obtaining information