process for child resistant cigarette lighters (16 CFR Part 1210, Subpart B).

The Commission carefully weighed the policy concerns raised by the commenters. A substantive rule would require firms to report the specified information and firms would be judged solely on whether they met the reporting requirements.

An interpretative rule should provide adequate guidance to firms as to what should be reported and the timeframes for reporting. Since reports cannot be used against firms, there are few disincentives to reporting under the CSPA than under section 15(b) of the CPSA. Assembling the limited information to report should pose only minimal burden on reporting firms. The Commission, therefore, concludes that while a substantive rule could be legally justified, it is unnecessary for policy reasons.

2. Section-by-Section Analysis of the Comments

(a) Section 1117.2—Definitions

Several industry commenters suggested that the Commission exempt from the choking hazard reporting requirement any products that are exempted from the small parts regulations at 16 CFR 1501.3 and small parts intended for adult assembly. Various consumer commenters opposed such changes. The Commission exempted certain items from the small parts ban because it believed that the risk of injury posed by the product was outweighed by some functional benefit of the product. Balloons, books, writing materials, clothing and other items were exempted.

Unlike a ban, the requirement to report hazards does not interfere with the sale of the exempt product, and the choking hazard report does not place an extraordinary burden on the reporting firm. Congress did not limit the reporting obligation to only those products subject to the small parts regulation. In fact, it specifically included categories of products that were subject to the exceptions or not covered by the small parts ban at 16 CFR Part 1501 (balloons, toys and games intended for use by the children 3 and older). With the exception of balloons which are specifically mentioned in the reporting provision, the Commissioners could not agree as to whether the choking hazard reporting provision applies to products that would have been exempt from the small parts requirements. Accordingly, that issue will remain unresolved until such time as a majority of the Commission concurs on its resolution. Pending that

resolution, reporting on these products exempt under section 1501.3 of Title 16 is not required.

(b) Section 1117.2(b)—Small Balls

One comment suggested that manufacturers of items with inaccessible small balls, such as pinball machines, should not have to report choking hazards with those balls. The Commission disagrees. Since the purpose of this provision is to inform the agency of choking hazards, the only salient factor is whether someone choked on a ball. If the ball is incorporated in a pinball machine but somehow got out and caused a choking, that is the very kind of information firms should be reporting to the Commission. If a ball is truly inaccessible, then there will be no choking incidents to report.

The Commission made a minor change to section 1117.2(b) spelling out the procedure for identifying small balls in this section rather than incorporating it by reference.

(c) Section 1117.2—Choked

Several commenters suggested changes in the definition of the word "choked." Some manufacturers thought the definition of "choked" in the regulation as "obstruction of the airways" was too vague. Some suggested that under this provision a momentary cessation of breathing might be considered a choking. Another suggested that the definition be changed to the Red Cross description in *First Aid & Safety*, (American Red Cross 1993, pp. 44, 91). Various consumer groups supported the proposed definition.

As Congress did not define the word "choked," the Commission proposal gave a dictionary definition of "choked" that is commonly understood by the public and health professionals. The definition of "choked" does not provide all the diagnostic guidance in the Red Cross document cited by one manufacturer. That document suggests "[i]f a child is coughing weakly or is making a high-pitched sound or if the child cannot speak, breathe, or cough, the airway is completely blocked." [Emphasis added.] This statement recognizes that the blockage of the airway is the essence of choking. While this Red Cross diagnostic guidance may be useful to firms in determining whether an airway was in fact obstructed, it is not a definition of choking.

Other commenters suggest that hiccuping or swallowing might be interpreted as obstructing the airway. The Commission does not intend that the definition cover such natural

phenomena. "Choked" in this context refers only to obstruction of an airway by a small part, balloon, small ball or marble, not to a natural functions such as swallowing.

(d) Section 1117.2(f)—Serious Injury

The proposal included a definition of serious injury drawn from the Commission's Substantial Product Hazard rule, 16 CFR at 1115.6(c). Although none of the commenters pointed it out, that definition includes various harms such as lacerations and fractures not likely to directly result from choking. The Commission has decided to amend the definition of serious injury to delete references to such inquries.

(e) Section 1117.3—Reportable Information

Section 1117.3 of the proposed rule emphasizes that subject firms must report whenever they obtain sufficient information to put a reasonable firm on notice of a reportable choking incident. The reporting provision originated in the Senate, and the Report of the Senate Committee on Commerce, Science and Transportation states this provision requires subject firms to "report to the CPSC any information obtained that supports the conclusion that an incident occurred in which a child, regardless of age, choked on such a product and, as a result of such choking incident, the child died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional." [Emphasis added. (S. Rep. No. 195, 103d Cong., 2d Sess. 10 (1993).] Under the proposed rule, if the allegations received by the firm meet the statutory test (choking on one of the specified products or small parts leading to a cessation of breathing or other specified effects) then no further inquiry is necessary.

Several industry commenters wanted time to investigate choking incidents. Many suggested 10 days. Essentially, they argue they should not be forced to take at face value the word of parents, physicians, attorneys, and others about an incident. They contend the Commission might be burdened with unreliable reports. They also argued that this provision could require them to report a choking incident involving someone else's product and objected to having to do so. Finally, at least one firm objected to the term "ceased breathing for any length of time" since it might require the report of a momentary cessation of breathing. Consumer group commenters approved of this provision, noting that it relieves firms of the obligation to investigate and