recordkeeping requirements, United States investments abroad.

Dated: February 2, 1995.

Carol S. Carson,

Director, Bureau of Economic Analysis.

For the reasons set forth in the preamble, BEA amends 15 CFR Part 806 as follows:

PART 806—DIRECT INVESTMENT SURVEYS

1. The authority citation for 15 CFR Part 806 is revised to read as follows:

Authority: 5 U.S.C. 301; 22 U.S.C. 3101–3108; and E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12013 (3 CFR, 1977 Comp., p. 147), E.O. 12318 (3 CFR, 1981 Comp., p. 173), and E.O. 12518 (3 CFR, 1985 Comp., p. 348).

§ 806.14 [Amended]

2. Section 806.14(e) is amended by removing ''$15,000,000'' and adding ''$20,000,000'' in its place.

[FR Doc. 95–4631 Filed 2–24–95; 8:45 am]

BILLING CODE 3510–EA–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1117

Interpretative Regulations for Reporting Choking Incidents to the Consumer Product Safety Commission Pursuant to the Child Safety Protection Act

AGENCY: Consumer Product Safety Commission (CPSC).

ACTION: Final rule.

SUMMARY: The ''Child Safety Protection Act'' requires manufacturers, distributors, retailers, and importers of marbles, small balls, latex balloons, and toys or games that contain such items or other small parts, to report to the Commission when they learn of choking incidents involving such products. The Commission is issuing a rule to implement this reporting requirement.

DATES: This regulation becomes effective March 29, 1995.

FOR FURTHER INFORMATION CONTACT: Eric L. Stone, Office of Compliance and Enforcement, CPSC, 4440 East West Highway, Bethesda, MD 20814 (Mailing address: Washington, D.C. 20207), telephone (301) 504–0626 extension 1350.

SUPPLEMENTARY INFORMATION:

A. Background

Section 102 of the Child Safety Protection Act, (Pub. L. No. 103–267 (June 17, 1994) (''the Act'' or the ''the CSPA'') requires:

Each manufacturer, distributor, retailer and importer of marble, small ball, or latex balloon, or a toy or 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—

(A) 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

(B) 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.

A failure to report is a prohibited act under section 19(a)(3) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2068(a)(3), punishable by civil penalties under section 20 of the CPSA, 15 U.S.C. 2069. The Act provides a high degree of confidentiality for choking reports. Reports shall not be interpreted as admissions of liability or of the truth of the information in the reports.

On July 1, 1994, the Commission proposed a rule to define several terms and resolve ambiguities and uncertainties in the statutory reporting scheme. (59 F.R. 33927) The Commission received over 200 comments from consumer groups, medical professionals, and individual consumers. Generally, these comments supported the proposed rule. Manufacturers, trade associations, testing labs, attorneys and others commented on behalf of industry. Generally, these groups sought to limit the reporting requirements and allow firms more time and discretion. In all, over 260 comments were received and analyzed.

B. Consideration of the Comments

1. Substantive Versus Interpretative

Several manufacturers, trade associations and industry consultants objected to this rule being issued as a substantive rule. Generally, these commenters believed interpretative rules were more appropriate. Consumers and consumer groups supported issuance of substantive rules.

The business commenters argued (1) a substantive rule would be binding and would eliminate the opportunity to challenge the Commission's interpretation of the reporting requirement on a case-by-case basis; (2) the Commission did not issue other reporting rules under section 15(b) or 37 of the CPSA as substantive rules; (3) since, unlike the provisions of section 101(c) of the Child Safety Protection Act, Congress did not grant the Commission specific authority to issue this rule, the Commission should limit itself to an interpretative rule; (4) section 16(b) of the CPSA is a recordkeeping and inspection provision and was not intended to be used for reporting rules except those limited to inspections; and (5) given the tight timeframes for reporting, the rule should be interpretative.

Section 102(a)(2) of the Child Safety Protection Act provides that ''[f]or purposes of section 19(a)(3) of the Consumer Product Safety Act [15 U.S.C. 2068(a)(3), describing prohibited acts], the requirement to report information under this subsection is deemed to be a requirement under such Act.'' While the Act does not explicitly require the Commission to issue rules to implement it, the Commission believes that Congress intended the entire reporting section to be considered part of the CPSA. The Commission believes its general authority under section 16(b) to issue rules concerning reporting applies.

Section 102 left unanswered several questions about reporting procedures and the contents of the report. The Commission has an obligation to further define the reporting obligation outlined in the statute through rulemaking and it has the authority to do so.

Section 16(b) of the CPSA (15 U.S.C. 2065(b)) authorizes the Commission to require manufacturers, private labelers and distributors to ''make such reports * * * as the Commission may, by rule, reasonably require for the purposes of implementing this Act.'' A failure to make reports or provide information under section 16(b) of the CPSA (15 U.S.C. 2065(b)) is a prohibited act under section 19(a)(3) of the CPSA (15 U.S.C. 2068(a)(3)). The Commission proposed this rule under section 102 of the Act and section 16(b) of the CPSA (15 U.S.C. 2065(b)).

Although section 16(b) falls within a section titled ''Inspection and Recordkeeping,'' the language of the provision does not by its terms limit reporting solely to an inspectional context. The Commission has consistently taken this ''plain language'' view of section 16(b). The Commission cited section 16 as part of the authority for the section 15(b) reporting regulations codified in 16 CFR Part 1115. In addition , the Commission has relied on section 16(b) for authority to require reports in the certification

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

determine whether the incident was real. They contend this provision will lead to quicker reports. The consumer groups also argued that firms under-report under section 15(b) of the CPSA and argued against giving firms leeway to avoid reporting under this provision.

The Commission is skeptical about how much additional information a firm might obtain in even a ten day period. If the person notifying the firm of an incident is unreliable, it is difficult to see how the firm would obtain useful information within that timeframe. Sometimes, firms do not learn the full details of such incidents until months or years later and then, only after extensive discovery in litigation. An additional 10 days is not likely to greatly assist a firm in determining whether the statement made to it by a parent, attorney, physician, or other person is true.

Based on its experience with section 15(b) of the CPSA, the Commission believes an immediate report may save lives. As a report involves a minimal burden on the reporting firm and cannot be used against the firm as an admission, there is little reason not to provide an immediate report. Since this statutory reporting provision went into effect in June 1994, the Commission has received only a handful of reports. After examining these reports, the Commission does not share the concern of some industry commenters that the Commission will be deluged with spurious reports.

This provision does not require manufacturers, distributors and retailers to report incidents which they know were not caused by their product. However, if they are informed of an incident which allegedly involved their product they should report unless a reasonable person would conclude their product was not involved. While it is conceivable a parent, attorney, physician or other party might mistakenly notify a firm that its product caused a reportable choking incident, that is not likely to be a common event. Moreover, if a firm's product is so similar to the object that caused the choking incident that it is mistakenly identified, it may present the same risk. The public benefits if firms err on the side of reporting. For the reasons enumerated above, the Commission has not changed this provision.

Section 102 of the CSPA states that reports are due if the child choked and ''ceased breathing for *any length of time*.'' [Emphasis added.] This language suggests that whether the cessation of breathing was momentary or prolonged, a report must be filed. Whether a parent or child succeeds in dislodging the time within a second, a minute, or never, the incident is still reportable. The Commission staff has received questions about whether this requires firms to report a child swallowing something, sneezing, or hiccuping. As noted earlier, the intent of this provision is to obtain reports of choking incidents, not incidents where a child swallowed something, or hiccuped. The Commission believes the words ''ceased breathing for any length of time'' are unambiguous. It sees no reason to provide further definition than is provided by the statute.

(f) Sections 1117.3 and 1117.4—Time for Filing a Report

A number of manufacturers, Members of Congress, trade associations, and industry consultants suggested the Commission give firms 10 days to route choking information to an appropriate corporate official, conduct a reasonable investigation, and assemble the information that must be reported. They point to the 10 day period for investigation of death and grievous bodily injury under 16 CFR 1115.12(d) and 1115.14(d) and the 30 days for law suit reporting allowed by section 37 of the CPSA as precedents. They also note that the statute did not specify a timeframe for reporting and, therefore, left the Commission with discretion to allow a longer time period. Many consumer groups and consumers supported the proposal's 24 hour requirement as an important lifesaving requirement.

If Congress did not expect immediate reporting it could have specified a time frame, such as the 30 days it provided in section 37 of the CPSA. It did not do so. Therefore, the Commission believes the legislative intent was to require immediate reporting. In the Commission's experience, immediate reporting may prevent additional choking incidents or deaths.

The 24 hour reporting requirement in this rule is consistent with the 24 hour requirement in the Commission's section 15(b) rules. The section 15(b) rules require firms to immediately report once they have obtained reportable information. Firms are given ten days to analyze whether an obligation to report exists under section 15(b) only when the obligation to report *is not immediately clear*. (Firms must report a death allegedly caused by a defect in their product if they cannot within a reasonably expeditious—usually 10 day—investigation determine the defect that caused the death does not trip the ''could create a substantial hazard'' reporting trigger of Section 15(b).) Section 15(b) requires firms to evaluate a wide range of information to determine whether the product contains a defect which could create a substantial risk or presents an unreasonable risk of serious injury or death. In contrast, the CSPA's choking reporting requirement is simple. A firm has either learned of an incident that meets the statutory criteria, or it hasn't. In addition, the content of a choking hazard report is limited compared to a ''full report'' under section 15(b) of the CPSA. For the reasons set forth above, the Commission declines to change the twenty four hour requirement.

In the event a firm obtains information indicating that a child choked, without any allegation of cessation of breathing, death or other triggering event, or without clear allegations that a small part, balloon, marble, or small ball was involved, the firm may investigate to determine whether a reportable incident has occurred. The firm does not have an obligation to report until it has learned that the choking incident did cause a death, cessation of breathing or other triggering incident.

The Commission has modified the final rule to adopt an imputation of knowledge provision identical to the one in its section 15 rules. This new provision is found at section 1117.4(b). In evaluating whether or when a subject firm should have reported, the Commission will deem a subject firm to have obtained reportable information when the information has been received by an official or employee who may reasonably be expected to be capable of appreciating the significance of the information. Section 1117.4(b) notes the Commission believes this process should usually occur within five days. However, if firms are capable of transmitting choking hazard data to a responsible official within a shorter timeframe, they should not wait five days.

(g) Section 1117.5—Content of Reports

Proposed section 1117.5 describes the information that firms must report. The Commission proposal attempted to limit the reporting requirements to information necessary to give the Commission staff sufficient information to understand the nature and content of the choking incident and to determine whether corrective measures may be necessary. Nevertheless, several manufacturers and trade associations had questions or concerns about the information that must be submitted.

At the outset, it should be noted that much of the information that must be reported under section 1117.5(b) will be contained in the letter or other record of contact with the person notifying the

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

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 children'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.

§ 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.

§ 1117.4 Time for filing a report.

(a) A subject firm must report within 24 hours of obtaining information which reasonably supports the conclusion that an incident occurred in which a child (regardless of age) choked on a marble, small ball, or 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. Section 1117.5 of this part sets forth the information that must be reported.

(b) The Commission will deem a subject firm to have obtained reportable information when the information has been received by an official or employee who may reasonably be expected to be capable of appreciating the significance of the information. Under ordinary circumstances, 5 days shall be the maximum reasonable time for information to reach such an employee, the Chief Executive Officer or the official or employee responsible for complying with the reporting requirements of section 102 of the Child Safety Protection Act.

§ 1117.5 Information that must be reported and to whom.

(a) Reports shall be directed to the Division of Corrective Actions, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20815 (Mailing Address: Washington, D.C. 20207) (Phone: 301–504–0608, facsimile: 301–504–0359).

(b) Subject firms must report as much of the following information as is known when the report is made:

(1) The name, address, and title of the person submitting the report to the Commission,

(2) The name and address of the subject firm,

(3) The name and address of the child who choked and the person(s) who notified the subject firm of the choking incident,

(4) Identification of the product involved including the date(s) of distribution, model or style number, a description of the product (including any labeling and warnings), a description of the marble, small ball, latex balloon or other small part involved, and pictures or sample if available,

(5) A description of the choking incident and any injuries that resulted or medical treatment that was necessary,

(6) Copies of any information obtained about the choking incident,

(7) Any information about changes made to the product or its labeling or warnings with the intention of avoiding such choking incidents, including, but not limited to, the date(s) of the change and its implementation, and a description of the change. Copies of any engineering drawings or product and label samples that depict the change(s).

(8) The details of any public notice or other corrective action planned by the firm,

(9) Such other information as appropriate.

(c) Retailers or distributors should supply as much of the information required in paragraph (b) of this section as is available to them but are not required to obtain information about product design changes or recall activities from the product manufacturer.

(d) Within ten days of their initial report, subject firms must supplement their reports to supply any of the information required by paragraph (b) of this section that was not available at the time of the initial report.

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

Section 15(b) of the CPSA requires subject firms to report when they obtain information which reasonably supports the conclusion that products they distributed in commerce fail to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA, contain a defect which could create a substantial product hazard, or create an unreasonable risk of serious injury or death. The Commission's rules interpreting this provision are set forth at 16 CFR part 1115. The requirements of section 102 of the CSPA and this part are in addition to, but not to the exclusion of, the requirements in section 15(b) and part 1115. To comply with section 15(b), subject firms must continue to evaluate safety information they obtain about their products. Subject firms may have an obligation to report under section 15(b) of the CPSA whether or not they obtain information about choking incidents. Firms must also comply with the lawsuit-reporting provisions of section 37 of the CPSA, interpreted at 16 CFR part 1116.

§ 1117.7 Confidentiality of reports.

The confidentiality provisions of section 6 of the CPSA, 15 U.S.C. 2055, apply to reports submitted under this part. The Commission shall afford information submitted under this part the protection afforded to information submitted under section 15(b), in accordance with section 6(b)(5) of the

CPSA and subpart G of part 1101 of title 16 of the CFR.

§ 1117.8 Effect of reports on liability.

A report by a manufacturer, distributor, retailer, or importer under this part shall not be interpreted, for any purpose, as an admission of liability or of the truth of the information contained in the report.

§ 1117.9 Prohibited acts and sanctions.

(a) Whoever knowingly and willfully falsifies or conceals a material fact in a report submitted under this part is subject to criminal penalties under 18 U.S.C. 1001.

(b) A failure to report to the Commission in a timely fashion as required by this part is a prohibited act under section 19(a)(3) of the CPSA, 15 U.S.C. 2068(a)(3).

(c) A subject firm that knowingly fails to report is subject to civil penalties under section 20 of the CPSA, 15 U.S.C. 2069. ''Knowing'' means the having of actual knowledge or the presumed having of knowledge deemed to be possessed by a reasonable person who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations. Section 20(d) of the CPSA, 15 U.S.C. 2069(d).

(d) Any person who knowingly and willfully violates section 19 of this Act after having received notice of noncompliance from the Commission may be subject to criminal penalties under section 21 of the CPSA, 15 U.S.C. 2070.

Dated: February 17, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 95–4483 Filed 2–24–95; 8:45 am]

BILLING CODE 6355–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 93C–0380]

Listing of Color Additives for Coloring Contact Lenses; 1,4-Bis[4-(2-Methacryloxyethyl) Phenylamino]Anthraquinone Copolymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of the colored reaction product formed by copolymerizing 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone with 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate (CAS Reg. No. 134072–99–4) and *N*-vinyl pyrrolidone to form contact lenses. This action is in response to a petition filed by Bausch & Lomb, Inc.

DATES: Effective on March 30, 1995, except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by March 29, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3092.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of November 3, 1993 (58 FR 58699), FDA announced that a color additive petition (CAP 3C0242) had been filed by Bausch & Lomb, Inc., 1400 North Goodman St., Rochester, NY 14692–0450. The petition proposed that the color additive regulations be amended in § 73.3106 *1,4-Bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymers* (21 CFR 73.3106) to provide for the safe use of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymerized with *N*-vinyl pyrrolidone and 3[tris(trimethylsiloxy)silyl] propyl vinyl carbamate to form contact lenses. The filing notice erroneously indicated that the petition was filed under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(b)(5)). The correct section of the act is 721(d)(1) (21 U.S.C. 379e(d)(1)).

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 (Pub. L. 94–295), Congress mandated the listing of color additives for use in medical devices when the color additive in the device comes in direct contact with the body for a significant period of time (21 U.S.C. 379e(a)). The use of the reaction product of 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymerized with 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate and *N*-vinyl pyrrolidone as a color additive in manufacturing contact lenses is subject to this listing requirement. The color additive is formed into contact lenses in such a way that at least some of the color additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed on the eye for several hours a day, each day, for 1 year or more. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the use of the color additive currently before the agency is subject to the statutory listing requirement.

III. Identity

The color additive, when used to color contact lenses, is produced by copolymerizing the dye 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone (CAS Reg. No. 121888–69–5) with 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate (CAS Reg. No. 134072–99–4) and *N*-vinyl pyrrolidone monomers. The dye 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone covalently bonds through two methacrylate groups to the polymer matrix during polymerization. The resulting copolymeric product is formed into a contact lens.

IV. Safety Evaluation

The agency believes that because 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone has a significantly lower molecular weight than the *N*-vinyl pyrrolidone/3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate/1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymer, it would be more readily absorbed into the body than the copolymeric color additive and would thus be expected to show a greater toxic effect. Therefore, the safety evaluation of the subject color additive focused primarily on 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone.

FDA concludes, from the data submitted in the petition and from other relevant information, that the maximum daily exposure to 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone from this petitioned use in contact lenses would be no greater than 0.08 micrograms per person per day (μg/p/d). The agency-calculated upper limit was based on two factors. First, the maximum use level anticipated by the petitioner is 300 parts per million (ppm) of the lens material or 15 μg of 1,4-bis[4-(2-methacryloxyethyl)