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Consumer Product Safety Commission

16 CFR Part 1240
Final Rule: Safety Standard for Magnet Sets; Final Rule

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1240

[CPSC Docket No. CPSC–2012–0050]

Final Rule: Safety Standard for Magnet Sets

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission (CPSC, Commission, or we) is issuing a rule establishing requirements for magnet sets and individual magnets that are intended or marketed to be used with or as magnet sets. As defined in the rule, magnet sets are aggregations of separable magnetic objects that are marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. Under the rule, if a magnet set contains a magnet that fits within the CPSC's small parts cylinder, each magnet in the magnet set must have a flux index of 50 kG^2 mm^2 or less. An individual magnet that is marketed or intended for use as part of a magnet set also must meet these requirements. The flux index is determined by the method described in ASTM F963–11, Standard Consumer Safety Specification for Toy Safety.

DATES: This rule will become effective on April 1, 2015. The incorporation by reference of the publication listed in this rule is approved by the Director of the **Federal Register** as of April 1, 2015.

FOR FURTHER INFORMATION CONTACT: Thomas Lee, Compliance Officer, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7737, or email: *tlee@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The Commission is issuing a safety standard under the Consumer Product Safety Act (CPSA) establishing requirements for magnet sets that have been associated with serious injuries and one reported death.[1] As discussed in greater detail in section B of this preamble, magnet sets are sets of small, powerful magnets marketed for general entertainment as construction toys, desk toys, sculpture sets, or stress relievers. The rule also covers individual magnets that are marketed or intended for use with or as magnet sets. The Commission concludes that this rule is necessary to address an unreasonable risk of injury and death associated with these magnet sets.

1. Initial Incident Reports to CPSC and CPSC's Response

Significant U.S. sales of magnet sets marketed for general entertainment began in 2009. CPSC staff received the first consumer incident report involving magnet sets in February 2010. No injury resulted from this incident. Shortly after receiving this report, CPSC staff collected and evaluated samples of the magnet sets.

In December 2010, we received our first consumer incident report involving the surgical removal of magnets that had been part of a magnet set. During 2011, CPSC staff collected magnet sets marketed to children under 13 years old, and staff evaluated the compliance of these products with ASTM F963–11, *Standard Consumer Safety Specification for Toy Safety.* Staff evaluated these products under ASTM F–963 because some of the products were labeled and marketed in a manner that appeared to promote use by children and this standard includes requirements for the strength and size of magnets that are part of a toy intended for children. For firms whose products did not have labeling or marketing information, CPSC staff encouraged those firms to develop marketing programs and labeling content to help ensure that these magnet sets were not marketed to children. In addition, CPSC staff issued Notices of Noncompliance to firms that marketed magnet sets to children younger than 14 years of age.

In November 2011, in response to continuing reports of injuries associated with the products, the CPSC, in cooperation with two manufacturers, launched a public awareness campaign, which included a video public service announcement (PSA). The PSA advised children: Not to put magnets from magnet sets into their mouth; described the risk of injury presented by the ingestion of high-powered magnets; and provided tips to avoid magnet ingestion injuries, along with guidance for children who had swallowed magnets and parents who suspect that their child has swallowed magnets. Despite the CPSC's compliance and public awareness activities, reported incidents of magnet ingestion by children increased from 13 in 2010, to 19 in 2011, and 52 in 2012. Likely due to CPSC enforcement and regulatory activity beginning in mid-2012, and because the largest distributor ceased operations at the end of 2012, reported incidents declined to 13 incidents in 2013, including one fatality, and two incidents in 2014. We received an additional magnet ingestion incident report for which there was insufficient information to determine the date of the incident. As of June 24, 2014, 100 ingestion incidents involving, or possibly involving, ingestion of magnets from magnet sets have been reported to CPSC. (As discussed in section C of this preamble, staff's analysis of incidents reported through the National Electronic Injury Surveillance System (NEISS) estimates that 2,900 possible magnet set, emergency department-treated ingestions occurred in the United States from January 1, 2009 through December 31, 2013).

2. Corrective Actions

In May 2012, Compliance staff contacted a total of 13 independent importers of magnet sets and asked these importers to provide reports required under Section 15 of the CPSA. Most of the firms agreed to stop selling the products pending the results of staff's evaluation of the products. Given the continued injuries to children, staff negotiated voluntary corrective action plans with 11 of the 13 magnet set importers. These firms agreed to cease importation, distribution, and sales of magnet sets. Two importers did not agree to stop selling the magnets and the Commission initiated an administrative action in July and August 2012 seeking a determination that the magnet sets present a substantial product hazard and an order that the firm cease importation and distribution of the products. The Commission initiated a third administrative action in December 2012 after one of the firms that had agreed to stop sale subsequently resumed selling magnet sets. Two of the three administrative actions have been resolved. In May 2014, the Commission settled the administrative action against Maxfield & Oberton Holdings, LLC, and Craig Zucker, individually, and as an officer of Maxfield & Oberton Holdings, LLC. The settlement established and funded a Recall Trust, which, in accordance with a corrective action plan (CAP), is recalling the firm's magnet sets. In July 2014, the Commission settled the administrative complaint against Star Networks USA, LLC (Star). Under that settlement, Star has agreed to implement a CAP providing for the recall of the firm's magnet sets. The third firm, Zen Magnets, LLC, remains the subject of a CPSC administrative

[1] The Commission voted 4–0–1 to publish this notice in the **Federal Register**. Chairman Elliot F. Kaye, Commissioner Robert S. Adler, Commissioner Marietta S. Robinson and Commissioner Joseph P. Mohorovic voted to approve publication of the final rule. Commissioner Ann Marie Buerkle abstained from the matter.

action and continues to market and sell magnet sets.

3. Notice of Proposed Rulemaking

In the **Federal Register** of September 4, 2012 (77 FR 53781), the Commission published a notice of proposed rulemaking (NPR) to address the unreasonable risk of injury associated with magnet sets. The NPR proposed a standard that would require magnets from magnet sets containing at least one magnet that fits within the CPSC's small parts cylinder to have a flux index of 50 kG^2 mm^2 or less. The proposed rule sought comment on whether the rule should include magnets sold individually that could be aggregated into a magnet set. The final rule modifies the proposal to include individual magnets marketed or intended for the same uses as a magnet set, *i.e.,* as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. We discuss this modification and other differences between the proposed and final rule in Section F of this preamble. The information discussed in this preamble comes from CPSC staff's briefing packages for the proposed and final magnet set rule, which are available on the CPSC's Web site at: *http://www.cpsc.gov/PageFiles/128934/magnetstd.pdf* (NPR briefing package) and *http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2014/SafetyStandardforMagnetSets-FinalRule.pdf* (final rule briefing package).

B. The Product

1. Description of the Product

The magnet sets covered by this rule typically are comprised of numerous identical, spherical, or cube-shaped magnets, approximately 3 millimeters to 6 millimeters in size, with the majority made from NdFeB (Neodymium-Iron-Boron or NIB). As discussed in section F of this preamble, the rule also covers individual magnets that are marketed or intended for use with or as magnet sets. These magnets exhibit strong magnetic properties. The magnetized neodymium-iron-boron cores are coated with a variety of metals and other materials to make them more attractive to consumers and to protect the brittle magnetic alloy materials from breaking, chipping, and corroding.

The magnets that are part of magnet sets are often referred to as ''magnet balls'' or ''rare earth magnets.'' Magnet sets are and have been marketed as: adult desk toys, the ''puzzles of the future,'' stress relievers, science kits, and educational tools for ''brain development.'' As shown in product instructions and in videos on related Web sites, magnet sets can be used and reused to make various two- and three-dimensional sculptures and figures, jewelry, and toys, such as spinning tops. Videos also show how these magnets can be used to mimic mouth and tongue piercings.

Magnet sets come with varying numbers of magnets, from as few as 27 magnets, to more than 1,000. Most of the magnets have been sold in sets of 125 balls or sets of 216 to 224 balls. The one firm that is currently marketing magnet sets that would not meet this rule sells one or more balls individually. Based on product information provided by marketers, the most common magnet size is approximately 5 millimeters in diameter, although balls as small as about 3 millimeters have been sold, as have sets of larger magnet balls (perhaps 15 millimeters to 25 millimeters in diameter). In addition to magnetic ball sets, magnet sets comprised of small magnetic cubes have also been sold, as have small magnetic rods. Sets made up of rods, however, have comprised a relatively small share of the market.

Most magnet sets contain magnets that are glossy and highly reflective with the spheres often described as similar in appearance to BBs or ball bearings. Magnet set magnets come in a variety of colors, including silver, blue, yellow, green and orange. The products are packaged in a variety of ways, including fabric pouches, wooden boxes, and metal tins.

The rule defines ''magnet set'' as: ''any aggregation of separable magnetic objects that is a consumer product intended, marketed or commonly used as a manipulative or construction item for general entertainment, such as puzzle working, sculpture, mental stimulation, or stress relief.'' As discussed in section F of this preamble, the rule also covers individual magnets marketed or intended for use with magnet sets.

2. Use of the Product

For the NPR, CPSC's Human Factors staff provided an assessment that discusses the appeal and use of magnet sets. Magnet sets have some appeal for virtually all age groups. These types of magnets tend to capture attention because they are shiny and reflect light. They are smooth, which gives the magnets tactile appeal, and these magnets make soft snapping sounds as they are manipulated. These properties or characteristics of magnets are likely to seem magical to younger children and may evoke a degree of awe and amusement among older children and teens. These features are the foundation of the magnet sets' appeal as a challenging puzzle, or as a manipulative, or as jewelry. These magnets may also be used like a stress ball and as a way to hold things in place.

Children, from toddlers through teens, have been exposed to magnet sets in the home setting and elsewhere. As the NPR preamble notes, we have reports of ingestion incidents that involve children 5 years of age and younger. The reports reflect similar scenarios to other ingestion incidents among this age group because mouthing and ingesting non-food items is a normal part of preschool children's exploratory behavior. In a number of reported incidents, the magnets were not in their original containers, and caregivers were unaware that some of the magnets from the set were missing and in the child's possession.

As noted in the NPR preamble, magnet sets also appeal to children of early-to-middle elementary school age. Younger children in this age group are interested in simple three-dimensional puzzles, and older elementary school children are interested in highly complex puzzles. Children in the latter age group also can engage in activities that require the type of meticulous work and attention that would be needed to create the complex patterns and structures found on paper and in video instructions for magnet sets. Additionally, magnets typically are included in science curricula for elementary school children to demonstrate the basic concepts of magnetism.

For all of these reasons, and consistent with reviews on retail Web sites, magnet sets are sometimes purchased for children under the age of 14, despite warnings or labeling to the contrary. For example, approximately one-third of 53 adults reviewing one manufacturer's product on Amazon.com reported purchasing the magnets for children 8 through 11 years of age.

Thus, it is foreseeable that some portion of these products will be purchased for elementary school children and teens. Moreover, given the relatively low cost for some magnet sets, elementary school children and teens may purchase the magnet sets themselves. The incident reports reflect behaviors that are beyond the intended use of the product but that are foreseeable for the groups using them. For example, it is foreseeable that some children will place these magnets in their mouth, even if the manufacturer

warns against this behavior. The mouthing of objects, common among younger children, develops into less obvious and more socially acceptable oral habits, which may continue through childhood and adolescence and into adulthood (*e.g.,* mouthing or chewing a fingertip, fingernail, knuckle, pen, pencil, or other object, especially while concentrating or worrying). Where details are provided, the incident reports describe scenarios that are consistent with the behaviors of young children and teens. Although exploratory play is generally associated with very young children, people of all ages use their senses to explore unfamiliar phenomena. 77 FR 53781, 53783 (Sep. 4, 2012).

3. The Market

Based on information reviewed by staff on product sales, including reports by firms provided to the Office of Compliance and Field Operations, the number of magnet sets that were sold to U.S. consumers from 2009 through mid-2012, may have totaled about 2.7 million sets, with a value of roughly $50 million. This estimate reflects retail sales directly to consumers (through company Web sites and other Internet retail sites) and sales to retailers who market the products. Staff's review of retail prices reported by importers, and observed on Internet sites in 2012, suggested prices of magnets sets typically ranging from about $20 to $45 per set, with an average price of about $25.

To our knowledge, all of the firms that have marketed the products, including the firm that continues to sell individual magnets and magnet sets, import the products packaged and labeled for sale to U.S. consumers. Several Chinese manufacturers have the facilities and production capacity to meet the orders of U.S. importers. Additionally, there are no major barriers to market entry for firms wishing to source products from China for sale in the United States. Firms may have sales arrangements with Internet retailers who hold stock for them and process orders.

We have identified about 25 U.S. firms and individuals who imported magnet sets for sale in the United States in 2012. The combined sales of the top seven firms probably have accounted for the great majority (perhaps more than 90%) of units sold. One firm, Maxfield & Oberton Holdings, LLC, believed to have held a dominant position in the market for magnetic desk sets since the firm entered the market in 2009, ceased operating in December 2012, and is no longer an importer of magnet sets. That now-defunct firm, along with a few larger firms (including a firm based in Canada with a branch office in the United States), marketed their products through accounts with retailers. They have also sold their products directly to consumers via the Internet, using their own Web sites, or other Internet shopping sites. In addition to products offered for sale by U.S. importers, consumers also have the ability to purchase magnetic sets directly from sources in Hong Kong or China that market products through a leading Internet shopping site.

C. Risk of Injury

The risk of injury addressed by this rule is damage to intestinal tissue caused when a person ingests more than one magnet from a magnet set (or one magnet and a ferromagnetic object). The magnets are attracted to each other in the digestive system, damaging the intestinal tissue that becomes trapped between the magnets. In rare cases, there can be interaction between magnets in the airways and digestive tract (esophagus). These injuries can be difficult to diagnose and treat because the symptoms of magnet ingestion often appear similar to those of less serious conditions, such as the flu, and because many doctors are unfamiliar with the risks of magnet ingestion. In addition, the limitations of standard diagnostic tools to identify and evaluate the presence of magnets in the body may make magnet ingestion difficult to identify. Serious injury and even death are consequences of ingestion of strong magnets by children.

1. Incident Data

NEISS data. CPSC staff reviewed data from the NEISS database of magnet-related ingestion cases treated in emergency departments from January 1, 2009 to December 31, 2013.[2] CPSC staff analyzed 456 magnet-related ingestion cases and determined that 121 of the cases involved or possibly involved ingestion of magnets from magnet sets. Staff further determined that an estimated 2,900 ingestions of magnets from magnet sets were treated in U.S. emergency departments during this 5-year period—an estimated average of 580 emergency department-treated magnet ingestions per year. The largest portion of these incidents involved children 4 through 12 years of age. An estimated 1,900 of the 2,900 victims are in the 4- through 12-year-old age group (65.3 percent). For more information about the process of developing the estimates of incidents, see the memorandum from the Directorate for Epidemiology, located at Tab B of staff's briefing package: *http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2014/SafetyStandardforMagnetSets-FinalRule.pdf.*

Databases other than NEISS. The preamble to the proposed rule (77 FR at 53784 through 53785) summarized the data for incidents reported through databases other than NEISS from January 1, 2009 through June 30, 2012. These incidents involved the ingestion of magnets by children between the ages of 1 and 15. For that period, we received reports of 50 incidents involving the ingestion of magnets by children in this age range. Of those 50 incidents, 38 involved the ingestion of high-powered, ball-shaped magnets contained in products that meet the definition above of ''magnet set''; five of the 50 incidents possibly involved ingestion of this type of magnet. In 35 of the 43 incidents involving or possibly involving magnets from a magnet set, two or more magnets were ingested. Hospitalization was required in 29 of the 43 incidents, with surgery necessary to remove the magnets in 20 of the 29 hospitalizations. In the other nine hospitalizations, the victim underwent colonoscopic or endoscopic procedures to remove the magnets. In 37 of the 43 incidents, the magnets were ingested by children younger than 4 years old or between the ages of 4 and 12 years.

Since publication of the NPR, the Commission has received reports of additional incidents involving the ingestion of magnets by children between the ages of 1 year and 15 years old, including one report of a fatality associated with the ingestion of small spherical magnets. We have now received reports of a total of 100 incidents involving or possibly involving the ingestion of high-powered, ball-shaped magnets contained in products that meet the definition of ''magnet set.'' The reports indicate that the incidents occurred between January 1, 2009 and June 24, 2014. Sixty-one of the 100 reported incidents required hospitalization. In 87 of the 100 reported incidents, the magnets were ingested by children younger than 4 years old or between the ages of 4 and 12 years.

Among the 100 reported incidents is one fatality that involved magnets from a magnet set. In August 2013, a 19-

[2] The Commission collects information on hospital emergency room-treated injuries through the NEISS database. This data can be used to provide national estimates of product-related injuries treated in U.S. hospital emergency departments. Incidents reported to the Commission represent a minimum count of injuries. To account for incidents that are not reported to the Commission, the staff calculates an estimated number of such injuries.

month-old female died from ischemic bowel caused by magnets from magnet sets in her small intestine.

2. Hazard Scenarios

As discussed in the preamble to the proposed rule, the incident reports describe scenarios that are consistent with behaviors of children in the identified age ranges. As noted in the NPR, mouthing of objects, which is common among younger children, develops into less obvious and more socially acceptable oral habits, which may continue through childhood and adolescence and into adulthood (*e.g.,* mouthing or chewing a fingertip, fingernail, knuckle, pen, pencil, or other object, especially while concentrating or worrying). 77 FR 53781, 53783 (Sep. 4, 2012). For example, in the incidents reported in the 8 through 12-year-old age group, one child described wanting to feel the force of the magnets through his tongue; one was trying to see if the magnets would stick to her braces; and another wanted to see if the magnets would stick together through her teeth. In another common scenario that accounted for half of the reported ingestion incidents among 8 to 15 year olds, children used multiple magnets to simulate piercings of their tongue, lips, or cheeks. In incidents reported among children under the age of 4 years, children put the magnets in their mouths and either intentionally or accidentally swallowed them.

The preamble to the proposed rule provides summaries of several incident reports that demonstrate a few of the reported hazard scenarios (77 FR at 53785 to 53786). These scenarios include two incidents in which young girls (10 and 13 years of age) swallowed multiple magnet balls while using the magnets to simulate tongue and lip piercings. The girls underwent surgical procedures to remove magnet balls from their intestines. In three other scenarios, magnet balls ingested by children under the age of 3 years had to be removed surgically from the children's stomach and intestines. In three of the five incidents described in the preamble to the proposed rule, the child's parent or caregiver did not realize the child had ingested magnets, which resulted in a delay in treatment and an increase in the severity of the injuries from the magnets, which attached to each other across intestinal tissue.

3. Details Concerning Injuries

Multiple factors complicate the diagnosis of injury from magnet ingestion (77 FR 53786). These factors include a lack of awareness by medical professionals of the dangers posed by the ingestion of high-powered magnets; the inability of standard diagnostic tools to demonstrate that the ingested item is a magnet; the similarities between symptoms resulting from magnet ingestion injuries and less serious conditions like the flu; and victims' inability or unwillingness to communicate to their caregivers or medical personnel that they have ingested magnets.

The preamble to the proposed rule discussed the manner in which ingested high-powered magnets can cause harm by compressing intestinal tissue, the specific types of injuries that can result when tissue is trapped between two magnets, and the risks associated with those injuries (77 FR 53786). These injuries include perforations that can result in infection due to leakage of gut contents into the abdominal cavity and obstructions that can lead to intestinal tissue becoming necrotic or rupturing and causing contamination of the abdominal cavity. Surgical procedures often are required to remove magnets from the digestive system. Complications can arise after these procedures, including bleeding, infection, and ileus (temporary paralysis of gut motility). Long-term complications resulting from this type of surgical procedure can include: (1) Adhesions (where bands of intra-abdominal scar tissue form that can interfere with gut movement and can cause obstruction); (2) removal of long sections of injured bowel; and (3) impaired digestive function.

D. Statutory Authority

This rulemaking is conducted pursuant to the Consumer Product Safety Act (CPSA). Magnet sets are ''consumer products'' that can be regulated by the Commission under the authority of the CPSA. 15 U.S.C. 2052(a).

Under section 7 of the CPSA, the Commission is authorized to promulgate a mandatory consumer product safety standard that sets forth performance requirements for a consumer product or that sets forth requirements that a product be marked or accompanied by clear and adequate warnings or instructions. 15 U.S.C. 2056. A performance, warning, or instruction standard must be reasonably necessary to prevent or reduce an unreasonable risk or injury associated with a consumer product.

Section 9 of the CPSA specifies the procedure that the Commission must follow to issue a consumer product safety standard under section 7. In accordance with section 9, the Commission commenced this rulemaking by issuing an NPR on September 4, 2012 (77 FR 53781), including the proposed rule and a preliminary regulatory analysis under section 9(c) of the CPSA. In addition, the Commission requested comments on the risk of injury identified, the regulatory alternatives under consideration, and other possible alternatives for addressing the risk. *Id.* 2058(c). As discussed in section E of this preamble, the Commission considered the comments received in response to the proposed rule.

Section 9 also requires the Commission to provide interested persons ''an opportunity for the oral presentation of data, views, or arguments,'' in addition to an opportunity to provide written comments. *Id.* 2058(d)(2). Accordingly, the Commission held a public hearing on the proposed rule on October 22, 2013, at agency headquarters in Bethesda, MD. The hearing notice was published in the **Federal Register** (78 FR 58491). The submissions forwarded to the agency by presenters before the hearing, can be read online at: *http://www.cpsc.gov/en/Newsroom/Public-Calendar/2014/Public-Hearing/Agenda/Magnet-/.* Videos of the presentations can be viewed at: *http://www.cpsc.gov/Newsroom/Multimedia/?vid=66455.* The Commission also allowed submitters to forward additional written comments for 1 week after the hearing. We considered all of the written and oral comments received.

With this notice, the Commission issues a final rule, along with a final regulatory analysis. *See id.* 2058(f)(1). According to section 9(f)(1) of the CPSA, before promulgating a consumer product safety rule, the Commission must consider and make appropriate findings to be included in the rule on the following issues: (1) The degree and nature of the risk of injury that the rule is designed to eliminate or reduce; (2) the approximate number of consumer products subject to the rule; (3) the public's need for the products subject to the rule, and the probable effect the rule will have on utility, cost, or availability of such products; and (4) the means to achieve the objective of the rule while minimizing adverse effects on competition, manufacturing, and commercial practices. *Id.* 2058(f)(1).

Pursuant to section 9(f)(3) of the CPSA, to issue a final rule, the Commission must find that the rule is ''reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product'' and find that issuing the rule is in the public interest. *Id.* 2058(f)(3)(A)&(B). In addition, if a voluntary standard

addressing the risk of injury has been adopted and implemented, the Commission must find that: (1) The voluntary standard is not likely to eliminate or adequately reduce the risk of injury, or that (2) substantial compliance with the voluntary standard is unlikely. *Id.* 2058(f)(3(D). The Commission also must find that the expected benefits of the rule bear a reasonable relationship to the cost of the rule and that the rule imposes the least burdensome requirements that would adequately reduce the risk of injury. *Id.* 2058(f)(3)(E)&(F).

E. Response to Comments on the Proposed Rule

This section summarizes the issues raised by comments on the proposed rule and provides that Commission's responses to those comments.

1. Oral Presentations

On October 22, 2013, the Commission provided the public an opportunity to present views on the proposed rule in person before the Commission Presenters at the hearing included representatives from the Consumer Federation of American, Consumers Union, the American Academy of Pediatrics, and the National Association of Pediatric Gastroenterology, Hepatology, and Nutrition. The medical experts reported that the available research most likely reflects an undercount of the true incidence of injuries associated with magnet sets. The doctors also stated there was no evidence suggesting that the victims' caregivers were negligent or otherwise impaired at the time of the ingestion incidents. Rather, the doctors noted that ingestion-related injuries, such as those associated with magnet sets, can be experienced in households with the most caring and well-educated caregivers. The doctors also testified that public education campaigns take a long time to show effects and that those campaigns would not be as effective in reducing magnet ingestion injuries as the proposed rule, which they strongly urged the Commission to finalize.

2. Written Comments

The preamble to the NPR invited comments concerning all aspects of the proposed rule. We received written comments from more than 5,000 commenters in response to the NPR. Many of the comments contained more than one issue, and many of the comments addressed the same or similar issues. Thus, we organized our responses by issue. All of the comments can be viewed at: *www.regulations.gov,* by searching under the docket number for this rulemaking, CPSC–2012–0050.

Commission's Authority To Promulgate the Rule

(Comment 1)—Many commenters opine that promulgating the rule exceeds the Commission's authority. More specifically, several commenters state that the Commission has no authority to issue a rule that would result in a prohibition of all magnet sets currently on the market simply because certain consumers use magnets in a manner that is inconsistent with the purpose intended for the product. Other commenters opine that the rule violates consumers' constitutional rights, including the right to freedom of expression through purchasing products they desire, and that a rule that prohibits the sale of covered magnet sets is drastically out of proportion to the risks presented by the product. Other commenters characterize the safety standard as the government usurping responsibility for the safety of children, which they say should properly reside with children's parents or caregivers.

(Response 1)—The Commission has the authority to issue a rule establishing performance requirements that a product must meet so that the product does not present an unreasonable risk of injury to consumers. Section 7 of the CPSA authorizes the Commission to promulgate consumer product safety standards as performance requirements or that require products to be marked or accompanied by clear and adequate warnings and instructions. The requirements of a standard issued under this provision must be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with the product. Determining whether a product presents an unreasonable risk of injury requires the Commission to consider the costs and benefits of regulatory action. The regulatory analysis discusses that assessment (see Section H of this preamble). The Commission must balance such factors as the severity of injury, the likelihood of injury, and the possible harm the regulation could impose on manufacturers and consumers. If evidence demonstrates that misuse of a product results in an unreasonable risk of injury, the Commission has the authority to promulgate a rule reasonably necessary to reduce or eliminate that risk. Certainly parents and caregivers must be responsible for their children's safety. However, as discussed elsewhere, parents and caregivers may not be aware of the hazards that magnets present. Finally, there is no constitutional right to purchase a product.

(Comment 2)—Several commenters characterize the Commission's enforcement activities (filing administrative complaints, requesting certain retailers and importers to stop sales of magnet sets, and requesting recalls of magnet sets) as improper means to prohibit certain magnet sets. The commenters suggest that rulemaking, rather than these enforcement actions, is the appropriate approach.

(Response 2)—Enforcement activities are intended to remove products from the market that present a substantial product hazard. This rulemaking proceeding is intended to establish requirements that magnet sets must meet from the effective date of the rule going forward. As such, this rulemaking proceeding seeks to impose requirements on all magnet sets subject to the rule that are sold after the rule becomes effective. The administrative proceeding and enforcement activities address only the products currently or previously distributed by specific importers and retailers.

(Comment 3)—Several commenters opine that the Commission would be acting arbitrarily or capriciously in violation of section 706(2) of the Administrative Procedures Act (APA) by promulgating the rule; that the rule violates due process requirements; and that the Commission should hold a formal hearing under Sections 556 and 557 of the APA, even if such a hearing is not required statutorily.

(Response 3)—The Commission is following the rulemaking procedures set forth in sections 7 and 9 of the CPSA and in section 553 of the APA. The commenters refer to section 556 and 557 of the APA. These provisions apply to formal rulemaking. However, the magnet proceeding is governed by section 553 of the APA, which codifies the procedure for informal rulemaking. By following the appropriate procedures under the CPSA and the APA, the Commission is providing the process that is due.

Lack of Product Defect

(Comment 4)—Commenters point out that magnet sets pose no risk of injury when used properly, that they function as intended, and therefore, they are not defective. The commenters contend that the improper use of a safe product by a minority of consumers does not render the product defective and does not warrant promulgating a rule that would remove the product from the market.

(Response 4)—To promulgate a consumer product safety standard, the

Commission must find that the rule is reasonably necessary to reduce an unreasonable risk of injury associated with the product. A product may present an unreasonable risk of injury, even if the product does not contain a fault, flaw, or irregularity that impacts the manner in which the product functions. When assessing risk, CPSC considers how consumers may actually use a product, not just the manner of use intended by the manufacturer. For example, the Commission's cigarette lighter standard requires disposable and novelty lighters to meet child-resistance requirements to protect against the misuse of lighters by children. 16 CFR part 1210. Similarly, the Commission's lawn mower standard includes requirements to guard against consumers intentionally removing a shielding safety device from the mower. 16 CFR part 1205. *See Southland Mower* v. *Consumer Product Safety Commission,* 619 F.2d 499, 513 (5th Cir. 1980) (reviewing the Commission's lawn mower standard, the court stated: ''Congress intended for injuries resulting from foreseeable misuse of a product to be counted in assessing risk'').

Impact of the Rule on the Availability of Magnet Sets for Certain Uses

(Comment 5)—Commenters state that high-powered magnets have many laudable uses, including for education and research in sciences, such as biology, chemistry, and physics. Other commenters note that magnet sets are used therapeutically for individuals with autism or attention-deficit disorder. These commenters presume that the rule would eliminate from the marketplace high-powered magnets intended for such uses.

(Response 5)—Magnets have long played a role in education. However, the specific products that are covered by the rule have been on the market only since 2008. The rule will cover only ''any aggregation of separable magnetic objects that is a consumer product intended, marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief.'' Magnets that are not subject to the restrictions of the rule would continue to be available. For example, less powerful magnets are sometimes included in science kits to demonstrate magnetism. In addition, high-powered magnets that serve industrial and commercial needs would not be covered by the rule.

Products that meet the definition of the ''magnet sets'' that do not comply with this rule would no longer be available for purchase, even if used by individuals to manage their attention deficit disorder or attention deficit hyperactivity disorder (ADD/ADHD) symptoms. However, magnets that are not restricted by the rule would still be available for purchase and perhaps could be used to manage ADD/ADHD symptoms. More generally, magnets are but one of many objects, including various types of stress balls, ''worry-beads,'' and chiming Baoding hand exercise balls that are available for the uses commenters cite. A variety of other products are marketed specifically as ''fidget toys'' to help children manage ADD/ADHD symptoms. Staff is aware of one study in which the authors reported successful use of simple stress balls to help sixth graders maintain focus in the classroom (Stalvey & Brasell, Summer 2006). In short, some substitutes for magnet sets are available for management of ADD/ADHD symptoms, and successful use of these substitutes predates the availability of magnet sets.

Magnet sets present the same hazards to children with ADD/ADHD as they do to children who do not have this condition. One comment summarizes a study of 38 cases of magnet ingestion. Among those were two children, a 12-year-old and a 14-year-old with ADHD, who swallowed strong magnets, although of a type different than those typically found in magnet sets. The first child required a laparoscopy; the other child required extensive surgical intervention. One teacher who reported giving magnets to children with ADD/ADHD in his middle school classes commented that he ''needed to buy a new set every year,'' suggesting the ease with which the pieces are lost over time and the difficulty adults may have maintaining control of the sets.

(Comment 6)—Commenters note that magnet sets are fun stress-relievers and have value as an artistic medium. The commenters also note that sculpture made from the magnet sets that are the subject of the rule constitute an art form that would be lost if the rule is promulgated.

(Response 6)—The Commission is aware that magnet sets are used to relieve stress; and likewise, the Commission is aware that some individuals have developed a form of art with the magnets that would be affected if the magnet sets used for this purpose are prohibited. Although magnet sets of the type that have been involved in incidents and are currently purchased by consumers for stress relief and sculpture-making would not comply with the rule, magnet sets made from weak magnets (*i.e.,* with a flux index 50 kG^2 mm^2 or less) or from magnets that do not fit within the small parts cylinder would be allowed by the rule. Magnet sets that comply with the rule could serve some of the purposes of magnet sets that are currently available. For example, Liberty Balls, marketed by Assemble, LLC, and sold in sets of eight large spheres, are an example of a type of magnet set that would meet the performance requirements of the rule. Due to the large size of the Liberty Balls magnets, their uses are more limited than the magnet sets that are the subject of this rule. However, the existence of Liberty Balls demonstrates the possibility that companies can develop magnet sets that meet the standard and serve some of the uses of the magnet sets that fail the standard.

Similarly, children's magnetic toys provide an example of how magnet sets might be developed that would meet the standard. Children's toy manufacturers have successfully adapted their magnetic construction toys since the adoption of the requirements for toys with magnets in the 2007 edition of ASTM F963, ''*Standard Consumer Safety Specification for Toy Safety.''* Following this example, individual magnets with a flux index over 50 could be permanently connected by rods or other means, such that the resulting magnetic objects are not small parts, *i.e.,* do not fit entirely within the small parts cylinder. Such a magnet set might not be a perfect substitute for current magnet sets but could fulfill some of the uses of current magnet sets, without posing the risk of injury or death.

(Comment 7)—Noting the popularity of magnet sets for educational, scientific, and therapeutic uses, some commenters claim that continued demand for small, high-powered magnets would result in a ''black market'' for the products after the rule is promulgated. Some commenters state that there could be consumer-to-consumer sales of used products, and others maintain that consumers would be able to purchase magnet sets directly from noncomplying companies (including firms located in China). A few commenters note that these black market magnet sets are less likely to be sold with warning labels or other accompanying information related to hazards.

(Response 7)—We acknowledge that there would continue to be a demand for magnet sets by some consumers, which could lead to increases in consumer-to-consumer sales and potentially black market sales of the products. Furthermore, such sales are probably less likely to be accompanied by labeling and warnings that alert buyers to the hazards associated with

the products. CPSC enforcement activities and continued dissemination of consumer information on the hazards of magnet sets might be necessary to reduce the future sales of noncomplying products.

(Comment 8)—Some commenters opine that magnet sets that comply with the size and flux index requirements of the rule will lose their utility as manipulative desk toys. Other commenters suggest that weaker magnets would be less safe because weaker, individual magnets could be separated more easily from the magnet set during use, or separate more readily within the gastrointestinal system if ingested while attached to other magnets.

(Response 8)—The intent of the rule is to reduce or eliminate the hazard presented by magnet sets currently on the market by requiring that magnet sets and individual magnets for use with magnet sets that are small enough to fit within the small parts cylinder must have a flux index of 50 kG^2 mm^2 or less. The rule would still allow strong magnet sets with magnets that do not fit entirely within the small parts cylinder. Magnetic products sold as toys that comply with the toy standard for children have included rods, balls, and various geometric shapes that do not fit within the small parts cylinder. Such products offer interesting entertainment, such as sculptures and construction activities, but they are much larger and safer than the subject magnet sets intended for adults. Another possibility would be to invent a magnet set composed of magnets with a flux index below 50 kG^2 mm. Because there currently are no magnet sets on the market with magnets that have a flux index of less than 50 kG^2 mm^2, we do not know how such magnets would perform when used in the same way currently available magnet sets perform.

Magnet sets that comply with the requirements of the rule would contain magnets that are too large to be swallowed easily or would have very weak attraction forces that would not pose the same ingestion hazards as magnet sets currently on the market. Review of incident data does not indicate that any injuries have been caused by magnets with flux index values below 50 kG^2 mm^2.

(Comment 9)—Some commenters disparage the intended uses of magnet sets, calling them, for instance, ''mindless desk ornaments,'' ''a diversion,'' and ''frivolous items.'' These commenters cite the high severity of the injuries associated with magnet sets and express dismay that the CPSC ever allowed them to be sold.

(Response 9)—The CPSC does not perform premarket approvals of consumer products; and typically, the CPSC will not engage in enforcement or regulatory activity regarding a product, until information is received or developed, which indicates that the product may present an unreasonable risk of injury to consumers. Reasonable parties may differ on the value to society of manipulative toys; however, many types of manipulative toys exist for children and adults.

Impacts of the Rule on Businesses and Jobs

(Comment 10)—Many commenters note that the rule would harm firms that import magnet sets and will result in lost jobs for employees of these firms.

(Response 10)—In the preliminary initial regulatory analysis, staff noted that the economic impact of the rule would be most severe for the seven firms that account for the great majority (perhaps more than 98%) of units sold as of June 2012. Five of these importers reportedly derived most or all of their revenues from the sale of the magnet sets that do not meet the performance requirements of the rule. The other two leading importers of magnet sets reportedly had fairly broad product offerings, which could lessen the severity of the economic impact of the rule. As a result of compliance activity pursued by the Commission's Office of Compliance and Field Operations, four of these seven importers agreed voluntarily to stop selling magnet sets that would not be compliant under this rule. One additional firm, Maxfield & Oberton Holdings, LLC, ceased operations. This firm (marketer of ''Buckyballs'') is believed to account for nearly 90 percent of magnet set sales through June 2012. Only one of the seven small importers, Zen Magnets, LLC, continues to market magnet sets that are subject to the rule. This firm apparently derives all of its revenues from the sale of magnet sets. Unless the firm can successfully market magnet sets that comply with the rule or other products, the firm might go out of business when the rule takes effect.

A large share of magnet sets have been sold directly to consumers by importers who used their own Internet Web sites or other Internet shopping sites, but the rule would also affect retailers of the products, whether the products are sold online or physically in stores. However, these retailers are not likely to derive significant proportions of total revenues from sales of affected magnet sets. Accordingly, the impacts on individual firms should be minimal.

The commenters are correct that the rule, by prohibiting the sale of noncompliant magnet sets in the United States, may also result in some job losses. However, the impact on job losses is probably limited because magnetic balls generally are produced outside the United States and are merely packaged and/or distributed by U.S. importers.

Costs and Benefits of the Rule

(Comment 11)—One commenter opines that the preliminary regulatory analysis overstates the societal costs of injuries from magnet sets because incidents involving other small magnets are improperly attributed to the magnet sets that are the subject of the proposed rule. In addition, this commenter opines that the injury costs used in the analysis were higher than indicated by the CPSC's Revised Injury Cost Model (ICM).

(Response 11)—Both the initial and final regulatory analyses acknowledge that there is some uncertainty concerning the estimated annual average of medically attended injuries, noting that some of the cases described as ''possibly'' involving magnet injuries, actually may not have involved the magnets that are the subject of the rule. Hence, it is possible that the analyses overstate the societal costs associated with the magnets included in the rule. The final regulatory analysis also points out that there were an additional 230 NEISS cases (representing about 1,500 emergency department-treated injuries annually) in which the magnet type was classified as ''unknown or other.'' Thus, to the extent that this category of incidents involved magnets covered by the rule, the analyses would tend to understate the societal costs associated with the magnets subject to the rule. Therefore, given the uncertainty concerning the societal costs associated with the magnet sets, the analyses could be underestimating or overestimating the societal costs.

Regarding the commenter's assertion that injury costs used in the preliminary regulatory analysis were higher than indicated by the ICM, we note that the commenter fails to take into account updates to the ICM based on new and improved cost databases. The ICM is fully integrated with NEISS and provides estimates of the societal costs of injuries reported through NEISS. The major aggregated components of the ICM include: Medical costs; work losses; and the intangible costs associated with lost quality of life or pain and suffering. The ICM is described further in section H.3.a of the preamble. The commenter also does not

take into consideration that the cost estimates in the preliminary regulatory analysis were age and sex specific and involved only those under the age of 15 who had ingested magnets from magnet sets. Furthermore, the commenter apparently also includes injury costs associated with the diagnosis category ''foreign body,'' *i.e.,* foreign objects propelled into the victim's body, which is a different hazard pattern than ''ingested foreign objects.'' The costs of injuries resulting from foreign objects being propelled into a victim's body are only about half of the costs of injuries associated with ingested foreign objects. Finally, the commenter applies inappropriate inflators in adjusting the injury cost estimates to 2011 dollars. The Commission maintains that the estimated injury costs associated with ingestions of small, high-powered magnets in the preliminary regulatory analysis and final regulatory analysis involved proper application of the ICM.

Risk and Severity of Injury

(Comment 12)—The Commission received a significant number of comments from health care professionals with personal experience in treating children who either narrowly avoided, or actually sustained, injuries following ingestion of small, high-powered magnets.

Virtually all comments received from medical professionals express support for a rule eliminating magnet sets of the type that have been involved in incidents. The medical professionals point out that injuries caused by the ingestion of high-powered magnets are often difficult to diagnose because of the inability of standard diagnostic tools to demonstrate that the ingested item is a magnet; there are similarities between symptoms resulting from magnet ingestion injuries and less serious conditions like the flu; and the victims are unable or unwilling to communicate to their caregivers or medical personnel that they have ingested magnets. The medical professional commenters express concern with the rapidly growing number of cases and note that magnet ingestions often result in rapid and severe injuries with devastating and costly long-term consequences.

(Response 12)—The Commission is aware of the severity of the injuries that often result from the ingestion of small, high-powered magnets from magnet sets and the difficulties frequently encountered by medical professionals in diagnosing and treating these injuries. The Commission is also aware that there are costs associated with the treatment of injuries resulting from the ingestion of these magnets that will be reduced substantially if magnet sets must comply with the rule. (See Section H of this preamble).

(Comment 13)—Commenters argue that high-powered magnet sets should not be prohibited because the number of injuries is low—43 reported injuries possibly involving magnet sets during the period from January 2009 to June 2012—considering that approximately 2.7 million magnet sets have been sold since 2009. These commenters also note that there have been no fatalities associated with the product.

(Response 13)—The number of incidents reported to the Commission, now totaling 100 cases through June 24, 2014, cannot be used to estimate the number of injuries in the U.S. population because case reports are anecdotal and are not based on a probability based sampling design. The anecdotal incidents reported to CPSC constitute a minimum number of incidents in the U.S. However, the incidents reported to CPSC through hospital emergency departments and captured in the NEISS database can be used to estimate the number of incidents nationwide because NEISS data come from a probability based stratified random sample of U.S. hospitals with emergency departments. An analysis of incidents obtained through the NEISS estimates that 2,900 possible magnet set, emergency department-treated ingestions occurred in the United States from January 1, 2009 through December 31, 2013. This amounts to approximately one incident per 930 magnet sets. We do not agree that this is a low figure for injuries. In addition, we are aware of one fatality involving a 19 month-old female, who died from ischemic bowel caused by the ingestion of magnets from a magnet set.

Furthermore, the benefits of the rule, notwithstanding the public's desire for current magnet sets that do not meet the rule, bear a reasonable relationship to the costs of the rule.

(Comment 14)—Several commenters point out that the dangers posed by the ingestion of small, high-powered magnets are not obvious.

(Response 14)—Staff agrees that the unique hazard resulting from the ingestion of small, strong magnets is unlikely to be obvious to the general public. People are generally aware of the choking hazard posed by small balls and other small parts, but they do not understand how the characteristics of magnets can cause injuries that are different from, and more severe than, swallowing another small object. Despite the publicity and response generated by the NPR, as well as the Commission's compliance and communications activities, some commenters misunderstand the hazard. Many commenters seem unaware that the majority of victims are older children and teens, and the commenters focus exclusively on the risk to young children. Similarly, commenters tend to mention magnets as a choking hazard, comparable to choking on foods, such as hot dogs and non-food small parts. In reality, choking is not the injury mechanism related to magnets. The ways that children and teens interact with magnets are not obvious and seem unclear to many commenters. For example, some commenters write derisively about ''people letting their children eat magnets.'' However, most incidents are unwitnessed, and based on data from choking and poisoning incidents in which children intentionally ingest non-food items, it is likely that only the youngest children voluntarily swallow magnets. This is because choking on non-food items occurs predominantly among children younger than three years, and ingestion of poisonous substances declines as children approach five years of age.

(Comment 15)—Other commenters point out that the Commission has not prohibited certain products, such as trampolines, balloons, and hazardous household chemicals, which commenters contend present a greater risk of injury to children than magnet sets. They assert that this weighs against a rule prohibiting certain magnet sets that do not meet the rule's performance requirements.

(Response 15)—Magnet sets, and the hazard patterns associated with them, are quite different from other products. Because of these differences, comparisons of injury rates between magnet sets and other products are not meaningful. Key differences include: the obviousness of the hazard; the severity of the resulting injury; the difficulty in diagnosing the resulting injury; the numbers of products in use; the breadth of products covered in the product category; the age of the victims sustaining injuries; and the existence of requirements to address the hazard.

Responsibility of Caregivers for Injuries Resulting From Magnet Ingestion

(Comment 16)—Several commenters claim that the incidents involving magnet sets are caused by negligent caregivers, who should supervise their children better. However, other commenters opine that caregiver supervision was not a relevant factor in determining the causation of the incidents.

(Response 16)—The issue of caregiver supervision is related to caregiver

compliance with warnings and other hazard communications. Consumers may be aware of a hazard, but they may not make changes in their behavior that would avoid the hazard. Securing or preventing access to magnet sets would be especially difficult regarding older children and adolescents because they are strongly independent and resourceful. Expecting caregivers to supervise these children constantly is unrealistic. Magnet ingestions can happen quickly, and the Commission believes that it is also unrealistic to expect caregivers to maintain continuous, focused attention on younger children, especially children at the upper end of the at-risk age range. Indeed, research has found that people cannot be perfectly attentive, particularly over long periods of time, regardless of their desire to do so.[3] Caregivers are likely to be distracted, at least occasionally, because they must perform other tasks, are responsible for supervising more than one child, are exposed to other salient but irrelevant stimuli, or are subject to other stressors.

Moreover, caregivers are unlikely to maintain high levels of vigilance, unless they believe that such vigilance is necessary. If caregivers who own magnet sets believe they have properly secured the sets or think that their children are not aware of the sets, caregivers are unlikely to assume that constant supervision is needed. Furthermore, children may be exposed to these magnet sets in locations where caregivers cannot supervise the children or do not have direct control over the amount of supervision required, such as at school or in other households. Adolescents, in particular, are strongly independent, and it is unrealistic to expect caregivers to supervise adolescents constantly.

Alternatives to the Rule: Warnings and Education Programs

(Comment 17)—Many commenters state that current warnings are sufficient to address the risk of injury presented by magnet sets, or they express the belief that more robust and prevalent warnings and educational programs are a better alternative than a rule prohibiting products that do not meet the rule's performance requirements. Some commenters state that the assumption that warnings do not work undermines past safety standards accepted by the CPSC and, in fact, calls into question the entire safety-monitoring process.

(Response 17)—As discussed in the Human Factors staff memorandum that was part of the NPR briefing package, warnings are widely recognized as a less reliable approach to controlling hazards than design or guarding approaches. Unlike these latter approaches, which directly limit hazard exposure, warnings and other hazard communications must first educate consumers about the hazard and then persuade consumers to change their behavior to avoid the hazard. In addition, to be effective, warnings must rely on consumers to behave consistently, regardless of situational or contextual factors (*e.g.,* fatigue, stress, social influences) that influence precautionary behavior.

The Commission's position is not that warnings are uniformly ineffective. However, consumer compliance with warnings depends strongly on the specific circumstances surrounding the hazard. Several factors suggest that compliance with warning labels related to magnet sets is likely to be low because consumers may not notice and attend to the warnings. Exposure to ingestion warnings is likely to be very limited because: (1) The individual magnets are too small to contain on-product warnings; (2) the magnet sets do not inherently require consumers to return the magnets to a storage case or other package after every use, in packaging that might include a warning; and (3) the magnet sets can be manipulated without the necessity of referring to instructions that might include a warning. In addition, the nature of the magnet-ingestion hazard and the resulting injuries can be difficult to convey to consumers; and the resulting injuries have been misunderstood even by medical personnel and by commenters to the NPR, some of whom erroneously identify choking on the magnets as the hazard presented by this product. Without a clear understanding of this information and how magnet ingestions differ from other small-part ingestions, consumers are unlikely to comply with a warning.

We acknowledge that developing understandable warnings aimed at parents and other caregivers may be possible; and we acknowledge that caregivers who receive such warnings may attempt to keep these products out of the hands of young children. However, as noted, consumer compliance with warnings depends strongly on the specific circumstances surrounding the hazard. Several factors suggest that compliance with warning labels related to magnet sets is likely to be low, even if consumers understand the hazard and its consequences. For example, the cost of compliance associated with magnet-ingestion warnings is high. ''Cost of compliance'' is defined as any cost, such as time, effort, or inconvenience that is required to comply with a warning; compliance is negatively associated with cost. The warnings on the packaging and instructional material for some magnet sets instruct consumers to secure the magnets and keep them away from all children ages 14 years and younger. As evidenced in the comments, many consumers are likely to reject these warnings as lacking credibility. We recognize that caregivers who receive warnings about magnet sets may attempt to keep these products out of young children's hands. However, warnings are likely to be particularly ineffective among caregivers with older children and adolescents because caregivers would not expect these children to mouth toys and other objects as frequently as younger children. Furthermore, even if caregivers attempt to comply with warnings about the magnet-ingestion hazard, preventing a child's access to these magnets still might prove quite difficult. The time and effort to secure the product after every use, and the difficulties associated with trying to identify a suitably secure location to store the product, may deter consumers from heeding the warnings.

Some adolescents have cognitive and motor skills similar to an adult's, making it extremely challenging to keep the product out of adolescents' hands, despite caregivers' efforts. Although adolescents also may be capable of understanding warnings about magnet ingestions, their behavior is influenced strongly by social and peer pressures, and adolescents are known to test limits and bend rules.[4] Thus, warnings against using magnets to simulate tongue or facial piercings are unlikely to be very effective among this age group, unless such piercings are viewed as socially unacceptable among their peers.

Educational programs may offer more opportunities to present the information in varied ways and in greater detail than is possible via a warning label.

[3] Wickens, C. D., & Hollands, J. G. (2000). Engineering *psychology and human performance* (3rd Ed.). Upper Saddle River, NJ: Prentice Hall.

[4] Brown, T., & Beran, M. (2008). Developmental stages of children. In R. Lueder & V. J. B. Rice (Eds.), *Ergonomics for children: Designing products and places for toddlers to teens* (pp. 13–30). New York: Taylor & Francis. Kalsher, M. J., & Wogalter, M. S. (2008). Warnings: Hazard control methods for caregivers and children. In R. Lueder & V. J. B. Rice (Eds.), *Ergonomics for children: Designing products and places for toddlers to teens* (pp. 509–539). New York: Taylor & Francis. Zackowitz, I.B., & Vredenburgh, A.G. (2005). Preschoolers, adolescents, and seniors: Age-related factors pertaining to forensic human factors analyses. In Y. I. Noy & W. Karwowski (Eds.), *Handbook of human factors in litigation* (Chapter 35). Boca Raton, FL: CRC Press.

However, mere knowledge or awareness of a hazard is not enough. Such programs suffer from limitations similar to those of warnings because, like all hazard communications, the effectiveness of educational programs depends upon the affected consumers, not only in terms of receiving and understanding the message, but also in being persuaded to heed the message. Magnet sets present an especially difficult challenge for public education programs because the hazard is obscure and difficult to convey in simple terms. Furthermore, teenagers are a significant part of the at-risk population, and they provide distinct challenges to the effectiveness of public education programs. Thus, even education programs that clearly communicate the hazard to consumers will not necessarily motivate appropriate behavioral change or reduce the frequency of incidents.

Alternatives to the Rule: Bitterants

(Comment 18)—A small number of commenters discuss bitterants (also known as aversives) as an option. Some conclude that adding a bitter coating to magnets would be an effective alternative to the prohibition of magnet sets that do not meet the rule's performance requirements. A few commenters assert that the method is unproven and question that approach for various reasons.

(Response 18)—In principle, adding an aversive agent to a product is a rational approach to reducing the risk of mouthing and ingestion. Laboratory studies have shown this approach to be effective among children and adults in deterring repeated ingestion of various substances. Yet, real-world investigations have not demonstrated the effectiveness of bitterants in preventing poisonings.[5] CPSC staff's 1992 final report of its study of the topic (*http://www.cpsc.gov/library/foia/foia99/os/aversive.pdf.* at p. 3) concluded that because bitterants do not deter initial ingestion, ''[a]versive agents are unlikely to protect children from being harmed after ingesting . . . substances that can injure or kill after one or two swallows.''

Bitterants are least likely to be effective among young children who gain access to high-powered magnets. Despite rejecting bitter substances in testing environments, children in home settings, nevertheless, frequently ingest unpalatable substances, such as gasoline, cleanser, toilet bowl cleaner, and ammonia. Younger children, particularly those under 3 years of age, may swallow a number of magnets at a time before reacting to any aversive agent applied to the magnets.

Aversives may be a more effective deterrent for older children and young teens, presuming these children are aware that the agent has been applied to the magnets and they are familiar with its taste. For older children who are not familiar with the taste of an aversive, the mere presence of the agent would not deter mouthing the magnets or trying to use them to mimic pierced lip or tongue jewelry. Older children and teens may also give magnets to others to try as a prank. Preteens and teens are prone to test what they have been told, particularly when what they have been told involves restrictions of any sort. Thus, warnings that the products taste bad may not prevent children in these age groups from tasting the magnets. (Some proportion of the population, possibly as high as 30 percent, may be insensitive to bitterants such as denatonium benzoate.) However, children are likely to reject magnets treated with bitterants, and the bitterant may indeed deter repeated attempts among most children.

Ingestions could still occur even if a bittering agent is found effective for this purpose. Ingestions may be intentional among the youngest children, but ingestions are likely to be accidental among older groups. The power of the magnetic forces inherent in these products can cause magnets to move erratically as pieces repel or attract, and movement of magnets toward the back of the throat could trigger the reflex to swallow the magnets before the person can remove them.

Alternatives to the Rule: Child-Resistant Packaging

(Comment 19)—Several commenters state that child-resistant (CR) packaging requirements are a better alternative than the proposed performance requirements. However, others believe that such requirements would be ineffective in reducing or eliminating the risk of injury.

(Response 19)—CR packaging could be devised to make an enclosed magnet set inaccessible to most young children. However, compliance with CR packaging is likely to be low and inconsistent; and the effectiveness of this approach depends on the caregiver and other users securing the magnets in the CR packaging after every use. This is behavior that we consider unlikely to occur. Although CR closures have been shown to be effective in reducing poisonings with various products (*e.g.,* Rodgers, 2002), non-use and incorrect use of CR closures on products containing chemicals or pharmaceuticals—products consumers are more likely to understand to be hazardous (as opposed to strong magnet sets)—can result in many poisonings annually among children younger than 5 years old. Furthermore, CR packaging, referred to as ''special packaging'' under the Poison Prevention Packaging Act, is designed to be significantly difficult for children under 5 years of age to open. 15 U.S.C. 1471(4). Thus, CR packaging is an impractical approach for older children, whose cognitive and motor skills overlap those of adults.

Flux Index

(Comment 20)—One commenter questions the relationship of the flux index (FI) to anatomical data, which the commenter considers to be most germane to the hazard. The commenter requests that the rule be modified to redefine the criteria, ''by relying on objective anatomical data tied to the potential risks associated with swallowing injuries and refine the testing protocol to isolate the field strength and/or attach forces that can reasonably be expected to develop at the distances reflected by anatomical data.'' Referencing an ultrasound study, the commenter asserts that the minimal gut wall thickness in children is 0.5 mm, and the commenter suggests that when measuring the magnet maximum surface gauss reading, instead of measuring at a probe distance of 0.25 to 0.51 mm above the magnetic pole surface, as currently required in ASTM F963–11, it is more appropriate to base the measuring distance on the minimum gut wall thickness. The commenter suggests that using a probe separation distance of 1.0 mm (2×0.5 mm = 2 sections of gut wall) makes more sense because 1 millimeter ''is the magnetic field strength at that critical distance that may bear a rational relationship to injuries.''

(Response 20)—Commission staff agrees that the strength of the magnet field and the separation of the magnets, or lack thereof, are important factors contributing to the risk of injury posed by any strong magnet. The gastrointestinal (GI) system is folded on itself within the abdominal cavity, and during transit through the GI system, there are many opportunities for magnets in different GI locations to pass nearby to each other and then interact when separated by only the thin gut walls. Commission staff believes that measuring the maximum surface gauss reading for the FI input at a set distance of 1.0 mm (equivalent to two

[5] Cf. White, N. C., Litovitz, T., Benson, B. E., Horowitz, B. Z., Marr-Lyon, L., & White, M. K. (2009). The impact of bittering agents on pediatric ingestions of antifreeze. *Clinical Pediatrics, 48*(9), 913–921.

thicknesses/layers of gut wall) is oversimplistic and inappropriate, unless the maximum surface gauss reading measured at that 1.0 millimeter distance is essentially zero.

Although the suggested value of 1.0 millimeter is anatomically valid, it is not particularly meaningful in terms of the injury mechanism. This is because conventional magnets do not ''wait'' to get within 1 millimeter of each other before they begin to interact, and the gut wall cannot block magnetic forces. Rather, once a pair of magnets comes within a distance where the extent or reach of their magnetic fields allows them to interact, the result is near-instantaneous attraction, with consequent near-instantaneous compression of any trapped tissues. Although the thin wall of the small intestine can be conveniently defined anatomically by its thickness, the tissue offers minimal resistance to the compression forces of the magnet. Thus, the tissue trapped between magnets may be compressed so that the distance between the magnets is much smaller than 1.0 millimeter. The compression forces deprive the tissue of its blood supply, and they also squeeze out the tissue fluids, rapidly reducing the gut wall thickness to micron values, and essentially mummifying the tissue *in situ.* The measurement distance for the FI in the rule is closer to this negligible distance than the 1.0 millimeter distance that the commenter suggests; and therefore, the measurement distance for the FI in the rule is more appropriate for defining powerful magnets capable of causing GI injuries.

(Comment 21)—Several commenters question whether a flux index value of 50 kG^2 mm^2 is low enough to prevent harm.

(Response 21)—The development of the flux index requirement that appears in ASTM F963, *Consumer Safety Specification for Toy Safety,* which is now a mandatory CPSC standard, was outlined in the NPR. (77 FR 53781–82, September 4, 2012). ASTM F963–11 defines a ''hazardous magnet'' and a ''hazardous magnet component'' as one that has a flux index greater than 50 kG^2 mm^2 and that is a small object. ASTM set the flux index value at 50 kG^2 mm^2, by measuring the weakest magnets in children's toys that were suspected of causing injuries, and then adding a safety factor. Review of incident data related to children's toys and magnet sets does not indicate that any injuries have been caused by individual magnets with flux index values below 70. CPSC staff will continue to monitor incidents and seek information about the lower-bound limits of the injury mechanism so that the established method continues to be appropriate.

(Comment 22)—Several commenters question whether the rule is adequate for assessing the hazard posed by an aggregation of individual magnets, each of which has a flux index of 50 or less.

(Response 22)—The staff memorandum included in the NPR briefing package acknowledged concerns with the existing ASTM F963 standard method regarding aggregated magnets, as follows: ''A toy with multiple weak small part magnets could present an issue that the existing ASTM F963 magnet requirements do not address, namely: stacking or stringing of magnets. . . . when these small part magnets are combined, they could create a(n aggregated) magnet with an effective flux index over 50 kG^2 mm^2 depending upon their characteristics.'' (Notice of Proposed Rulemaking for Hazardous Magnet Sets, Staff Briefing Package, pp. 54 – 55). Individual magnets with a flux index of 50 kG^2 mm^2 or less (which currently do not exist in the market) would be smaller and more difficult to manipulate and have less attraction force than magnets in existing magnet sets. Individual magnets with a flux index of 50 kG^2 mm^2 or less could be mounted permanently or attached side-by-side to create a magnetic object with multiple magnetic poles on one surface. Doing so would create a multipole magnetic object that has a higher attraction force than the individual magnets on its surface. Because there currently are no magnet sets on the market with magnets that have a 50 kG^2 mm^2 flux index or less, we do not know how they would perform when used as a part of a magnet set.

(Comment 23)—One commenter disagrees with the proposed flux index method, stating that the commenter's proprietary technology could be used to make ''safe'' magnet sets, even if the flux index measurement of individual magnets is greater than 50. The commenter uses a proprietary technology to magnetize the surface of a single magnet to create multiple poles (positive and negative regions) on the surface of a single magnet. The commenter refers to these proprietary magnets as ''Polymagnets.®'' Essentially, this process creates a permanent aggregation of north and south poles in the surface of a single magnet. The commenter requests that the Commission narrow the scope of the rule to apply only to magnet sets comprised of magnets having no more than two magnetic pole regions on any exposed magnet surface, thereby, exempting multiple pole magnets.

(*Response 23)*—The commenter's claim that a process exists that could be used to make ''safe'' magnet sets, even if the flux index measurement of individual magnets is greater than 50 kG^2 mm^2, is based on proprietary technology, which, to our knowledge, has not been applied to any magnet sets currently on the market. The commenter concedes that he ''has not fully analyzed the use of a densely coded pattern'' on small cubes or spheres and claims only that ''early indications suggest that dramatic improvements to the magnetic field * * * can be achieved'' using the proprietary technology. These statements indicate that the commenter has not applied this technology to small, high-powered magnet sets or even concluded that such an application is scientifically possible or economically feasible. CPSC is not aware of any magnet set products on the market that are comprised of magnets with multipole surfaces using the commenter's technology. Moreover, it is not likely that this process will be applied to small, high-powered magnet sets in the foreseeable future. Thus, the Commission does not believe that any exemption for these types of magnets is necessary or appropriate, particularly because currently, no Polymagnet® magnet sets exist that could be tested to determine whether such magnet sets present an unreasonable risk of injury.

(Comment 24)—The same commenter also states that the flux index measurement method is imprecise because it provides a range of acceptable distances between the gauss meter and the magnetic surface being measured.

(Response 24)—The flux index measurement method specifies the use of a gauss meter and an axial probe with a distance between the active area (diameter of 0.76 +/− 0.13 mm) and probe tip of 0.38 +/− 0.13 mm. This means the magnetic flux density is measured at a distance of between 0.38 millimeters and 0.51 millimeters above the magnet surface. The tolerance cited accounts for variations in the length of the axial probe tip, which is a function of the equipment used, and therefore, does not constitute a precise value.

F. Description of the Final Rule

The Commission is issuing a rule establishing a standard for magnet sets and individual magnets that are marketed or intended for use with or as magnet sets. This section of the preamble describes the rule, including differences between the proposal and the final rule.

1. Scope, Purpose, and Effective Date—§ 1240.1

This section of the final rule states that the requirements in 16 CFR part 1240 are intended to reduce or eliminate an unreasonable risk of injury to consumers who ingest magnets that are part of magnet sets and individual magnets that are marketed or intended for use with or as a magnet set. The standard applies to all magnet sets, as defined in § 1240.2, and relevant individual magnets manufactured or imported on or after the date 180 days after publication of the final rule.

Individual magnets. The scope of the final rule has been revised from the proposal so that the rule explicitly covers magnets that are sold individually and are intended or marketed to be used in the same way as magnet sets or as a part of a magnet set. The Commission is aware of one firm that sells magnet sets and also sells single magnet spheres at a per-magnet price through the same Web site on which the firm promotes and sells sets of magnets. This firm sells individual magnet spheres for 10 cents each and allows customers to purchase up to 1,152 magnets in a single order. The firm charges a shipping rate of $5.00 for any quantity of individual magnets purchased. Another firm, Star, which recently settled an administrative complaint with the Commission, sold individual magnet spheres for between 9 and 19 cents each (depending on the number ordered), and allowed customers to purchase up to 10,000 magnets in a single order.

Because the proposed rule described the scope of the rule as covering aggregations of magnets, magnets that are sold individually, arguably would not be subject to the requirements of the safety standard under the scope provision, as proposed. Thus, under the proposed scope, firms might be able to circumvent the safety standard requirements simply by pricing and selling magnet spheres individually that are intended to be used as part of an aggregation of magnets as a magnet set. Under the final rule, all magnet spheres intended for use as magnet sets, as defined by the rule, are subject to the requirements of the safety standard, whether they are sold individually or in the aggregate.

Changing the word ''children'' to ''consumers.'' The proposed scope section stated that the rule is intended to reduce or eliminate an unreasonable risk of injury to children. The final rule changes the word ''children'' to ''consumers'' to clarify that the rule is intended to address risks posed to teens as well as young children. As the incident data make clear, both teens and young children have been harmed when swallowing magnets from magnet sets. Because the term ''children'' could be subject to interpretations that might exclude teens, the final rule uses the term ''consumers.''

2. Definitions—§ 1240.2

This section of the final rule provides definitions for the terms ''magnet set'' and ''individual magnet.'' The final rule modifies the proposed definition of ''magnet set'' to clarify certain aspects of the definition. The Commission does not intend for these modifications to change the scope of the rule from the proposal, but rather, to describe more clearly the products subject to the rule. The final rule also adds a definition for the term ''individual magnet.''

Definition of ''magnet set.'' To respond to comments on the NPR and to provide greater precision, the Commission has modified the definition of ''magnet set'' in the proposed rule by:

- Removing the word ''permanent'';
- Replacing the phrase ''intended or marketed by the manufacturer primarily'' with the phrase ''intended, marketed or commonly used'';
- Replacing the word ''desk toy'' with ''item''; and
- Specifying factors that could indicate whether a magnet set meets the definition.

The final rule definition removes the word ''permanent'' from the phrase ''separable, permanent magnetic objects'' because the word ''permanent'' is superfluous. Any magnet, whether it maintains its magnetic strength permanently or not, can cause serious damage to intestinal tissue, if ingested.

The final rule replaces the phrase, ''intended or marketed by the manufacturer primarily,'' with the phrase: ''intended, marketed or commonly used.'' The revision seeks to prevent a manufacturer or importer of magnet sets from avoiding the rule by simply stating in marketing and other materials that the magnets are intended for uses other than those specified in the definition. For example, this modification will preclude firms from claiming that their products are intended as science kits to avoid the rule, if, in fact, the products are commonly used as magnet sets (*i.e.,* as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief). Common uses may be indicated by information found in consumer reports to the CPSC, firm reports to the CPSC, injury reports, and consumer comments/reviews posted on product Web sites stating that a product, regardless of whether it is intended or marketed by the manufacturer as such, was, in fact, being used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation or stress relief. This change clarifies that the common usage of a firm's magnet products could be a consideration in determining whether the magnets are intended for use as manipulatives for entertainment, irrespective of the firm's stated intentions.

The final rule definition replaces the term ''desk toy'' with ''item'' to prevent excluding magnet sets from the scope of the rule if a particular product is not explicitly labeled or expressly marketed as a desk toy.

The final rule specifies factors that are relevant in determining the intended uses of a magnet set. These are factors that Commission staff may consider in determining whether a product falls under the definition of ''magnet set.'' Explicitly stating these factors in the rule should provide clearer direction to firms and the public about what products will be covered by the rule. We may consider the manner in which the individual magnet or magnet set is promoted, marketed, and advertised. As part of this inquiry, staff may review the labeling and packaging of the product, information on the firm's Web site about intended uses of the product, information in other promotional materials, and where and how the product is displayed at retail stores or on the Internet. In addition, we may consider the uses for which the product is commonly recognized by consumers. Information provided by consumers and firms, injury reports, and consumers' online reviews or comments for the product are examples of sources that could be useful to determine what consumers consider to be the uses of the product.

In developing this part of the ''magnet set'' definition, the Commission considered regulatory and statutory provisions that describe factors to be used in determining the intended use of a product. The Commission's small parts regulation specifies factors relevant to a determination of which toys and other articles are intended for use by children under 3 years of age. 15 U.S.C. 1501.2(b). The small parts regulation states: ''In determining which toys and other articles are intended for use by children under 3 years (36 months) of age, for purposes of this regulation, the following factors are relevant: the manufacturer's stated intent (such as on a label) if it is a reasonable one; the advertising,

promotion, and marketing of the article; and whether the article is commonly recognized as being intended for children under 3.'' *Id.* The definition of ''children's product'' in the CPSA lists factors to consider in determining whether a product is primarily intended for children 12 years of age or younger. 15 U.S.C. 2051(a)(2). The ''magnet set'' definition draws from both the regulatory definition in the small parts rule and the statutory definition of ''children's product'' to specify factors, which include the manufacturer's stated intent, information provided with or on the product, and the commonly recognized uses of the product.

The definition does not include other magnetic products, such as toys intended for children and jewelry. Magnets that are part of a toy intended for children are already covered by the requirements in ASTM F963–11, which is a mandatory CPSC standard. The definition also does not include magnets intended for industrial or commercial applications, such as motor components, magnetic bearings, magnetic couplings, welding clamps, oil filters, disc drives, loudspeakers, headphones, microphones, instrumentation, switches, and relays.

Definition of ''individual magnet.'' The final rule adds a definition of ''individual magnet.'' As discussed above, the Commission is aware that the firm that currently sells magnet sets that would be prohibited by the rule also sells individual magnets for use with magnet sets. The Commission seeks to prevent firms from circumventing the rule by selling individual magnets for the same uses as the magnet sets that have been involved in incidents, and at the same time claiming that the individual magnets are not subject to the rule because the magnets are not sold as sets. The individual magnets covered by the rule are only the magnets that are intended or marketed for use with or as a magnet set. The Commission does not intend to cover the many types of individual magnets that are sold for other uses, such as refrigerator magnets, collar stays, or various commercial and industrial uses.

3. Requirements—§ 1240.3

This section sets forth the requirements for magnet sets. If a magnet set contains a magnet that fits within the small parts cylinder that CPSC uses for testing toys, all magnets from that set must have a flux index of 50 kG^2 mm^2 or less. Because the final rule covers individual magnets that are intended or marketed for use with or as a magnet set, the requirements section of the final rule states that individual magnets, as defined in the rule, must meet the requirements. The proposed rule set out the small parts and the flux index requirements in two subsections of § 1240.3. The final rule consolidates these provisions into one section.

The small parts cylinder referenced in the rule is specified in 16 CFR part 1501—Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts. If an object fits completely within the small parts cylinder, this indicates that the object is small enough to be ingested. If a magnet that is part of a magnet set (or an individual magnet, as defined) is too large to fit within the small parts cylinder, the magnet meets the standard, regardless of the magnet's flux index.

Small magnets (*i.e.,* those that fit within the small parts cylinder) that are part of a magnet set (and individual magnets, as defined) must have a flux index of 50 kG^2 mm^2 or less. This limit is based on the level that is specified in ASTM F963–11. As discussed in the preamble to the NPR (77 FR 53781), the flux index of a magnet is an empirical value developed by ASTM to estimate the attraction force of a magnet. The flux index limit of 50 kG^2 mm^2 was developed by ASTM, with CPSC staff's participation, to address injuries resulting from strong magnets that separate from toys. Because the magnets from toys involved in incidents had flux index measurements greater than 70 kG^2 mm^2,the ASTM working group chose a flux index of 50 kG^2 mm^2 as a cutoff because that value was significantly below the value for the magnets involved in incidents.

4. Test Procedure for Determining Flux Index—§ 1240.4

This section of the rule describes how to determine the flux index of magnets that are part of a magnet set. If the magnet set contains more than one shape or size of magnet, at least one of each shape and size is selected for testing. The flux index of the selected magnets is measured in accordance with the procedure set forth in sections 8.24.1 through 8.24.3 of ASTM F963–11, *Standard Consumer Safety Specification for Toy Safety.* The flux index of the magnet is calculated by multiplying the square of the magnet's surface flux density (in KGauss), by its maximum cross-sectional area (in mm^2). The ASTM standard uses a gauss meter and probe that measures the surface flux density at 0.015 inches (0.38 mm) above the magnet's surface. The area is measured at the largest cross-section of the magnet that is perpendicular to the axis of its magnetic poles.

In the NPR, we noted that the products at issue are typically aggregations of magnets, rather than individual magnets that often separate from toys. We also observed that when magnets are aggregated, their magnetic strength may increase. We requested comments on whether it may be desirable to develop a method for testing the strength of aggregated magnets in addition to the method for testing the strength of individual magnets. We received no comments proposing methodologies for testing the strength of an aggregation of magnets. Furthermore, because there are no magnet sets currently on the market with magnets that have a 50 kG^2 mm^2 flux index or less, we believe that the aggregation scenario is adequately addressed in the rule.

5. Findings—§ 1240.5

In accordance with the requirements of the CPSA, we have made the findings stated in section 9 of the CPSA. The findings are discussed in section N of this preamble.

G. Alternatives

The Commission has considered alternatives to reduce the risk of injury related to the ingestion of magnets contained in magnet sets. However, as discussed below, the Commission does not believe that any of these alternatives would adequately reduce the risk of injury.

1. Voluntary Recalls

Although most of the companies that manufacture or import magnet sets have voluntarily agreed to stop selling (and in some cases recall) these products, and several retailers have agreed to recall and stop sale, the Commission has been unsuccessful in negotiating voluntary recalls and stop sales with one company that continues to market magnet sets. Pursuing voluntary recalls with current and possibly future manufacturers and importers of magnet sets would be reactive and would entail waiting for new incidents to occur rather than preventing them. Moreover, recalls would not prevent new entrants into the market in the future; a rule will set requirements that all products must meet from the effective date of the rule going forward.

2. Voluntary Standard

Currently, there is no applicable voluntary standard in effect. Before publication of the NPR, a group of magnet set importers and distributors requested that ASTM International

develop a voluntary standard for the labeling and marketing of these products. Specifically, these companies requested the creation of a voluntary standard to: (1) Provide for appropriate warnings and labels on packages of these magnets sets; and (2) establish guidelines for restricting the sale of these magnet sets to children, by not selling to stores that sell children's products exclusively, and advising retailers not to sell the magnet sets in proximity to children's products. To date, ASTM has not formed a committee to consider the development of a voluntary standard for magnet sets.

Moreover, whether such a voluntary standard would be effective in reducing or eliminating the risk of injury associated with magnet sets is questionable. Despite companies' marketing and labeling their products in an attempt to limit children's exposure to magnets, ingestion incidents involving children have continued to occur; and labeling does not change the attractiveness of the product to children or the intrinsic play value of the magnet sets. From March 2010, when the firm with the largest share of the market undertook certain labeling enhancements and marketing restrictions, through June 2012, the Commission learned of 47 additional incidents of ingestion of magnets from magnet sets, 26 of which involved ingestion of that company's magnets. As discussed more fully in the next section of this preamble, we do not believe that warnings would adequately reduce the injuries associated with magnet sets.

We also note that Zen Magnets has announced its own ''voluntary standard'' for magnet sets requiring that:

- Customers must be 18 years of age or older to purchase magnets and that the sales location must have an age floor for persons 18 and older or 21 and older, or age must be otherwise verified by Government ID; and
- All stores must verbally remind customers to keep magnets away from mouths.

We do not consider a standard issued by one company to be a ''voluntary standard'' as that term is used in the CPSA. Moreover, the measures that Zen magnets announced would have the same limitations discussed above.

3. Warnings

A possible alternative to the rule would be to require warnings with or on magnet sets. As discussed in the NPR preamble and in response to comments set forth in section E of this preamble, it is unlikely that warnings on the packages of magnet sets would significantly reduce the ingestion-related injuries caused by high-powered magnets. Safety and warnings literature consistently identifies warnings as a less effective hazard-control measure than eliminating the hazard through design or guarding the consumer from a hazard. Warnings do not prevent consumer exposure to the hazard but rely on persuading consumers to alter their behavior in some way to avoid the hazard. With this product, warnings are particularly unlikely to reduce or eliminate the ingestion of these magnets. Warnings are especially unlikely to be effective among young children because children may lack the cognitive ability to appraise a hazard or appreciate the consequences of their own actions and may not understand how to avoid hazards effectively.

Although older children are better at appreciating the hazards described in a warning, peer acceptance and social influences can strongly influence adolescent behavior. Because adolescents have a tendency to test limits and bend rules, warnings about keeping the product away from children could have the unintended effect of making the product more appealing to some children. For example, warnings against specific uses, such as mimicking piercings, might actually encourage this behavior among older children. If children repeatedly use the product in this way, without ingesting the magnets, these children most likely will become convinced that the hazard is not especially likely, or is not relevant to them.

In the NPR, we noted that staff generally found the content of warnings accompanying magnet sets to be lacking in several ways. For example, the warnings often did not describe the incident scenarios prevalent among older children and adolescents, whom caregivers may not believe are likely to put magnets into their mouth. Warnings lacked detailed information that would allow consumers to understand how swallowing magnets differs from swallowing other small parts, or how magnets sticking together could pose a hazard because the magnets will not simply pass through the child's system. Without a clear, explicit, and accurate description of the nature of the hazard and its consequences, consumers may find the warning implausible. Moreover, even with enhanced warnings, consumers are unlikely to comply with the action recommended in the warning.

Even if warnings could effectively communicate the ingestion hazard, the consequences of ingesting magnets, and appropriate hazard-avoidance measures, warnings still may not be effective if consumers do not concur with the content of the warning. Warnings are particularly likely to be ineffective among caregivers of older children. Unless caregivers are convinced that their older child is likely to mimic lip, nose, or similar piercings, or perform other activities that might lead these adolescents to place magnets into their mouth or nose, caregivers may doubt that the warnings are relevant to their child, despite the warnings' assertions to the contrary.

As noted in the NPR preamble and in section E of this preamble, even if caregivers believe the warnings, several factors may limit compliance. Caregivers, particularly those with older children, might feel significant social pressure from children who are accustomed to using the magnet sets. Caregivers who own the product and attempt to heed the warnings might find it quite difficult to prevent their child's access to the magnets and still keep the product reasonably accessible for their own use.

The cost of compliance with warnings for these products is high. Caregivers may be reluctant to secure the product from a child after every use. Identifying an appropriate location to store the magnet sets may dissuade consumers from doing so, particularly for a product often marketed to be for ''stress relief.'' Caregivers may underestimate their child's abilities and place the product in locations that seem secure but that are still accessible to the child. All of these factors may lead caregivers to reject the warning message.

Based on these concerns about the likely ineffectiveness of warnings for magnet sets, we do not believe that warning labels would adequately reduce the risk of injury presented by these products.

4. Packaging Restrictions

Theoretically, magnet sets could be sold with special storage containers to reduce the likelihood that children would access the magnets. Possible storage might include a container that would clearly indicate when a magnet is missing from the set. Such a requirement might prevent injuries resulting from a small number of magnets being separated from a set without the owner being aware. However, many consumers may not use such containers because using them could require time to gather the magnets and put them in the container, or consumers may be reluctant to dismantle a shape or structure that took them time and effort to construct. Thus, the effectiveness of such special containers to reduce ingestions is doubtful. Finally, it is not clear that the

Commission would have the regulatory authority to issue a rule prescribing requirements for packaging, other than child-resistance requirements (discussed below).

Another alternative might be to require that magnet sets be sold in child-resistant packaging. Child-resistant packaging, also called ''special packaging,'' is packaging that is significantly difficult for children under five years of age to open or obtain a harmful amount of the substance. 15 U.S.C. 1471(4). The ability of such an approach to reduce ingestion injuries of magnets from magnet sets would be limited. Child-resistant packaging would not prevent teens and adolescents (and even some younger children) from opening the packaging. Additionally, the packaging would have to be secured after each use. According to the Division of Human Factors, it is unlikely that adults would accept child-resistant packaging for a product like the magnet sets because of the level of inconvenience involved in returning the magnets to the package.[6] Additionally, for the reasons described above, consumers may leave magnets out of their container.

5. Restrictions on Sales of Magnet Sets

Another possible alternative to address the hazard of children ingesting magnets from magnet sets might be to limit the places where magnet sets are sold, keeping magnet sets away from toy stores, children's sections of stores, and other such locations. Sales limitations or requirements for strong warnings might also be required on Web sites that offer magnet sets for sale on the Internet. However, these restrictions are unlikely to reduce ingestions significantly because children can access magnet sets from many sources other than stores. Moreover, sales restrictions are unlikely to deter teens. Finally, the Commission does not have the regulatory authority to impose such sales restrictions by rule.

6. Adoption of a Standard With Different Performance Requirements

Another alternative to the rule would be to establish a different set of requirements. For example, such requirements might allow a different flux index for magnet sets, different specifications regarding shapes and sizes of magnets within the scope of the standard, or some other criteria that have yet to be developed (but would not be as stringent as the rule requires). If different requirements would be effective, they could reduce the risk of injury associated with magnet sets, and at the same time, potentially allow the product to maintain the qualities that would facilitate use by adults. It is unclear, however, whether alternative requirements for the sizes and flux index of magnets would eliminate or substantially affect the physical qualities of the products that make them enjoyable for adults.

A competing concern is whether an alternative set of requirements could reasonably be expected to reduce or eliminate the risk of injury associated with magnet sets. Because the hazard presented by these magnet sets is ingestion by children, we are concerned that any requirements that allow magnets with a greater attractive force and permit sizes or shapes that could fit through the small parts cylinder would not address the risk of injury adequately.

As noted in Section E, some commenters suggest that, as an alternative to the rule, the Commission could require manufacturers to add an aversive (bittering) agent to the product. However, as discussed in the response to Comment 18, aversives are unlikely to be effective in deterring initial ingestion by young children because children frequently ingest unpalatable substances.

7. No Action

Another option for the Commission is to take no regulatory action to address the risk of injury posed by magnet sets. As the NPR preamble mentioned, it is possible that, over time, increased awareness of the hazard could result in some reduction in ingestions. The magnitude of any such reduction in incidents is uncertain. The Commission could rely entirely on enforcement activities, rather than regulatory action, to address the risk of injury posed by magnet sets. However, as discussed in the ''voluntary recall'' section above, several manufacturers/importers of magnet sets have refused to participate in any recall or stop sale of their products; and in any event, recalls and/or stop sales conducted by these companies would not prevent new entrants into the market in the future.

H. Final Regulatory Analysis

The Commission is issuing this rule under sections 7 and 9 of the CPSA. The CPSA requires that the Commission prepare a final regulatory analysis and publish the final regulatory analysis with the text of the final rule. 15 U.S.C. 2058(f). This section of the preamble presents the final regulatory analysis of the rule.

1. Need for and Description of the Rule

The CPSC has received information regarding injuries with, and hazards posed by, sets of small, powerful magnets. Some of these injuries have required surgical removal of individual magnets originally contained in the sets and ultimately ingested by children. Reported magnet ingestions have ranged from young children, who put the magnets in their mouths, to adolescents and teens, who experimented with the sensation of magnets (*e.g.,* on their braces), or paired magnets to mimic tongue or lip piercings. These behaviors have led to the accidental swallowing of the powerful magnets, with unexpected, and sometimes severe, medical consequences, including significant damage to the gastrointestinal tract (Inkster, 2012) and death. From January 1, 2009 through December 31, 2013, there were an estimated 2,900 possible magnet set, emergency department-treated ingestions. There was also one fatal incident in 2013 (Garland, 2014).

The final rule establishes a standard limiting the size and strength of magnets in a magnet set. The rule applies to any aggregation of separable, magnetic objects that is a consumer product intended, marketed, or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief.[7] Under the rule, magnet sets would not comply with the standard if: (1) The individual magnets are small enough to fit into the small parts cylinder (*e.g.,* a ball-shaped magnet with a diameter of less than 31.7 mm, or 1.25 inches); and (2) the individual magnets have a flux index of more than 50 kG^2 mm^2, as measured by the procedures for determining the flux index described in the toy standard. Because these requirements already apply to magnets used in products marketed as toys for children, the rule essentially extends the toy requirements to the subject magnet sets.

The current designs of magnet sets containing small powerful magnets of the type that are the subject of this regulatory proceeding (which are typically comprised of individual ball-shaped magnets with diameters of 5mm and, based on testing by CPSC staff, having flux index values in the range of 400–500) would not meet the

[6] Sedney, C.A., & Smith, T.P. (2012). *Human factors assessment of strong magnet sets.* CPSC memorandum to Jonathan D. Midgett, Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD.

[7] Although the definition of ''magnet set'' changed slightly from the NPR, and the rule extends to the individual magnets sold for use as or with a magnet set, these changes did not affect the scope of products considered in conducting the Final Regulatory Analysis.

requirements of the standard. To meet the requirements, the individual magnets would have to be much weaker (*i.e.,* have a flux index of 50 kG^2 mm^2 or less, rather than an index of 400 to 500); or the magnets would have to be much larger (*i.e.,* be at least 31.7 mm (1.25 inches) in diameter rather than 5 mm). Either requirement eliminates a distinctive product attribute and would limit greatly the magnet sets as candidates for manipulative novelty products. Magnets with a flux index of 50 kG^2 mm^2 or less may be too weak for building sculptures or too weak to be used in other construction activities; magnets with diameters of 1.25 inches or more would be too large to have any practical value in such activities.

Staff has identified magnet sets in the market, Liberty Balls, marketed by Assemble, LLC, that would meet the definition of magnet sets, would meet the performance standard, and might serve some of the uses of magnet sets that would not meet the standard. The Liberty Balls magnet sets consist of a set of eight large ball-shaped magnets. The Liberty Balls magnet sets consist of a set of eight large ball-shaped magnets selling for $30 to $40 per set. The Ball of Rights generally consists of a set of two large ball-shaped magnets selling for $10 to $13 per set. The balls in these sets are 33 mm (1.3 inches) in diameter, and consist of ferrite magnets, rather than rare earth materials (See *http://unitedweball.org/,* accessed February 25, 2014).

Even though these products satisfy the performance requirements of the rule, for purposes of the economic analysis, we do not consider any impacts due to the entry of Liberty Balls and Ball of Rights in the market because we do not consider these sets to be good substitutes for the subject magnet sets. To be considered a good or close substitute, we would need to observe that consumers, who would have purchased the subject magnet sets (if they had remained available at historical prices and quantities) are now, to a large degree, purchasing the Liberty Balls sets instead, and the available data suggest otherwise.[8] Moreover, Liberty Balls magnet sets are not marketed as a substitute for the smaller and powerful neodymium magnets sets. Rather, Liberty Balls apparently have been sold specifically to generate funds to defend the producer against the recently settled lawsuit with the CPSC (Helm, 2014).

Rather than develop a complying alternative that serves the same niche as the subject magnet sets, producers of magnet sets have opted to exit the market altogether. Although Liberty Balls comply with the standard, we base the benefit cost analysis presented below on the disappearance of the noncompliant magnet sets containing small powerful magnets from the market.

2. Description of the Product and Market

Magnet sets that would be affected by the scope of the rule are comprised of small, powerful magnetic balls, cubes, and/or cylinders that can be arranged in many different geometric shapes. These magnet sets were introduced in 2008, but 2009 marked the first year with significant sales to U.S. consumers.[9] Most magnet sets have been sold in sets of either 125 balls or sets of 216 to 224 balls; although some firms have sold just a few balls as extras or replacements, others have sold large sets of more than 1,000 magnetic balls.

Product information provided by marketers indicates that the most common magnet size is approximately 5 millimeters in diameter; although balls as small as about 3 millimeters have been sold, in addition to sets of larger magnet balls (perhaps 15 millimeters to 25 millimeters in diameter).[10] In addition to magnetic ball sets, sets of small magnetic cubes have also been sold, although magnetic cubes have comprised a relatively small share of the market. In 2012, the leading marketer of magnet sets also added to its desk toy product line small magnetic rods intended to be used with magnetic balls to make geometric shapes.

Based on information reviewed on product sales, including reports by firms provided to the Office of Compliance and Field Operations, the number of such magnet sets that were sold to U.S. consumers from 2009 through mid-2012 may have totaled about 2.7 million sets, with a value of roughly $50 million. This value reflects a combination of retail sales directly to consumers (through company Web sites and other Internet retail sites) and sales to retailers who marketed the products. A review of retail prices reported by importers, and observed on Internet sites during that period, suggested prices typically ranging from about $20 to $45 per set, with an average price of about $25. Larger sets of more than 1,000 individual magnets reportedly were sold at prices as high as $300, depending on the number of magnets and the type of packaging. Such larger sets only accounted for about 0.5 percent of all sets (and a little over 2 percent of all magnets) sold to consumers during the period from 2009 to mid-2012.

The small, powerful magnets to be affected by the rule are made of alloys of neodymium, iron, boron, or other rare earth metals. This composition has been confirmed in analyses of product samples by CPSC staff from the Directorate for Laboratory Sciences. The magnetized neodymium-iron-boron cores are coated with a variety of metals and other materials to make them more attractive to consumers and to protect the brittle magnetic alloy materials from breaking, chipping, and corroding. Nearly 100 percent of neodymium and other rare earth metals are now mined in China, which also reportedly holds close to a worldwide monopoly on the production of neodymium-iron-boron magnets (Dent, 2012). Based on available information, all of the small magnets used in magnet sets, as well as most of the finished and packaged products that would be subject to CPSC regulation, are produced by manufacturers located in China.[11]

a. Importers of Magnet Sets

As noted above, none of the magnets found in sets that are within the scope of the rule are produced domestically. Nearly all of the firms that have marketed magnet sets are believed to have imported them packaged and labeled for sale to U.S. consumers. Several Chinese manufacturers have the facilities and production capacity to meet the orders of U.S. importers.

The Directorate for Economic Analysis identified about 25 U.S. firms and individuals who imported magnet sets for sale in the United States in 2012. The combined sales of the top seven firms have probably accounted for

[8] Sales of Liberty Balls have not come close to matching the levels observed for the subject magnet sets (estimated at 800,000 sets and $20 million annually, and discussed below). Based upon available information, sales revenue for Liberty Balls appears to have amounted to about $200,000 during October and November 2013, or about $100,000 per month. (See *http://unitedweball.org/,* accessed February 25, 2014). By March 2014, reported sales revenue from Liberty Balls had increased to about $250,000 (Helm, 2014), suggesting that for December 2013 through February 2014, sales were only about $15,000 (($250,000–$200,000)/3) per month. By comparison, monthly sales for the subject magnet sets were about $1.7 million on average. (CPSC staff conducted no independent evaluation of the accuracy of these figures for Liberty Balls.)

[9] However, small neodymium-iron-boron magnets previously have been, and continue to be, marketed by firms such as magnet suppliers and distributors of educational products.

[10] One firm's larger magnet balls are reportedly made with cores of strontium ferrite ($SrO{\cdot}6Fe_2O_3$), rather than neodymium-iron-boron.

[11] One importer reported to a CPSC Compliance investigator that some of the magnet sets it sold and shipped to U.S. consumers were made from bulk magnets received from its supplier in China that the importer packaged for sale.

the great majority (perhaps more than 98%) of units sold since the product was introduced in 2008. One firm, Maxfield & Oberton Holdings, LLC, is believed to have held a dominant position in the market for magnet sets from its entry in the market in 2009, until it ceased operations late in 2012. That firm, and a few of the larger firms (including a firm based in Canada with a branch office in the United States), have marketed the products through accounts with retailers, in addition to selling directly to consumers on the Internet, using their own Web sites or other Internet shopping sites.

Some of the firms with smaller sales volumes reported to Compliance staff that they mainly marketed products (sourced from manufacturers in China) through Internet sales arrangements with Amazon.com, which held stock for them and processed orders. A review of the product listings of the Internet retailer found that several other firms had similar business models. Other U.S. firms and individuals have sold magnet sets they imported from China through Internet ''stores'' they maintain on eBay. In addition to products offered for sale by U.S. importers, consumers have also been able to purchase magnet sets directly from sources in Hong Kong or China, many of which marketed products through ''stores'' on eBay.[12]

b. Market Disruption Related to Other CPSC Actions on Magnet Sets

CPSC Compliance staff contacted 13 magnet set importers for corrective actions before the Commission published the NPR.[13] At staff's request in July 2012, 10 firms agreed to stop the manufacture, importation, distribution, and sale of high-powered, manipulative magnetic products of the types that would be subject to the rule. Three other firms did not stop selling the products (although one of these firms initially had agreed to cease sales voluntarily). The Commission voted to initiate administrative actions seeking a determination that certain magnet sets are a substantial product hazard, along with an order requiring the firms that import these products cease sales and offer refunds to customers.[14] The three firms that have been subject to the administrative complaints by the CPSC, and the 10 firms that have agreed to stop sales voluntarily, accounted for virtually all sales of the products during the period from 2009 to mid-2012. Additionally, the largest importer of magnet sets subject to the rule (one of the three firms sued in administrative complaints), Maxfield & Oberton Holdings, LLC, announced that it ceased operations, effective December 27, 2012. Another of the three firms sued in administrative complaints, Star Networks USA, LLC, agreed to stop further sales of magnet sets in July 2014, leaving just one major magnet set importer, Zen Magnets, LLC. As a result of these actions and events, sales of the subject magnet sets currently are dramatically lower than they were at the time of the enforcement actions.

3. Evaluation of the Rule

a. Societal Costs and the Potential Benefits

i. Estimated Societal Costs of Injuries

The purpose of the final rule is to prevent serious intestinal injuries that can result when children ingest two or more of the magnets from a subject magnet set (or one magnet and another metallic object). The final rule would establish a standard for magnet sets and individual magnets that are marketed or intended for use as parts of a magnet set. Distributing magnet sets and individual magnets intended for magnet sets that do not meet specified requirements would be prohibited. Therefore, a reduction in injuries would be the resulting benefit of the rule.

Baseline. Our analysis of the potential benefits of the rule focuses on injuries reported through the National Electronic Injury Surveillance System (NEISS), a probability sample of U.S. hospital emergency departments that can be used to provide national estimates of product-related injuries initially treated in U.S. hospital emergency departments. The expected benefits of a product safety regulation must be measured against a baseline representing the best assessment of how the market would operate and how products would be used in the absence of the intervention. In the case of the rule prohibiting the subject magnet sets, the baseline would represent the time period before the actions by which the CPSC: (1) Requested that importers and retailers stop selling the magnet sets; (2) initiated administrative actions against importers that refused to stop selling the magnet sets (each of which seeks an order directing the importer to offer refunds in exchange for the return of purchased magnet sets); (3) publicized corrective actions, whereby certain importers and retailers of magnet sets agreed to provide refunds to consumers in exchange for the return of purchased magnet sets; and (4) issued warnings to the public regarding the grave dangers that the subject magnet sets posed to children. Because CPSC compliance actions have significantly altered the state of the market, the environment before these actions occurred represents the best approximation of how the market would have operated in the absence of CPSC intervention and is the appropriate reference baseline for evaluating the impact of the rule. Consequently, although the Directorate for Epidemiology's hazard analysis described injuries involving magnets that occurred from 2009 through December 2013 (Garland, 2014), our analysis will be limited to the period from 2009 through June 2012, before the request to stop sales, administrative actions, recalls, and public warnings ensued.

Based on a review of incident narratives coded from emergency department medical records for magnet ingestion cases obtained from NEISS hospitals, the Directorate for Epidemiology staff has identified 86 ingestions of high-powered and/or ball-shaped magnets, which occurred from 2009 through June 2012. These incidents were determined to involve, or possibly involve, the magnets of interest. Although manufacturer or brand name information is rarely available in the medical records extracted for NEISS, nine of the 86 NEISS-reported cases (10.5%) mentioned a brand name of magnet sets that are the magnets of interest; 77 cases (89.5%) were determined possibly to have involved the magnets of interest because the case narratives included terms such as ''high powered,'' ''magnetic ball,'' ''magnetic marble,'' ''BB size magnet,'' or ''magnetic beads'' (Garland, 2014).

Injuries and Societal Costs. Based on the 86 NEISS-reported magnet cases, there were an estimated 2,138 injuries treated in U.S. hospital emergency departments from 2009 through June 2012. About 11 percent of these NEISS-reported cases were injuries requiring hospitalization, as opposed to the 89 percent that were treated and released. The benefits of the rule can be estimated as the reduction in the societal costs associated with the injuries that would be prevented by the rule. The

[12] More than 40 such stores shipping magnet sets directly from Hong Kong or China were identified in a brief review of product offerings on the Internet site in 2012.

[13] Although other importers were identified, these other importers were believed to sell so few magnet sets that staff did not have the resources to pursue these matters on a case-by-case basis against all known importers. Thus, targeting for corrective actions was limited to 13 firms believed to account for the largest portion of the market.

[14] For example, see the December 19, 2012, CPSC press release related to the administrative complaint filed against Star Networks (*http://www.cpsc.gov/en/Newsroom/News-Releases/2013/CPSC-Sues-Star-Networks-USA-Over-Hazardous-High-Powered-Magnetic-Balls-and-Cubes/*).

Directorate for Economic Analysis bases estimates of the societal costs of emergency department-treated magnet injuries on the CPSC's Injury Cost Model (ICM) (Miller et al., 2000).

The ICM is fully integrated with NEISS and provides estimates of the societal costs of injuries reported through NEISS. The major aggregated components of the ICM include: medical costs; work losses; and the intangible costs associated with lost quality of life or pain and suffering.[15]

Medical costs include three categories of expenditure: (1) Medical and hospital costs associated with treating the injury victim during the initial recovery period and in the long run, the costs associated with corrective surgery, the treatment of chronic injuries, and rehabilitation services; (2) ancillary costs, such as costs for prescriptions, medical equipment, and ambulance transport; and (3) costs of health insurance claims processing. Cost estimates for these expenditure categories were derived from a number of national and state databases, including the National Healthcare Cost and Utilization Project—National Inpatient Sample and the Medical Expenditure Panel Survey, both sponsored by the Agency for Healthcare Research and Quality.

Work loss estimates, based on information from the National Health Interview Survey and the U.S. Bureau of Labor Statistics, as well as a number of published wage studies, include: (1) The forgone earnings of parents and visitors, including lost wage work and household work, (2) imputed long term work losses of the victim that would be associated with permanent impairment, and (3) employer productivity losses, such as the costs incurred when employers spend time juggling schedules or training replacement workers. The earnings estimates were updated most recently with weekly earnings data from the Current Population Survey conducted by the Bureau of the Census in conjunction with the Bureau of Labor Statistics.

Intangible, or non-economic, costs of injury reflect the physical and emotional trauma of injury as well as the mental anguish of victims and caregivers. Intangible costs are difficult to quantify because they do not represent products or resources traded in the marketplace. Nevertheless, they typically represent the largest component of injury cost and need to be accounted for in any benefit-cost analysis involving health outcomes (Rice et al., 1989). The Injury Cost Model develops a monetary estimate of these intangible costs from jury awards for pain and suffering. While these awards can vary widely on a case-by-case basis, studies have shown them to be systematically related to a number of factors, including economic losses, the type and severity of injury, and the age of the victim (Viscusi, 1988; Rodgers, 1993). Estimates for the Injury Cost Model were derived from a regression analysis of about 2,000 jury awards in nonfatal product liability cases involving consumer products compiled by Jury Verdicts Research, Inc.

In addition to estimating the costs of injuries treated in U.S. hospital emergency departments and reported through NEISS, the Injury Cost Model uses empirical relationships between emergency department injuries and those treated in other settings (*e.g.,* physicians' offices, clinics, ambulatory surgery centers, and direct hospital admissions) to estimate the number, types, and costs of injuries treated outside of hospital emergency departments (Miller et al., 2000; Lawrence, 2013). Thus, the Injury Cost Model allows us to expand on NEISS by combining (1) the number and costs of emergency department injuries with (2) the number and costs of medically attended injuries treated in other settings to estimate the total number of medically attended injuries and their costs across all treatment levels.

Table 1 below provides *annual* estimates of the injuries and the societal costs associated with ''high-powered and/or ball-shaped magnet ingestions'' that involve, or possibly involve, the magnets that are the subject of the rule. As shown in Table 1, the 2009 through June 2012 NEISS estimates suggest an estimated annual average of about 610 emergency department-treated injuries, including 544 injuries that were treated and released and 66 injuries that required hospitalization. About 60 percent of these emergency department-treated ingestions involved children ages 4 through 12 years. Just over half of the magnet cases from the emergency departments of the hospitals that comprise the NEISS sample appear to have involved the ingestion of more than one magnet. Additionally, based on estimates from the ICM, there were another 319 injuries treated annually in locations other than hospital emergency departments.[16]

TABLE 1—ESTIMATED AVERAGE ANNUAL MEDICALLY ATTENDED INJURIES AND ASSOCIATED SOCIETAL COSTS FOR HIGH-POWERED AND/OR BALL-SHAPED MAGNET INGESTIONS THAT WERE DETERMINED TO INVOLVE, OR POSSIBLY INVOLVE, THE MAGNETS OF INTEREST, 2009–JUNE 2012

Injury disposition	Estimated number	Estimated societal costs ($ millions) *
Treated and Released from Hospital Emergency Department (NEISS)	544	11.4
Admitted to Hospital Through the Emergency Department (NEISS)	† 66	8.6
Medically Treated Outside of Hospital Emergency Department (ICM)	319	8.6
Total Medically Attended Injuries	929	28.6

* In 2012 dollars.

† According to the Directorate for Epidemiology, the estimated number of hospital-admitted, emergency department-treated injuries is a not a reliable estimate because of the small number of cases upon which the estimate was based.

After including the injuries treated outside of hospital emergency departments, there was an estimated annual average of about 929 medically attended injuries involving ingestions of the magnets of interest. Based on the ICM, these injuries resulted in annual societal costs of about $28.6 million (in 2012 dollars) during the 2009 to June 2012 time period. The injury cost estimates differ from those presented in the preliminary regulatory analysis

[15] A detailed description of the cost components, and the general methodology and data sources used to develop the CPSC's Injury Cost Model, can be found in Miller et al. (2000).

[16] Although no deaths were reported during the baseline time period for this analysis, one death involving the subject magnets was reported in 2013.

because of an expansion of the baseline time period from 2009 through 2011 to 2009 through June 2012 and because of updates to the CPSC's Injury Cost Model (Lawrence, 2013). The injury cost estimates were also inflated from 2011 to 2012 dollars.

The average estimated societal costs per injury was about $27,000 for injuries treated in locations other than emergency departments (such as physicians' offices, clinics, ambulatory surgery centers, or direct hospital admissions); about $21,000 for injuries that were treated and released from emergency departments; and about $130,000 for injuries that required admission to the hospital for treatment. Medical costs and work losses (including work losses of caregivers) accounted for about 30 percent of these injury cost estimates, and the less tangible costs of injury associated with pain and suffering accounted for about 70 percent of the estimated injury costs.

Uncertainty. As noted in the preliminary regulatory analysis, there is uncertainty concerning these estimates. Some of the cases described as involving the magnets of interest that were included in Table 1 may not have involved the magnets that are the subject of the rule. As noted above, about 90 percent of the cases upon which the table was based were described as only possibly involving the magnets of interest because NEISS narratives are not required to list manufacturer or brand name. Hence, it is possible that Table 1 overstates the societal costs associated with the magnets that would be included in the rule.

On the other hand, in addition to the magnet cases upon which the table was based, there were also 230 NEISS cases (representing about 1,526 emergency department-treated injuries annually), in which the magnet type was classified as ''unknown or other.'' These cases included narratives that mentioned that a magnet was involved but presented insufficient information to classify the magnet type. Consequently, to the extent that the unknown magnet types involved magnets that would be covered by the rule, the Table 1 results would tend to understate the societal costs associated with the magnets subject to the rule.

ii. Estimated Benefits of the Rule

As noted above, the benefits of the magnet rule would be the reduction in the societal costs of the injuries that would be prevented. Because the rule will eliminate from the market all magnet sets involved in the ingestion injuries described above, all injuries that would have occurred in the absence of a rule would be prevented. Although no deaths involving magnet sets occurred during the time period covered by our analysis, we know of a magnet set related fatality that occurred in 2013. Thus, we anticipate that the rule would prevent future fatalities as well as injuries. However, if children, adolescents, and teens cannot play with or use the prohibited magnets, they could play with or use substitute products (including high-powered magnets intended for other uses [17]) that also may result in injury. Hence, the overall benefits of the rule should be measured as the net reduction in injuries and the concomitant reduction in societal costs that would result. Based on the injury estimates presented in Table 1, and given the absence of information on expected use and risks of alternative products or activities, the expected benefits of the rule might amount to about $28.6 million annually.

b. Potential Costs of the Rule

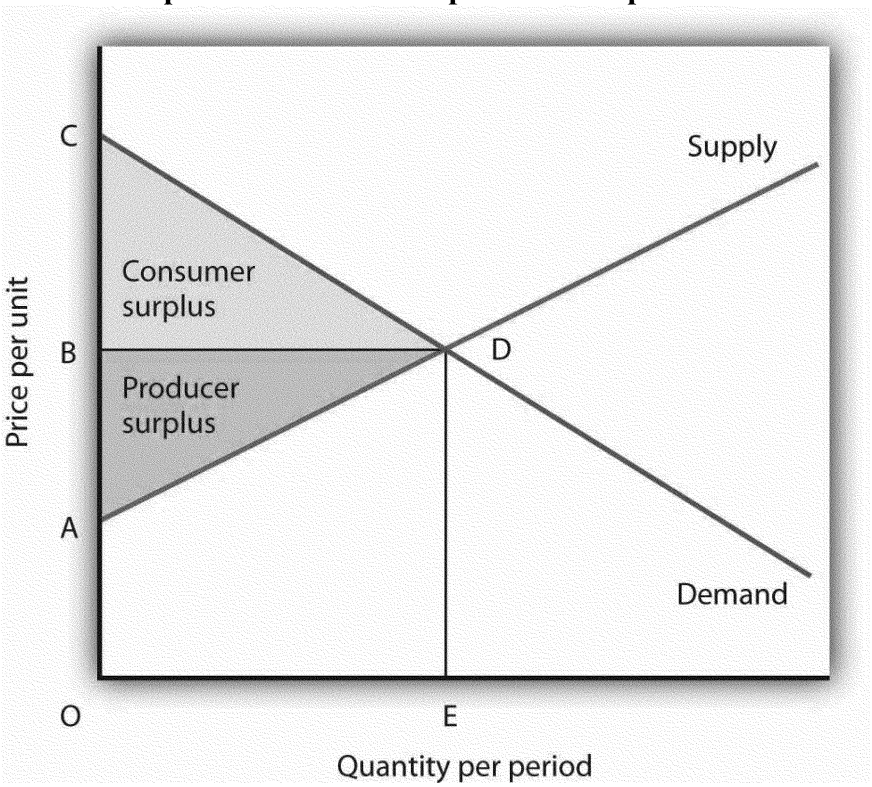
Both consumers and producers benefit from the production and sale of consumer products. The consuming public obtains the use value or ''utility'' associated with the consumption of products; producers obtain income and profits from the production and sale of products. Consequently, the costs of a rule that eliminates certain magnetic sets would consist of: (1) The lost use value experienced by consumers who would no longer be able to purchase magnets that do not meet the standard at any price; and (2) the lost income and profits to firms that could not produce and sell non-complying products in the future. The same baseline used in the benefits assessment, 2009 to June 2012, is used for the cost analysis.

i. Lost Utility to Consumers

First, consider the lost utility to consumers. We cannot estimate in any precise way the use value that consumers receive from these products, but we can describe use value conceptually. In general, use value includes the amount of: (1) Consumer expenditures for the product, plus (2) what is called ''consumer surplus.'' In the case of the magnet sets, given sales of about 800,000 sets annually during the 2009 to June 2012 time period, and assuming an average retail price of about $25 in 2012, consumer expenditures would amount to about $20 million annually in 2012 dollars. These expenditures represent the minimum value that consumers would expect to get from these products. It is represented by the area of the rectangle OBDE in the standard supply and demand graph below, where B equals $25, and E equals 800,000 units.

[17] Common commercial and industrial applications of small neodymium-iron-boron magnets include their use in holding systems, motors (DC, servo, linear, and voice coil), magnetic bearings, magnetic couplings, jewelry, welding clamps, oil filters, disc drives, loudspeakers, headphones, microphones, instrumentation, switches, and relays.

Figure 1. Supply and demand graph illustrating the concepts of consumer and producer surplus



The consumer surplus is given by the area of the triangle BCD under the graph's demand function and represents the difference between the market clearing price and the maximum amount consumers would have been willing to pay for the product. This consumer surplus will vary for individual consumers, but it represents a benefit to consumers over and above what they had to pay (McCloskey, 1982).[18] For example, although tickets to a concert or football game might sell for $100 each, some consumers who buy them for $100 would have been willing to pay $150 per ticket. In other words, they paid $100 and received benefits that they value at $150. Hence, each of these consumers would receive a consumer surplus of $50.[19]

In general, the use value of the magnet sets obtained by consumers is represented by the area of the trapezoid OCDE. However, the prospective *loss* in use value associated with the rule, which would prohibit certain magnet sets that do not comply with the rule, would amount to, at most, the area of the triangle representing the consumer surplus. This is because consumers would no longer be able to obtain utility from the prohibited product, but they would, nevertheless, still have the $20 million (represented by the rectangle OBDE) that they would have spent on magnet sets in the absence of a rule. Although consumers would no longer be able to purchase magnet sets, which would have been their first choice, they can use this money to buy other products providing use value.

We have no information regarding aggregate consumer surplus; and hence, no information on the amount of utility that would be lost from a magnet set rule. Although the magnet sets clearly provide ''utility'' to purchasers, magnet sets are not necessities. Consequently, the demand for magnet sets is probably not price inelastic, a factor that would tend to reduce estimates of utility losses.[20] Additionally, if the magnetic sets are ''faddish,'' they may not be the type of product that will be used intensely by consumers over long periods of time. However, if, for example, consumers who purchased the magnetic sets at an average price of $25 would have been willing to spend, on average, $35 per set, the lost utility from the magnet sets might amount to about $8 million on an annual basis (*i.e.,* $[\$35 - \$25] \times 800{,}000$ units annually).

Finally, we note that the loss in consumer surplus just described represents the maximum loss of consumer utility from the rule; the actual loss is likely to be lower. This is because consumers are likely to gain some amount of consumer surplus from products that are purchased as an alternative to those magnet sets that would no longer be available because of the rule. If, for example, there were close substitutes for the magnet sets that do not meet the standard (*e.g.,* desk toys that are almost as satisfying and similarly priced), the overall loss in consumer surplus (and, hence, the costs of the rule) would probably tend to be small. On the other hand, if there are no close substitutes, the costs of the rule would tend to be higher.

[18] The concept of consumer surplus is discussed in OMB's Circular A–4 (OMB, 2003) and has been applied in several CPSC staff analyses, including Tohamy (2006) and Rodgers (2004).

[19] If the above graph represents the market for tickets, the demand curve describes the quantity of tickets demanded at each price (*i.e.,* the quantity of tickets consumers are willing and able to purchase at each price). In this example, the $150 that the consumer would have been willing to pay for the ticket is represented on the demand curve at a point to the left of point D. The consumer surplus is given by the relevant point on the demand curve (*i.e.,* where price = $150), minus the market clearing price of $100.

[20] To say that the demand for a product is price ''inelastic'' means that the quantity demanded tends to be insensitive to changes in the price of the product. Gasoline is an example of a product with an inelastic demand. Consumers are not likely to reduce substantially their purchase of gasoline (at least in the short run), even if the price increases substantially.

Some alternative products might serve some of the same uses of the subject magnet sets. For example, consider the Liberty Balls mentioned earlier, which are comprised of large (1.3 inch) ferrite magnetic objects. Their size, weight, and relatively high price per ball make Liberty Balls unsuitable and impractical for use in most sculpturing and other construction activities for which the subject magnet sets are used. They might still be used by some for ''fidgeting,'' but there does not seem to be any unique attribute of this product that would cause a consumer to purchase Liberty Balls specifically for fidgeting; common objects, such as paper clips or ball bearings, could serve the same fidgeting purpose at a lower price.

Another possible alternative product discussed by the Directorate for Engineering Sciences (Amodeo, 2013) could be magnet sets comprised of individual magnets permanently connected by rods or other means, such that the resulting magnetic objects are not small parts. Such sets are marketed as children's toys because the individual pieces in the set do not fit into the small parts cylinder. Although these products have not been marketed for adults, and we have no evidence that they could be considered a good substitute for the subject magnet sets, if such sets could satisfy some consumers' needs in constructing geometric shapes, then the lost consumer surplus might be reduced.

Notwithstanding the availability of alternatives to the subject magnet sets, the rule will still result in some level of lost utility. By purchasing the products in question, rather than other products, consumers are revealing that they have a preference for the subject magnet sets that they believe are likely to provide them more utility than a substitute purchase.

ii. Lost Benefits to Producers

The lost benefits to firms resulting from a rule that effectively eliminates a product they produce are measured by a loss in what is called producer surplus. Producer surplus is a profit measure that is somewhat analogous to consumer surplus. Whereas consumer surplus is a measure of benefits received by individuals who consume products, net of the cost of purchasing the products, producer surplus is a measure of the benefits accruing to firms that produce and sell products, net of the costs of producing them. More formally, ''producer surplus'' is defined as the total revenue (TR) of firms selling the magnet sets, less the total variable costs (TVC) of production. Variable costs are costs that vary with the level of output and usually include expenditures for raw materials, wages, distribution of the product, and the like.[21]

In Figure 1, total revenue is given by the area OBDE, which is simply the product of sales and price. The total variable costs of production are given by the area under the supply function, OADE. Consequently, producer surplus is given by the triangle, ABD, which is the area under the market clearing price and above the supply function.

As described earlier, sales of the magnet sets averaged roughly 800,000 sets annually during the 2009 through mid-2012 time period, with an average retail price of about $25 per set in 2012. Thus, total industry revenues averaged about $20 million annually (*i.e.,* 800,000 sets × $25 per set) in 2012 dollars. Additional information provided by firms to the Office of Compliance and Field Operations suggests that the average import cost of the magnets to U.S. importers, a major variable cost, may have amounted to about $10 per set, or an average of about $8 million annually (*i.e.,* 800,000 sets × $10 import cost per set). We have no information on other variable costs associated with the production, packaging, marketing, and distribution of the magnet sets. However, it seems likely that variable costs would constitute a significant proportion of the remaining difference between revenues ($20 million) and import costs ($8 million). If we assume that variable costs amount to about half of the difference, lost producer surplus would amount to about $6 million.[22]

iii. Summary of Costs of the Rule

The costs of the rule, in terms of reduced benefits for firms and lost utility by consumers, are uncertain. However, based on annual sales estimates available for 2009 through mid-2012, these costs could amount to as much as $6 million in lost producer surplus and some unknown quantity of lost utility. The estimate of lost producer surplus differs from impacts estimated in the NPR (7.5 million, expressed as lost profits) because of a revised estimate of annual sales, and different assumptions regarding profit rates and variable costs.

c. Sensitivity of Results to Product Life Assumptions

Implicit in this analysis is the assumption that the expected useful life of the magnet sets is about 1 year. Because this product has only been in widespread consumer use since 2009, this assumption is made without extensive knowledge about the actual use of the magnetic sets by consumers. We consider magnet sets to be novelty products, which means for many consumers, they may lose much of their appeal quite quickly. Accordingly, we chose a one-year rather than a longer useful life even though the magnets may be physically durable products. Even if some of the products remain in homes or offices longer than a year, the risk of ingestion by children may be much higher in the first month or two after the magnet sets are purchased, when the appeal of the product is at its highest and the consumer actively uses or plays with the product frequently. Once novelty products lose their appeal, they are likely to be put away and stored indefinitely or perhaps even discarded.

However, we note that the results of our analysis are not particularly sensitive to this product life assumption. For example, had we assumed that the average product life was about 2 years, rather than 1 year, estimates of the number of sets in use at any given time would approximately double, reducing the estimated annual risk of injury, per magnet set in use (and hence, reduce estimated societal costs per set), by about half. However, this reduced estimate of annual societal costs would be offset by the fact that the sets remain in use for 2 years, rather than 1 year. Thus, annual benefits, per magnet set in use, would be about halved, but the present value of benefits would be accrued over 2 years, rather than 1 year. Consequently, even if we had doubled the assumed product life, the relationship between benefits and costs would have remained roughly the same. Estimated benefits would be slightly lower under a two year useful product life due to discounting second year benefits.

[21] Note that although producer surplus (PS) is a measure of profits, it is not the same as profits. Whereas PS = TR − TVC, profits (π) = TR − (TFC + TVC), where TFC represents total fixed costs (*i.e.,* those costs borne by the firm regardless of the level of output). If we substitute PS into the profit equation, and rearrange terms, we have PS = π + TFC. Thus, producer surplus is equal to profits, plus total fixed costs. In the case of the market for magnet sets, the fixed costs of production for American importers are small. The magnet sets were generally produced, packaged, and shipped from China and sometimes sent directly to the importer's point of sale. Even when the magnet sets were shipped directly to importers, most additional costs incurred by importers, such as shipping and marketing costs, would be considered variable. Consequently, in the case of the market for magnet sets, lost profits would be approximately equal to lost producer surplus.

[22] This value is lower than the value presented in the preliminary regulatory analysis, due to the use of more refined sales figures for the affected producers.

d. Alternatives to the Rule

There are several possible alternatives to the rule. We are unable to quantify either the costs or the benefits of these alternatives, in part because the requirements of such alternatives have not been specified. To estimate the potential costs of the alternatives, we would need a precise description of what the requirements would be. Moreover, even with this information, it would still be difficult to determine the expected injury reduction from the various alternatives.

Nevertheless, the costs of each of the alternatives discussed below are expected to be substantially lower than the costs of the rule. This is because, generally speaking, the alternatives would allow consumers and businesses to continue buying, selling, and using the magnet sets that would no longer be available under the rule. Similarly, the benefits of these alternatives, in terms of injury reduction, would also be expected to be lower than the benefits for the rule. This is because, under these alternatives, some children would continue to have access to the magnet sets.

The Commission may not have authority for some of the alternatives discussed. None of the alternatives was chosen because the expected injury reduction from each was believed to address the hazard inadequately. Comments on the NPR did not alter this decision.

i. Alternative Performance Requirements

As an alternative to the rule, the Commission could consider promulgating an alternative set of requirements that could reduce the risk of injury from magnet sets but not necessarily eliminate the risk. For example, some alternatives to the rule might include: Setting a different flux index for the magnets sold as manipulative desk sets; requiring different specifications for shapes and sizes of magnets within the scope of the standard; or setting forth some other criteria that have not yet been developed (but are not as stringent as in the final rule). If these alternative requirements led to the production of magnet sets with physical characteristics that appealed to consumers, the cost of the rule for both consumers and businesses would be reduced. Businesses would continue to be able to produce and sell magnet sets, and consumers would continue to be able to buy and use them. However, these alternative requirements would likely reduce the benefits of a rule: Magnets that present a risk of harm would still be available and some children would undoubtedly have access to them and be injured by them.

One practical question, however, is whether alternative requirements for the sizes and flux index of magnets would eliminate or substantially affect the physical qualities of the products that make them enjoyable for adults. Regarding the alternative size requirements, consumers can use magnet sets of 216 or more 5mm balls to make a variety of constructions. Larger individual magnets that would meet an alternative (that is smaller than the 1.25-inch diameter specified in the final rule) might be determined to reduce the risk associated with ingestions somewhat, but, depending upon their size, might make them unsuitable for many of the uses of the sets with smaller magnets.

Similarly, allowing a flux index greater than the 50 kG^2 mm^2 flux limit of the rule might improve the usefulness of the magnet sets in construction activities. However, given that the subject magnet sets have flux index values typically in the range of 400–500 for spherical magnets, the flux index limit might have to be increased substantially higher than the flux index limit of 50 kG^2 mm^2 to provide levels of satisfaction that are similar to those of the subject magnet sets. Moreover, a flux index limit of substantially more than 50 kG^2 mm^2 could, relative to the proposed rule, substantially increase the harms associated with the ingestion risk—the harms the rule is intended to prevent.

Another alternative might be to create specifications for the application of bittering agents on the magnets to make them less appealing to young children. However, the effectiveness of bittering agents in reducing magnet ingestions is questionable (Sedney & Smith, 2012).

Neither the costs, nor the benefits of these alternative sets of requirements are quantifiable with available information. The staff is reasonably certain that magnets with a flux index of less than 50 kG^2 mm^2 will substantially reduce the risk injury. However, the risk associated with flux indices greater than 50 kG^2 mm^2 but less than the indices of 400 to 500 for the subject magnet sets are unknown and cannot be estimated with available data. The staff is also reasonably certain that the risk of ingesting magnets is substantially reduced if the magnets are too large for the small parts container. However, the increased risk of ingestion with smaller sized magnets is unknown.

Require Safer Packaging

The Commission could require magnet sets to be sold with special storage containers that are fitted to the product so that consumers would be able to determine whether any of the magnets were missing from the sets. Such a requirement might prevent injuries resulting from a small number of magnets being separated from a set without the owner being aware. In reality, however, many consumers may not use such containers because using them could require time to form the magnets into a shape, such as a cube; or consumers might wish to keep the magnets out of their container to preserve a shape or structure that took time and effort to construct.

Alternatively (or in combination), the Commission could require the magnets to be sold in child-resistant packaging. The benefit of such an approach is the potential to reduce ingestion injuries. However, the benefits of this approach would be limited. Child-resistant packaging would not prevent teens and adolescents (and even some younger children) from opening the packaging. Additionally, the packaging would have to be secured after each use. According to the Division of Human Factors, it is unlikely that adults would accept child-resistant packaging for a product like the magnet sets because of the level of inconvenience involved in returning the magnets to the package (Sedney & Smith, 2012). Additionally, for the reasons described above, consumers may leave magnets out of their container.

The costs of this alternative would depend upon the packaging requirements but would be substantially less costly than the rule, which eliminates the subject magnet sets from the marketplace. It seems unlikely that the costs would amount to more than a dollar or so per magnet set, although these costs might be somewhat higher if child-resistant packaging was required. The benefits of requiring safer packaging are unknown, but based on the HF discussion above, the benefits may be relatively small if consumers would not use the packaging containers appropriately.

ii. Warnings

The Commission could require strong warnings on labels and on-product instructions designed to prevent the use of the magnet sets by children. Based on HF staff's examination, the ingestion warnings that currently accompany magnet sets are generally aimed at adults, but the warnings are deficient in their content. For example, some

warnings caution against children swallowing the magnets, but the warnings do not describe the incident scenarios. Some warnings refer to the propensity of swallowed magnets to stick to intestines, without referring to the presence of other magnets or metal objects. Other warnings refer to magnets sticking together or attaching to other metallic objects inside the body, but the warnings do not explain that the magnets can attract through the walls of the intestines and forcefully compress these tissues, resulting in serious injuries. According to HF staff, without detailed information in the warnings, consumers may not really understand how swallowing magnets differs from swallowing other small parts or how magnets sticking together could pose a hazard.

HF staff believes that it may be possible to develop warnings that could communicate the ingestion hazard, the consequences of ingestion, and how to avoid the hazard. To the extent that the subject magnets present a ''hidden'' hazard about which consumers are unaware, explicit and adequate warnings could reduce ingestions and allow adults to continue to enjoy the use of the product.

The costs of such warnings would most likely be small, and consumers could make informed decisions about the purchase and use of magnet sets. However, although HF staff believes warnings could be developed to communicate the hazard, HF staff also believes that injury reduction would be limited. They point out that avoiding the ingestion hazard requires consumers to keep the product away from all children in the incident age group, and while caregivers who read and understand the warnings may attempt to keep this product out of the hands of young children, HF staff doubts that many caregivers are likely to be so diligent about heeding the warning with older children and adolescents (Sedney & Smith, 2012). Also, HF staff doubts that caregivers will think that constant supervision is needed if they believe the sets have been properly secured or that their children are not aware of the sets (Sedney & Smith, 2013). As noted in the NPR (77 FR 53781), a corrective action in 2010, which included stronger warnings combined with provisions for controlling distribution of magnet sets, was found to be inadequate because of a subsequent increase in ingestion injuries involving the products. Consequently, warnings (combined with sales restrictions and other measures) have not been judged to address the risk posed by the subject magnet sets adequately.

iv. Restrictions on the Sale of Magnet Sets

Another lower-cost option the Commission could consider is to prohibit sales of magnet sets in toy stores, children's sections of general purpose stores, and near cash registers of stores that sell any children's products. The costs of this option would be lower than the rule because this would allow the magnet sets to be marketed to and used by consumers. Sales limitations or requirements for strong warnings might also be required on Web sites advertising the sale of magnets on the Internet.

The details of developing a set of sales limitations and requirements would need to be worked out, but the idea would be to make sure that magnet sets, to the extent possible, are not sold at locations where children are likely to be present. Sales requirements might also be combined with strong and explicit warnings that HF staff has suggested could be developed.

However, the benefits of this option are probably limited. Some parents would still allow their children (especially older children and adolescents) to play with the magnet sets, despite the warnings.[23] In addition, some children will get into the packaging, even if parents try to restrict the use of the desk toys.

v. Address Through Corrective Actions Rather Than Regulatory Action

The Commission could continue to address the hazard through corrective action plans. However, this approach may be inadequate because this approach is reactive and would entail waiting for new incidents to occur rather than preventing them.

vi. Take No Action

The Commission could determine that no rule is reasonably necessary to reduce the risk of ingestion injuries associated with small, powerful magnet sets. Under this alternative, future societal losses would be determined by the numbers of products in use, and other factors that affect the likelihood that young children, adolescents, and teens will ingest the magnets. Although there would be no costs, such a determination would not reduce injuries.

4. Summary

Based on reports to the CPSC, ingestions of small magnets contained in certain magnet sets have caused multiple, high-severity injuries that require surgery to remove the magnets and repair internal damage. Based on the NEISS cases identified by the Directorate for Epidemiology staff as involving high-powered and/or ball-shaped magnet ingestions, the estimated benefits of the rule might amount to about $28.6 million annually.

The costs of the rule consist of the reduced producer surplus for firms and lost utility by consumers, also are uncertain. Based on annual sales estimates available for 2009 through mid-2012, these costs could amount to as much as $6 million in lost producer surplus and some unknown quantity of lost utility.

There are alternative regulatory actions that might allow the magnet sets to continue to be marketed. For example, the Commission, by regulation, could issue alternative requirements; issue requirements for the packaging of the magnet sets (*e.g.,* develop requirements for child-resistant packaging); require warnings that describe explicitly the hazard and how to avoid it; and/or place limitations on how and where the magnet sets can be sold. These alternative actions—which might be considered alone, or in combination—would have varying levels of effectiveness, but all of them would be result in lower reductions in injuries associated with magnet ingestion.

I. Paperwork Reduction Act

The rule does not require manufacturers (including importers) to perform testing or require manufacturers or retailers to keep records. For this reason, the rule does not contain ''collection of information requirements,'' as that term is used in the Paperwork Reduction Act, 44 U.S.C. 3501–3520. Therefore, the rule need not be submitted to the Office of Management and Budget (OMB) in accordance with 44 U.S.C. 3507(d) and implementing regulations codified at 5 CFR 1320.11.

[23] As noted in the NPR (77 FR 53781), one firm agreed to a corrective action in 2010, which included provisions for controlling distribution by agreeing to ask retailers who market products primarily to children to execute a Responsible Sellers Agreement prohibiting marketing and sales to children, as well as agreeing to stop the sale of magnet sets to retailers who market products exclusively to children. However, with a subsequent increase in ingestion injuries involving the products, Compliance began negotiation of corrective action plans with 11 of 13 magnet set importers that voluntarily agreed to cease the importation, distribution, and continued sale of their magnet sets, and administrative actions were initiated by the Commission against two firms that did not agree to cease sales voluntarily. By implication, sales restrictions (combined with warnings and other measures) have not been judged to address the risk posed by the subject magnet sets adequately.

J. Regulatory Flexibility Analysis

1. Introduction

The Regulatory Flexibility Act (RFA) requires that agencies review rules for their potential economic impact on small entities, including small businesses. Section 604 of the RFA calls for agencies to prepare a final regulatory flexibility analysis, describing the impact of the rule on small entities and identifying impact-reducing alternatives. The final regulatory flexibility analysis is to contain:

(1) A statement of the need for, and objectives of, the rule;

(2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the agency's assessment of those issues, and a statement of any changes made to the proposed rule as a result of such comments;

(3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a statement of any changes made in the final rule as a result of the comments;

(4) a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;

(5) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the types of professional skills necessary for the preparation of the report or record; and

(6) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

Accordingly, staff prepared a final regulatory flexibility analysis, which is summarized below.

2. Statement of the Need for, and Objectives of, the Rule

The rule prohibits the sale or distribution in commerce of magnet sets and individual magnets intended to be used with or as magnet sets that do not meet the specific requirements described in section F of this preamble. The current designs of magnet sets of the type that became popular in recent years would not meet the rule's requirements. The CPSC has received information, described in section C of this preamble, regarding incidents with, and hazards posed by, sets of small, powerful magnets. According to the final regulatory analysis, there was an annual average of about 929 medically attended magnet ingestions that were defined as at least ''possibly of interest'' during the period from 2009 through June 2012. These ingestions resulted in societal costs of about $28.6 million per year.

The objective of the rule is to eliminate or reduce the risk of injury to consumers from the ingestion of one or more small powerful magnets that comprise the subject consumer products. Because the magnet sets that have been involved in incidents would not meet the rule's requirements, the rule will substantially reduce the future incidence and cost to society of ingestions of magnet sets.

3. Comments on the Initial Regulatory Flexibility Analysis

The Commission received comments from more than 5,000 people in response to the NPR. Many of the comments related to issues that have a bearing on the economic impacts of the proposed rule on small businesses. The Commission's responses to comments that address issues that were mentioned in the initial regulatory flexibility analysis (IRFA) are in included in Section E of this notice.

4. Small Entities Subject to the Rule and Possible Economic Impacts

The final rule would impact U.S. importers and retailers of magnet sets comprised of small, powerful magnets of the size and magnetic force proscribed by the rule. None of the magnet sets within the scope of the rule is produced domestically. All of the U.S. firms that have marketed the products are believed to have imported them from manufacturers in China. The one remaining firm that currently imports magnet sets is a small business under U.S. Small Business Administration (SBA) size standards (SBA, 2012).

Based on information reviewed on product sales, including reports by firms to the Office of Compliance and Field Operations, the number of such magnet sets that were sold to U.S. consumers from 2009 through mid-2012 may have totaled about 2.7 million sets, with a value of roughly $50 million in 2012 dollars. This value reflects a combination of retail sales directly to consumers (through company Web sites and other Internet retail sites) and sales to retailers who market the products. A review of retail prices reported by importers and observed on Internet sites suggests prices typically ranged from about $20 to $45, with an average price of about $25 for magnet sets that commonly contain 216 to 224 magnets. Larger sets of more than 1,000 individual magnets have reportedly been sold at prices up to $300, depending on the number of magnets and the type of packaging.

We noted in the IRFA that the economic impact of the rule would be most severe for seven small importing firms, which account for the great majority (perhaps more than 98%) of units sold according to sales information provided to CPSC Compliance staff; and five of these importers reportedly derived most or all of their revenues from the sale of the magnet sets or related products. We judged that these firms could go out of business as a result of the rule. Two of the other leading importers of magnet sets apparently had fairly broad product offerings, which could lessen the severity of the economic impact of a rule. Nevertheless, we noted that the expected impacts of a final rule could also be significant for these small importers.

As discussed in section H.2.b. of this preamble, due to CPSC's enforcement actions, current sales of magnet sets are dramatically smaller than at the time of the enforcement actions. We are aware of only one major importer of magnet sets that remains active in the market. The rule will likely have an adverse impact on this remaining firm. That firm might go out of business, unless the firm successfully markets other products, including magnet sets that would comply.

5. Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

The rule does not contain any reporting or record keeping requirements.

6. Alternatives to the Rule

The Commission could pursue other options, including: Adopting an alternative set of requirements for the flux index or size of the magnets; requiring safer packaging; requiring warnings on the packaging and promotional materials; imposing restrictions on the locations where magnet sets can be sold; addressing the risk of injury presented by magnet sets through corrective actions; and taking no action at all. Each of these alternatives is addressed in Section G of this preamble and in the Final

Regulatory Analysis at Section H of this preamble. All of these alternatives would reduce the expected impact of the rule on small business. However, as discussed in Sections G and H of this preamble, these alternatives would not be expected to achieve the same injury reductions as the rule, and some of the suggested alternatives would be beyond the Commission's authority.

K. Environmental Considerations

CPSC rules establishing performance requirements are considered to ''have little or no potential for affecting the human environment,'' and environmental assessments are not usually prepared for these rules (16 CFR 1021.5 (c)(1)). This rule falls within the categorical exemption.

L. Executive Order 12988 (Preemption)

As required by Executive Order 12988 (February 5, 1996), the CPSC states the preemptive effect of the rule as follows:

The rule is promulgated under authority of the CPSA. 15 U.S.C. 2051–2089. Section 26 of the CPSA provides that ''whenever a consumer product safety standard under this Act is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as the performance, composition, contents, design, finish, construction, packaging or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal Standard.'' 15 U.S.C. 2075(a). Upon application to the Commission, a state or local standard may be excepted from this preemptive effect, if the state or local standard: (1) Provides a higher degree of protection from the risk of injury or illness than the CPSA standard, and (2) does not unduly burden interstate commerce. In addition, the federal government, or a state or local government, may establish and continue in effect a nonidentical requirement that provides a higher degree of protection than the CPSA requirement for the hazardous substance for the federal, state, or local government's use. 15 U.S.C. 2075(b).

Thus, with the exceptions noted above, the magnet set requirements would preempt nonidentical state or local requirements for magnet sets designed to protect against the same risk of injury.

M. Effective Date

The Commission has determined that the rule will become effective 180 days from publication of the final rule in the **Federal Register** and will apply to all magnet sets imported into or otherwise distributed in the United States that are manufactured or imported on or after that date. The CPSA requires that consumer product safety rules take effect not later than 180 days from their promulgation, unless the Commission finds there is good cause for a later date. 15 U.S.C. 2058(g)(1). In the NPR, the Commission proposed that the rule would take effect 180 days after promulgation of a final rule. The Commission received no comments on the proposed effective date.

N. Findings

The CPSA requires the Commission to make certain findings when issuing a consumer product safety standard. Specifically, the CPSA requires that the Commission consider and make findings about the degree and nature of the risk of injury; the number of consumer products subject to the rule; the need of the public for the rule and the probable effect on utility, cost, and availability of the product; and other means to achieve the objective of the rule, while minimizing the impact on competition, manufacturing, and commercial practices. The CPSA also requires the rule to be reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with the product; and issuing the rule must be in the public interest. 15 U.S.C. 2058(f)(3).

In addition, the Commission must find that: (1) If an applicable voluntary standard has been adopted and implemented, that compliance with the voluntary standard is not likely to adequately reduce the risk of injury, or compliance with the voluntary standard is not likely to be substantial; (2) that benefits expected from the regulation bear a reasonable relationship to the regulation's costs; and (3) that the regulation imposes the least burdensome requirement that would prevent or adequately reduce the risk of injury. *Id.* These findings are stated in § 1240.5 of the rule and are based on information provided throughout this preamble and the staff's briefing packages for the proposed and final rules.

O. Conclusion

For the reasons stated in this preamble, the Commission concludes that magnet sets and individual magnets that do not meet the requirements specified in this rule present an unreasonable risk of injury.

List of Subjects in 16 CFR Part 1240

Consumer protection, Imports, Infants and children, Labeling, Law enforcement, Incorporation by reference.

For the reasons stated in the preamble, the Commission amends Title 16 of the Code of Federal Regulations by adding part 1240 to read as follows:

PART 1240—SAFETY STANDARD FOR MAGNET SETS

Sec.

1240.1 Scope, purpose, and effective date.
1240.2 Definitions.
1240.3 Requirements.
1240.4 Test procedure for determining flux index.
1240.5 Findings.

Authority: 15 U.S.C. 2056 and 2058.

§ 1240.1 Scope, purpose, and effective date.

This part 1240, a consumer product safety standard, prescribes requirements for magnet sets, as defined in § 1240.2, and for individual magnets that are marketed or intended for use with or as magnet sets. These requirements are intended to reduce or eliminate an unreasonable risk of injury to consumers who ingest magnets that are part of magnet sets. This standard takes effect on April 1, 2015 and applies to all magnet sets and individual magnets, as defined in § 1240.2, that are manufactured or imported on or after that date.

§ 1240.2 Definitions.

(a) The definitions in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) apply to this part 1240.

(b) *Magnet set* means: Any aggregation of separable magnetic objects that is a consumer product intended, marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. Relevant factors in determining intended uses of a magnet set include, but are not limited to: The manufacturer's stated intent (such as on a label or Web site), if reasonable under the circumstances; the content and nature of advertising, promotion, marketing, packaging, or display relating to the product; and the uses for which the product is commonly recognized by consumers.

(c) *Individual magnet* means: An individual magnetic object intended or marketed for use with or as a magnet set as defined in paragraph (b) of this section.

§ 1240.3 Requirements.

Each magnet in a magnet set, and any individual magnet, that fits completely within the cylinder described in 16 CFR 1501.4 must have a flux index of 50 kG^2 mm^2 or less when tested in accordance with the method described in § 1240.4.

§ 1240.4 Test procedure for determining flux index.

(a) Select at least one magnet of each shape and size in the magnet set.

(b) Measure the flux index of each selected magnet in accordance with the procedure in sections 8.24.1 through 8.24.3 of ASTM F963–11, *Standard Consumer Safety Specification for Toy Safety,* approved on December 1, 2011. The Director of the **Federal Register** approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Barr Harbor Drive, PO Box 0700, West Conshohocken, PA 19428; telephone 610–832–9585; *www.astm.org.* You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

§ 1240.5 Findings.

(a) *Degree and nature of the risk of injury.* (1) Based on a review of National Electronic Injury Surveillance System (NEISS) data, we have determined that an estimated 2,900 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2013, an average of about 580 ingestion incidents per year. From review of databases other than NEISS, we are aware of 109 reported incidents occurring from January 1, 2009 through June 24, 2014, involving the ingestion of magnets by children between the ages of 1 and 15. Of those 109 incidents, 83 involved the ingestion of high-powered, ball-shaped magnets that were contained in products that meet the above definition of ''magnet set,'' and 17 of those 109 incidents possibly involved ingestion of this type of magnet. Thus, 100 reported incidents of ingestions involved or possibly involved magnets from magnet sets. Hospitalization was required to treat 61 of the 100 incidents. In 81 of the 100 incidents, the magnets were ingested by children younger than four years old, or between the ages of four and 12 years.

(2) Once ingested, these strong magnets begin to interact in the gastrointestinal tract, which can lead to tissue death, perforations, and/or fistulas, and possibly intestinal twisting and obstruction. If left untreated, these injuries can lead to infection of the peritoneal cavity and other life-threatening conditions. The number of magnets swallowed increases the risk of attraction and injury; but as few as two magnets can cause serious internal damage in a very short time. The fact that many medical professionals do not appreciate the health consequences of magnet ingestion increases the severity of the risk because a doctor who is unfamiliar with these strong magnets may send a child home and expect the magnets to pass naturally. There are also health consequences to the treatment and surgery for removal of ingested magnets. There may be a risk of gastrointestinal bleeding; leakage of holes that were repaired; rupturing of resectioned bowels; temporary paralysis of the bowels; use of a colostomy bag; IV feeding initially, or for some longer time period; and compromise of nutrition and digestive function. Long-term health consequences can be severe, as well: loss of intestinal tissue; compromised nutrition absorption; adhesions and scarring of intestines; need for a bowel transplant; and possible impediments to fertility for girls. Even children who pass the magnets naturally and do not require surgery still need close observation by doctors and may undergo sequential x-rays, thus, exposing children to repeated dosages of radiation.

(b) *Number of consumer products subject to this part.* The market for magnet sets increased substantially from the time magnet sets were first introduced, through mid-2012. We estimate that the number of magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, representing a value of roughly $50 million. Because of CPSC enforcement activity and actions taken by firms since mid-2012, most firms have ceased selling the magnet sets. Actual sales since the end of 2012 by the firms remaining in the market are unknown but believed to be small. The remaining major importing firm that continues to sell the products is estimated to hold a market share of less than 2 percent of pre-enforcement action sales. The approximate number of products subject to this part (in terms of unit sales) could be fewer 25,000 sets per year.

(c) *The need of the public for magnet sets and the effects of this part on their utility, cost, and availability.* (1) We cannot estimate precisely the use value that consumers receive from magnet sets. In general, use value would be the amount of money that consumers expend on the product, plus the consumer surplus (*i.e.,* the difference between the market price and the maximum amount consumers would have been willing to pay for the product). Magnet sets of the type that have been involved in incidents would not comply with this part. Therefore, consumers will no longer be able to obtain utility from these magnet sets. Although magnet sets clearly provide utility to purchasers, magnet sets are not necessities. Products that meet the requirements of this part might be developed that would serve some of the purposes of magnet sets. This part would continue to allow strong magnets for other uses, such as commercial or industrial uses.

(2) Individual magnets that are intended or marketed for use with or as magnet sets also must comply with the requirements of this part. The Commission is aware that firms selling magnet sets have offered individual magnets. To avoid firms circumventing the rule by selling individual magnets that are nevertheless intended or marketed to be used as magnet sets, this part covers such individual magnets. Individual magnets sold for other uses are not subject to this part. Thus, this part does not affect the need for, utility, or availability of individual magnets that are sold for uses other than as magnet sets.

(d) *Other means to achieve the objective of this part, while minimizing the impact on competition and manufacturing.* (1) The Commission considered various alternatives to the requirements specified in this part. This part requires that if a magnet set contains a magnet that fits within the small parts cylinder that CPSC uses for testing toys, all magnets from that set must have a flux index of 50 kG^2 mm^2 or less. In addition, individual magnets intended or marketed for use with or as magnet sets must meet these requirements. We do not believe that options other than a rule establishing these requirements would sufficiently reduce the number and severity of injuries resulting from the ingestion of magnets from these magnet sets. The circumstances associated with this product limit the likely effectiveness of warning labels. Despite existing warning labels and market restrictions, ingestion incidents have continued to occur. Parents and caregivers may not

appreciate the hazard associated with magnet sets. Accordingly, parents and caregivers will continue to allow children access to the product. Children may not appreciate the hazard and will continue to mouth the items, swallow them, or in the case of young adolescents and teens, use the magnets to mimic body piercings. Once the magnets are removed from their carrying case, the magnets bear no warnings to guard against ingestion or aspiration; the small size of the individual magnets precludes the addition of any warning. Because individual magnets from magnet sets are shared easily among children, many end users of the product are likely to have had no exposure to any warning.

(2) The Commission has considered other alternatives to reduce the risk from magnet sets: alternative performance requirements, such as setting a different flux limit or requiring bittering agents; safer packaging requirements, such as requiring a specific design for storage containers or requiring child resistant packaging; sales restrictions; continued corrective actions; and taking no action. Some of these alternatives may not be within the Commission's authority. Although each of the alternative actions would have lower costs and less impact on small business, none is likely to significantly reduce the injuries associated with ingestion of magnets from magnet sets.

(e) *Unreasonable risk.* (1) As stated in paragraph (a) of this section, according to NEISS, an estimated 2,900 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2013, an average of about 580 ingestion incidents per year. From sources other than NEISS, CPSC has reports of 100 incidents of ingestions that involved or possibly involved magnets from magnet sets, including one fatality.

(2) For the regulatory analysis, we considered the period of time, 2009 through June 2012, before CPSC's compliance activities affected the market. We identified 86 ingestions of high-powered and/or ball-shaped magnets, which occurred from 2009 through June 2012 reported through NEISS. These incidents were determined to involve, or possibly involve, magnet sets. Based on these 86 incidents, we have determined that an estimated 2,138 ingestions of magnets from magnet sets were treated in emergency departments from January 1, 2009 to June 2012. About 11 percent of the victims of these ingestion incidents required hospitalization, as opposed to victims who were treated and released. The 2009 through June 2012 NEISS estimates suggest an estimated *annual* average of about 610 emergency department-treated injuries, including 544 injuries that were treated and released and 66 injuries that required hospitalization. About 60 percent of these emergency department-treated ingestions involved children ages 4 through 12 years. Additionally, based on estimates from the Commission's injury cost model (ICM), there were another 319 injuries treated annually in locations other than hospital emergency departments (such as doctors' offices, clinics, ambulatory surgery centers, or direct hospital admissions).

(3) After including the injuries treated outside of hospital emergency departments, there was an annual average of about 929 medically attended injuries involving ingestions of magnets that were defined as at least ''possibly of interest'' during the period from 2009 through June 2012. Injuries resulting from such ingestions of magnets can be severe and life threatening. The risk posed by these magnets may not be appreciated by children or caregivers, who may assume, mistakenly, that the consequences of ingesting magnets would be similar to ingesting any other small object. However, once ingested, these strong magnets do not pass naturally. Rather, these magnets are mutually attracted to each other and exert compression forces on the trapped gastrointestinal tissue.

(4) We estimate that these injuries resulted in annual societal costs of about $28.6 million (in 2012 dollars) during the 2009 through June 2012 time period. The average estimated societal costs per injury was about $27,000 for injuries treated in locations other than emergency departments (such as physicians' offices, clinics, ambulatory surgery centers, or direct hospital admissions); about $21,000 for injuries that were treated and released from emergency departments; and about $130,000 for injuries that required admission to the hospital for treatment. Preventing these injuries would be the expected benefit resulting from the rule.

(5) The costs of the rule would consist of the lost producer surplus to firms that produce and sell magnet sets, plus the lost use value that consumers would experience when magnet sets that do not comply with the rule are no longer available. Sales of magnet sets averaged roughly 800,000 sets annually during the 2009 through mid-2012 time period, with an average retail price of about $25 per set in 2012. Thus, total industry revenues averaged about $20 million annually (*i.e.,* 800,000 sets × $25 per set) in 2012 dollars. The average import cost of the magnet sets to U.S. importers, a major variable cost, may have amounted to about $10 per set, or an average of about $8 million annually (*i.e.,* 800,000 sets × $10 import cost per set). We estimate other variable costs associated with the production, packaging, marketing, and distribution of the magnet sets would constitute a significant proportion of the remaining difference between revenues ($20 million) and import costs ($8 million). If we assume that variable costs amount to about half of the difference, lost producer surplus would amount to about $6 million.

(6) Thus, we estimate costs of the rule to be about $6 million in lost producer surplus and some unknown quantity of lost utility. Considering the injuries associated with magnet sets—and the resulting societal costs, balanced against the likely impact that the rule would have on firms producing and selling the product, and on consumers who would lose the utility of the product—we conclude that magnet sets pose an unreasonable risk of injury and that the rule is reasonably necessary to reduce that risk.

(f) *Public interest.* The regulations in this part are in the public interest because they would reduce deaths and injuries associated with magnet sets in the future. A rule establishing requirements that would eliminate magnet sets of the type that have been involved in incidents will mean that children will have less access to this product, thereby reducing the number of incidents of children swallowing the magnets and the resulting cost to society of treating these injuries.

(g) *Voluntary standards.* Currently, there is no voluntary standard for magnet sets, nor any activity to develop a voluntary standard for magnet sets.

(h) *Relationship of benefits to costs.* (1) Based on reports to the CPSC, ingestions of small magnets contained in magnet sets have caused multiple, high-severity injuries that require surgery to remove the magnets and repair internal damage. Based on the information discussed in paragraph (e) of this section, we estimate that the benefits of this part might amount to about $28.6 million annually.

(2) The costs of the rule, in terms of reduced profits for firms and lost utility by consumers, also are uncertain. However, based on annual sales estimates available for the 2009 through June, 2012, study period, these costs could amount to about $6 million in lost producer surplus and some unknown quantity of lost utility.

(i) *Least burdensome requirement.* We have considered several alternatives to

this part. We conclude that none of these alternatives would adequately reduce the risk of injury. Alternative performance requirements might allow a different flux index for magnets contained in magnetic sets or require the addition of an aversive (bittering) agent to the magnets. Theoretically, these alternatives might allow continued production of some current products. However, it is unclear whether a different flux index would succeed in making products that have the desired physical qualities that make them sufficiently enjoyable to adults, and at the same time eliminate the characteristics that make these strong magnets hazardous to children. Furthermore, the effectiveness of aversive agents in reducing magnet ingestions is questionable. We have considered the possibility of requiring rigorous warnings on the products or in the instructions for the products. However, magnet sets currently and formerly on the market provide warnings concerning the potential hazard to children. Accordingly, it is unlikely that even strengthened warnings would substantially reduce the incidence of magnet ingestions. This is particularly true for incidents involving older children and adolescents. Moreover, children who are old enough to understand the warnings may still not abide by them. Some type of sales restriction, limiting the location where magnet sets could be sold, might be possible. However, even with restrictions on sales, ingestions are still likely to occur as children encounter these magnets in the home, at school, or other locations where adults have brought them and made them available to children. The Commission could continue to address the hazard from magnet sets through corrective actions, *i.e.,* recalls of the product. However, these actions would not prevent additional companies from entering the market and importing magnet sets into the country in the future. The Commission also has the option of taking no regulatory action. Although it is possible that, with increased awareness of the hazard over time, some reduction in ingestions could occur, the magnitude of any such reduction in incidents is uncertain and would likely be smaller than those resulting from the requirements of this part.

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Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

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