

make its decision on the petition on or before November 30, 2012. This extension will not prejudice the petitioner.

Minority Business Development Agency.

David Hinson,
National Director.

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1240

Safety Standard for Magnet Sets

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: Based on available data, the U.S. Consumer Product Safety Commission (the Commission, the CPSC, or we) has determined preliminarily that there may be an unreasonable risk of injury associated with children ingesting high-powered magnets that are part of magnet sets. These magnet sets are aggregations of separable, permanent, magnetic objects intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. In contrast to ingesting other small parts, when a child ingests a magnet, the magnetic properties of the object can cause serious, life-threatening injuries. When children ingest two or more of the magnets, the magnetic forces pull the magnets together, and the magnets pinch or trap the intestinal walls or other digestive tissue between them, resulting in acute and long-term health consequences. Although magnet sets have only been available since 2008, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments between January 1, 2009 and December 31, 2011.

To address the unreasonable risks of serious injury associated with these magnet sets, the Commission is issuing this notice of proposed rulemaking (NPR), which would prohibit such magnet sets. Under the proposal, if a magnet set contains a magnet that fits within the CPSC's small parts cylinder, magnets from that set would be required to have a flux index of 50 or less, or they would be prohibited. The flux index would be determined by the method described in ASTM F963-11, Standard

Consumer Safety Specification for Toy Safety.

The Commission solicits written comments concerning the risks of injury associated with these magnet sets, the regulatory alternatives discussed in this NPR, other possible ways to address these risks, and the economic impacts of the various regulatory alternatives. This proposed rule is issued under the authority of the Consumer Product Safety Act (CPSA).

DATES: Written comments in response to this document must be received by the Commission no later than November 19, 2012.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2012-0050, by any of the following methods:

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (email), except through www.regulations.gov.

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

FOR FURTHER INFORMATION CONTACT: Jonathan D. Midgett, Ph.D., Project Manager, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814-4408; telephone: (301) 504-7692, or email: jmidgett@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

The Commission is proposing a safety standard that would prohibit magnet sets that have been involved in serious injuries. The Commission believes that this proposed rule is necessary to address an unreasonable risk of injury

and death associated with these magnet sets.

1. History With Magnetic Toys

In the mid-2000s, construction toys for children featuring small, powerful magnets were introduced into the toy market. Several children's magnetic construction toys were recalled because the magnets detached from the plastic housing of the toy. (Release #07-164). We received reports of incidents in which children and infants had swallowed the small magnets that had detached from such toys. In some incidents, children swallowed intact magnetic components that were small parts.¹ These incidents revealed that if a child swallows more than one small, powerful magnet or one such magnet and a ferromagnetic object, the objects can attract each other across tissue inside the stomach and intestines and cause perforations and/or blockage, which, if not treated immediately, can be fatal. We are aware of one death and numerous cases requiring intestinal surgery following ingestion of multiple small, powerful magnets from these toys.

To address the hazard in toys, the CPSC worked with ASTM to develop voluntary standard requirements for toys containing magnets. These requirements became part of ASTM F963, *Consumer Safety Specification for Toy Safety*, which is now a mandatory CPSC standard. ASTM F963-11 defines a "hazardous magnet" and a "hazardous magnetic component" (*i.e.*, a toy piece that contains an embedded hazardous magnet) as one that has a flux index greater than 50 and that is a small object. ASTM F963 applies to toys intended for children under 14 years of age. The flux index of a magnet is an empirical value developed by ASTM as a way to estimate the attraction force of a magnet. The ASTM working group established a flux index of 50 as a cutoff for what it considered to be a "safe" magnet, based on measurements of toys on the market. Most of the measured magnets were cylindrical in shape, and some had been involved in known incidents. When the ASTM graphed their measurements, they showed a good correlation (fairly linear relationship) between calculated flux index and measured attraction force for

¹ The requirements of 16 CFR part 1501 are intended to minimize the hazards from choking, ingestion, or inhalation to children under 36 months of age created by small objects. The requirements state, in part, that no toy (including removable, liberated components, or fragments of toys) shall be small enough without being compressed to fit entirely within a cylinder of the specified dimensions.

a majority of the magnets. Based on this graph, ASTM considered the flux index a reliable way to gauge a magnet's relative attraction force. Since the magnets from toys involved in incidents had flux index measurements greater than 70, the ASTM working group chose a flux index of 50 as a cutoff because it was significantly below the values for the incident magnets.

2. Introduction of Magnetic Sets

In 2008, a new type of magnet product came onto the market. The basic product was an aggregated mass of 216 BB-size powerful magnets, generally marketed as adult desk toys for general amusement. These magnet sets were introduced in 2008, but 2009 was the first year with significant sales to U.S. consumers. The products are described more fully in section B of this preamble.

In February 2010, CPSC staff received its first incident report involving this product. No injury resulted from this incident. Shortly after receiving this report, CPSC staff collected and evaluated samples of magnet sets.

In December 2010, we received our first consumer incident report involving the surgical removal of magnets that were part of a magnet set. Information about incidents involving magnet sets is discussed in section C of this preamble.

3. Prior Compliance Actions Concerning Magnet Sets

The CPSC has been warning consumers about the hazards of magnet ingestion since 2006, because of the injuries that have occurred to children from hazardous magnets that were part of construction toys intended for children. Several recalls have been issued for toys containing magnets.

In December 2009, we received a consumer complaint that the magnet sets intended for adults posed hazards similar to magnets in toys. As a follow-up to that complaint, during that month, a sample was collected by staff and age graded by the Directorate for Engineering Sciences, Division of Human Factors to be, in developmental terms appropriate for children ages 9 years old and up.

In February 2010, the CPSC received its first consumer incident report involving a child and a set of magnets intended for adults. A 9-year-old boy swallowed 7 spherical magnets while mimicking body piercings. He was not injured because the magnets passed through his system as a single mass. The magnets had been purchased for a 13-year-old.

Samples of the product were detained and collected at the Customs and Border Protection site in February 2010. At the

time of collection, the product was labeled for use by children 13+ years of age. Because of the age grade on the product and the manufacturer's intent, it was subject to the requirements of the toy standard. The Office of Compliance and Field Operations (Compliance) issued a Notice of Noncompliance to the firm in March 2010. At the time, there was very little incident data associated with this product. The firm agreed to a corrective action that included, in part, new warnings to keep the product away from children, a change in the appropriate age for use of the product, and requests to retailers to list the product as appropriate only for consumers over 14 years of age. The firm also removed inventories labeled "13+." The firm also agreed to ask retailers who market products primarily, though not exclusively, to children to execute a Responsible Sellers Agreement prohibiting marketing and sales to children; stop the sale of these magnets to retailers that market products exclusively to children; and providing a Responsible Sellers Agreement to general use stores for their information.

In December 2010, we received the first report of the surgical removal of magnets from a child who had ingested multiple magnets that came from a magnet set intended for adults. During 2011, Compliance activity included evaluation of the marketing and labeling of the product category, collecting product marketed to children under 13 and evaluating compliance with ASTM F963. In addition, where products did not have labeling or marketing information, the agency encouraged those firms to develop marketing and labeling to ensure that they were not marketed to children. More firms were issued Notices of Noncompliance for marketing to children younger than 14 years.

In response to continuing injuries associated with the products and children of various ages, we published a public service announcement (PSA) in November 2011, concerning the hazard in cooperation with two manufacturers. Reported incidents involving children continued to increase unabated from 8 cases in 2010, 17 cases in 2011, and 25 cases in 2012 (as of July 8, 2012). Twenty-two incidents were reported before the PSA; 28 more followed during the eight months after it. A high percentage of the injuries resulted in surgeries or other invasive procedures. Of the 50 reports known to staff, 22 required surgery, and 10 required either invasive procedures such as endoscopies or colonoscopies. In 2011, and into spring 2012, staff continued to

identify additional firms offering this product on the Internet with labeling and marketing violations.

Given the continued injuries to children, 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. Two of the importers did not agree to stop sale and are the subject of administrative actions recently initiated by the Commission. As those complaints allege, among other things, CPSC staff experts do not believe warnings will ever be effective in protecting children from this hidden hazard.

B. The Product

1. Description of the Product

The magnet sets covered by this proposed rule typically are comprised of numerous identical, spherical, or cube-shaped magnets, approximately 3 to 6 millimeters in size, with the majority made from NdFeB (Neodymium-Iron-Boron or NIB). These magnets exhibit strong attractive qualities. 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.

Often referred to as "magnet balls" or "rare earth magnets," the products currently are 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, these products can be used and reused to make various two- and three-dimensional forms, jewelry, and toys, such as a spinning top.

The products are sold in sets of varying size, from as few as 27 magnets to more than 1,000. Most of the magnets 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. Based on product information provided by marketers, the most common magnet size is approximately 5 mm in diameter, although balls as small as about 3 mm have been sold, as have sets of larger magnet balls (perhaps 15 mm to 25 mm in diameter). In addition to magnetic ball sets, desk sets of small magnetic cubes have also been sold, although they have comprised a relatively small share of the market. The leading marketer of such magnet sets recently added small magnetic rods—intended to be used with balls to make

geometric shapes—to its desk toy product line.

The most common color of these magnets is a glossy, highly reflective silver, with the spheres often described as similar in appearance to BBs or ball bearings. Some firms now include sets in a wide range of colors, or combinations of colors, ranging from bright pink, green, and blue, to darker shades, such as purple and black. Most, with the exception of the smaller sets, are sold with a container, such as a square plastic cube, a metal tin, and/or a soft pouch. Most brands are sold in nondescript containers, such as metal tins or black fabric boxes. The largest seller uses colorful, transparent packaging that simulates the cube floating within.

The age labeling of hazardous magnet sets varies; currently, most products carry an age label and are marked “14+.” Some sets have no specific age recommendation on the package, even though retail Web sites may identify them as intended for ages “13+” or “14+.” The small parts warning² is sometimes included on the packaging (*i.e.*, “choking hazard, not for children under 3”), as are warnings to keep the product away from all children.

The proposed rule would define magnet sets as: “any aggregation of separable, permanent magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture, mental stimulation, or stress relief.”

2. Use of the Product

Although firms that sell magnet sets state that they intend them as desk toys for adults, these sets are found in offices and homes and in locations within the home beyond desk tops, such as on refrigerators. Magnet sets have some appeal for virtually all age groups. They tend to capture attention because they are shiny and reflect light. They are smooth, which gives them tactile appeal, and they make soft snapping sounds as they are manipulated. They have the properties of a novelty, which arouses curiosity; incongruity, which tends to surprise and amuse; and complexity, which tends to challenge and maintain interest. Their strong magnetic properties cause them to move in unexpected ways, with pieces snapping together suddenly, and moving apart—occasionally quite quickly. 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 product’s appeal as a challenging puzzle or as a manipulative or jewelry. They may also be used as a stress ball and as a way to hold things in place.

Children from toddlers through teens have been exposed to these products in the home setting and elsewhere. Ingestion incidents have been reported to involve children 5 years of age and younger and follow similar scenarios as other ingestion incidents among this age group. Mouthing and ingestion of non-food items is a normal part of the exploratory behavior of preschool children. Caregivers, in a few cases, said they had intended to keep the sets away from the victims, but did not realize they had failed to do so, until after the child became ill and the magnets had already caused internal injuries. In other incidents, the child reportedly had never mouthed or ingested objects previously, and as a result, they were permitted by the caregiver to play with the magnets. As might be expected, in a number of cases, the magnets were not in their original containers, and caregivers were unaware that some were missing from the set and in the child’s possession. Several importers sell sets of spares, small numbers of balls to replace those lost or missing from a larger set.

These products would also be appealing to children of early-to-middle elementary school age, who might be capable of controlling the magnetic forces exhibited by the pieces while constructing various forms depicted in the product instructions and on the related Web sites. Simple three-dimensional puzzles begin to interest children as they approach 8 and 9 years of age; and 9 through 12 year olds are interested in highly complex puzzles. Children in the 9 through 12 year age group have the reading skills to follow directions for three-dimensional puzzles, and they have the fine motor skills required to handle small, abstract, or interlocking pieces. Nine-year-olds can complete puzzles with 100 to 500 pieces; and 10 through 12 year olds enjoy the challenge of puzzles with 500 to 2,000 pieces. Children in this 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 in the paper and video instructions related to the magnet sets. Additionally, magnets typically are included in elementary school (ages 6 through 12) science curricula, the age at which children are taught the basic concepts of magnetism.

For all of these reasons, magnet sets are sometimes purchased for children under the age of 14, despite the warnings or labeling. This is consistent with reviews on retail Web sites, which indicate that these products are being purchased for children. Approximately one-third of 53 adults reviewing one manufacturer’s product on Amazon.com reported purchasing them 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. Given the relatively low cost for some sets, children in these age groups also 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. 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). This tendency toward mouthing behavior involving magnets could account for some reported ingestions, where incident details are lacking.

Where details are provided, the incident reports describe scenarios that are consistent with the behaviors of children in this age range. Although exploratory play is generally associated with very young children, people of all ages use their senses to explore unfamiliar phenomena. More discussion of the hazard scenarios involving these products is provided in section C.2 of this preamble.

3. The Market

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 have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly \$50 million. This 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 ranging from about \$20 to \$45, with an average price of about \$25.

The small powerful magnets most likely to be affected by this proposed rule are made from alloys of

² See 16 CFR § 1500.19(b)(1).

neodymium, iron, and boron. They 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. 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.

All of the firms that have marketed the products are believed to import 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, and there are no major barriers to market entry for firms wishing to source products from China for sale in the United States. Firms often 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 have recently imported magnetic sets for sale in the United States. The combined sales of the top seven firms have probably accounted for the great majority (perhaps more than 98%) of units sold. One firm is believed to have held a dominant position in the market for magnetic desk sets since it entered the market in 2009. 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. 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; many that market products through “stores” on a leading Internet shopping site.

C. Risk of Injury

The risk addressed in this proceeding concerns damage to intestinal tissue caused by the ingestion of more than one magnet from a magnet set, magnets that are attracted to each other in the digestive system, damaging the intestinal tissue trapped between the magnets. In rare cases, there can be interaction between magnets in the airways and digestive tract (esophagus). Serious injury and death are likely consequences when children ingest strong magnets.

1. Incident Data

NEISS data. CPSC staff reviewed data from the National Electronic Surveillance System (NEISS) database of magnet-related ingestion cases treated in emergency departments from January 1, 2009 to December 31, 2011.³ To derive estimates, CPSC staff considered all cases reported through NEISS from January 1, 2009 to December 31, 2011, which mentioned “magnet” in the narrative field of NEISS reports. This review produced an estimated 6,100 magnet-related ingestions for that period of time (note that this includes incidents involving all types of magnets, not just magnet sets). This excludes cases with descriptions such as “kitchen magnet” or “plastic-covered magnet.” Staff further analyzed cases that possibly involved magnets that were from magnet sets. This review yielded a count of 72 magnet ingestion cases during this time period, which staff determined (based on a review of narratives in the NEISS reports) to involve or possibly involve magnets from magnet sets. Based on the magnet ingestion cases treated in NEISS hospital emergency departments, staff determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in U.S. emergency departments during this time period. NEISS cases are coded from medical records so brand name is rarely available, but descriptions of the products from the NEISS narrative suggests that the magnets involved in these cases are magnets from magnet sets. For more information about the process for developing the estimates of incidents, see the memorandum from the Directorate for Epidemiology at Tab A of staff’s briefing package <http://www.cpsc.gov/library/foia/foia12/brief/magnetstd.pdf>. It is possible that some number of the estimated 4,400 magnet ingestion-related injuries not classified as high-powered magnets could be attributable to the ingestion of magnets from high powered magnet sets. However, the information provided in the NEISS reports did not provide sufficient detail to place them into that category.

Staff reviewed the NEISS data to obtain more information about incidents involving magnet sets. With regard to

age, the largest portion of these incidents involved children 4 through 12 years of age. Of the estimated 1,700 ingestion incidents related to magnet sets, 1,200 of the victims are in the 4-through 12-year-old age group (70.6 percent). It is quite possible that some portion of the estimated 4,400 “magnets, type unknown/other type” category of incidents also involved magnet sets and children in the 4- through 12-year-old age group. Of the estimated 1,700 ingestions, most (approximately 1,600) were treated and released from the hospital.

Databases other than NEISS. In addition to reviewing NEISS data, staff also reviewed incidents reported through other CPSC databases, such as the Injury or Potential Injury Incident database (IPII) and the In-depth Investigation database (INDP). These databases provided more detailed descriptions, and thus, included more information about the products involved and the incident scenarios. In reviewing the initial set of incidents from these databases, staff considered all reported incidents from January 1, 2009 through June 30, 2012, that involved a magnet and an ingestion or injury was reported. Excluded from this review were magnets in children’s toys, as well as magnets that were determined to be a different type other than small, strong magnets from sets of magnets. Staff focused on one hazard pattern: ingestion of magnets. Other reported hazard patterns, such as allergic reactions, ear injuries, and a hand injury were excluded.

From review of INDP and IPII databases, we are aware of 50 reported incidents occurring from January 1, 2009 through June 30, 2012 involving the ingestion of magnets by children between the ages of 1 and 15. 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”; and 5 of those 50 incidents possibly involved ingestion of this type of magnet. We discuss these 43 incidents (the 38 incidents, plus the 5 possible incidents) in more detail below.⁴

In 35 of the 43 incidents, two or more magnets were ingested. Hospitalization was required in order to treat 29 of the 43 incidents, with surgery necessary to

³ 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.

⁴ Six of the remaining seven incidents (out of the 50 incidents) involved ingestion of magnets that were part of, or designed to be, part of jewelry, including beads, faux tongue rings, and earrings. One incident involved the ingestion of a magnetic rock. The rock magnet and magnets in jewelry would not meet the proposed definition of “magnet set” and would not be covered by this proposed rulemaking.

remove the magnets in 20 of the 29 hospitalizations. In 9 of the 29 hospitalizations, the victim underwent colonoscopic or endoscopic procedures to remove the magnets. In 37 of the 43 incidents that likely involved magnets from hazardous magnet sets, the magnets were ingested by children younger than 4 years old or between the ages of 4 and 12 years.

In 20 of the 43 incidents, the victims reportedly put the magnets in their mouths because they thought the magnets were edible; they wished to emulate jewelry piercings; or they simply mouthed the magnets while playing with them. In 23 of those 43 incidents, there is insufficient information to determine how the magnets were being used at the time of the ingestion.

In 30 of the 43 incidents, the reports indicate the source of the magnets ingested. In 10 of the incidents, the magnets were owned by a relative and were obtained, presumably by the victim, without the relative's knowledge. In 5 incidents, the magnets were given to the child by an adult; and in 12 incidents, the magnets were obtained from a friend or classmate. In three instances, the magnets were purchased by the victim. The number of ingestion incidents involving magnets from magnet sets has increased over time, from 7 in 2010, to 16 in 2011, and 20, as of June 30, 2012.

2. Hazard Scenarios

The incident reports describe scenarios that are consistent with behaviors of children in the age range described in the incidents. In the incidents reported among 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. Another common scenario accounted for half of the reported ingestion incidents among 8 to 15 year olds. Children used at least two and as many as seven magnets to simulate piercings of their tongue, lips, or cheeks. On the tongue or lip, children sometimes used more than two magnets to form the appearance of a ring. This is a type of role-play behavior, particularly for the younger children in the group, and the magnets serve as highly realistic props.

In this section, we summarize some of the incident reports to demonstrate a few of the hazard scenarios that have been reported in incidents involving ingestion of magnets from magnet sets.

In one incident, a 10-year-old girl simulating a tongue piercing, accidentally swallowed two magnetic balls. That same day, her mother took her to the local emergency room, and she was admitted for 5 days; during that time, the movement of the magnets was monitored by 10 x-rays, 3 CT scans, and an endoscopy. Ultimately, the magnets were manipulated from their eventual position in the colon into the appendix via laparoscopic surgery and removed by an appendectomy.

In another incident, a 13-year-old girl accidentally swallowed five small, spherical, high-powered magnets when they suddenly snapped together while she was mimicking a lip piercing. Although her abdominal pains began and worsened over the next 2 days, she did not tell her mother of the ingestion until 3 days later. She was then taken to hospital, where abdominal x-rays confirmed ingestion of five magnetic balls. Medical staff initially tried unsuccessfully to remove the magnets using an oral bowel cleansing solution and then a colonoscopy procedure. Eventually she underwent surgery, and the magnets—located in three different places in her small intestine—were removed during a surgical procedure that involved resection of damaged bowel tissue and removal of her appendix. The victim's complicated recovery resulted in hospitalization for 14 days, and the surgery left a 4-inch abdominal scar.

In another incident, an 18-month-old boy sustained life-threatening intestinal injuries and will have lasting adverse health effects after ingesting three small, spherical magnets. The boy exhibited symptoms of diarrhea and vomiting and was clutching at his right side. When his mother took him to the local hospital, he was diagnosed with an ear infection. When his symptoms did not resolve a few days later, she took him to a second hospital where, reportedly, he was diagnosed with bronchitis, given some medication, and released. One or 2 days later, his mother noticed that his stomach was distended and took him to a third hospital. Abdominal x-rays revealed three small balls, requiring immediate surgical intervention to remove the foreign objects. The procedure required resection of 6 inches of the child's small intestine and resection of 3 inches of his large intestine. The victim remained in intensive care for 1.5 weeks before being released. He continued to have diarrhea and other intestinal problems (at least 2 months post-surgery when the IDI was completed).

In another incident, a 3-year-old girl swallowed eight small spherical

magnets from a magnet set, which she found on a refrigerator door. An x-ray revealed two joined magnets that appeared to be located in the victim's esophagus, plus another six magnets that appeared to be joined together in the victim's stomach. A second x-ray image, taken the next day at a different hospital, showed that the magnets had not moved. A third x-ray at a Children's Hospital showed no movement of the magnet pair (described as 3mm beads) in the esophageal area, and some movement of the group in the abdomen. Pre-intervention, the treating physicians correctly recognized that she might have aspirated a magnet into her airways that was interacting through tissues with a magnet located in the esophagus. The girl underwent three coordinated procedures: (1) A bronchoscopy that removed one "magnetic bead" from her right bronchus; (2) an esophagogastroduodenoscopy (endoscopy) that removed one magnetic bead from the mid-esophagus, and five magnetic beads from the stomach; and (3) a diagnostic laparoscopy, followed by laparoscopic-assisted removal of the remaining magnet, plus laparoscopic repair of a gastric perforation and a small bowel perforation.

In another incident, a 23-month-old male ingested eight small spherical magnets from a product described as a "magnetic puzzle." He started vomiting overnight and worsened the next day. He was taken to an urgent care facility, where a bilateral ear infection initially was suspected. A few hours later, as the child's condition worsened and he lost consciousness intermittently, an abdominal x-ray indicated six small balls that the mother recognized immediately, and informed the staff, were magnets from the puzzle. He was transferred to a Children's Hospital where an x-ray revealed some slight movement of the magnets. According to the mother, the doctors thought the magnets would pass naturally. An x-ray taken the following day showed the magnets to be located between the small and large intestine; therefore, surgery was undertaken to remove them. During surgery, two balls were found in the small intestine and six balls were found outside of the bowel in the abdominal cavity. These were removed and a small intestine perforation repaired. Staff does not have access to the full medical records, but according to the parents, extremely serious complications ensued after the first surgery. The child underwent several sequential surgeries over the next 10 days to repair leaks (unclear if this involved missed perforations/failure of repairs/new

perforations) and treat a blood clot, ischemic necrotic bowel, and serious infection stemming from the initial magnet injury. Ultimately, after what appears to be at least five or six operations, the child was stabilized but was still retained in an intensive care unit for more than a month, having lost all but 10 to 15 centimeters of small intestine (*HS staff notes the small intestine is about 600 to 700 centimeters long*). He is being fed intravenously and has a colostomy bag to remove waste products. He will require a bowel transplant and his long-term prognosis is poor.

As these scenarios demonstrate (and further discussed in the next section), parents and caregivers may not realize that the child has ingested magnets. Thus, diagnosis and treatment is delayed, and the severity of the resulting injuries increases.

3. Details Concerning Injuries

As indicated in the previous section describing some of the incident scenarios, diagnosis of injury from magnet ingestion is complicated by multiple factors, and the resulting injuries can be very serious. Medical professionals may not be aware of the dangers posed by ingestion of high-powered magnets and the corresponding need for immediate evaluation and monitoring. Standard diagnostic tools, such as x-rays, may not demonstrate fully that the ingested item is a magnet and they may not allow medical professionals to identify the number of magnets ingested. Moreover, magnets may appear in an x-ray to be other nonmagnetic items that children commonly ingest, such as beads, which typically are monitored without surgical intervention and are allowed to pass through the child's gastrointestinal tract. Furthermore, treatment for injuries resulting from the ingestion of these magnets often is delayed, much to the serious detriment of the patient because the symptoms associated with damage to intestinal tissue resulting from the ingestion of these magnets frequently resemble the symptoms associated with less serious conditions, such as the stomach flu.

Accurate and timely diagnoses also are complicated by the fact that children and teens may not attribute their gastrointestinal symptoms to prior ingestion of magnets, and they may be unable or unwilling to communicate to their parents, caregivers, or medical personnel that they have ingested magnets. Accordingly, the delay of surgical intervention due to the patient's presentation with non-specific symptoms and/or medical personnel's

lack of awareness of the dangers posed by multiple magnet ingestion can exacerbate life-threatening internal injuries and has resulted in the need for a bowel transplant.

In medical terms, the magnet injuries are pressure necrosis injuries. The unique mechanism of injury involving harmful tissue compression by strong magnets has become established in recent years. Ingested magnets residing in relatively close proximity to one other are mutually attracted through intestinal walls. The magnets interact rapidly and forcefully. The magnetic attraction can occur over distances of about 10 to 20 mm for a pair of magnets, to distances much greater than that, as the number of magnets involved increases. The attraction forces operating between just one pair of magnets (or a magnet and another ferromagnetic object) is strong enough to withstand any normal muscular contractions of the gastrointestinal tissues (GI) (peristaltic or mixing motions), as well as the intermittent turbulent flow of the considerable volumes of gastrointestinal fluid in the small intestine, or the passage of semisolid contents in the large intestine. The magnets remain coupled, exerting strong bilateral compression forces on the trapped GI tissues, sufficient to block their blood and nutrient supply. The extreme pressure exerted on the trapped tissues ultimately is directly responsible for the progressive tissue injury, which starts with local inflammation and ulceration, progressing to tissue death, then perforation, or fistula formation.

Fistulas (abnormal connections or passageways between two organs or vessels that normally do not connect) cause serious, debilitating symptoms, but generally are not as acutely urgent as perforations. Perforations present a serious risk of leakage of gut contents into the abdominal cavity which, within hours, can escalate quickly from an area of local infection, to peritonitis (an inflammation of the peritoneum, the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs), then life-threatening systemic infection (sepsis).

In some rare cases, ingested magnets have caused loops of the bowels to become twisted; this obstructs passage of gut contents and deprives the twisted gut segment of blood. It is considered an extremely urgent situation, requiring immediate surgical intervention to prevent the trapped segment from becoming necrotic, and/or from rupturing and causing contamination of the abdominal cavity. Magnets have also trapped and perforated mesenteric

tissues, presenting the possibility that larger blood vessels in the gut mesentery could be damaged, which could cause an intra-abdominal hemorrhage.

Once attracted magnetically to each other through intestinal walls, the magnets involved in GI injuries are unlikely to disengage spontaneously or to move position until they are removed by clinicians. A pair of magnets might be uncoupled by stronger attraction forces exerted by a larger number of magnets in a separate GI location (which then could cause further injury, perhaps unrecognized, in a different GI location). If magnets fall through perforations into the peritoneal cavity, they are expected to require surgical intervention and to have a relatively high associated morbidity.

Complications after these abdominal surgeries include bleeding, infection, and ileus (temporary paralysis of gut motility). Adhesions (where bands of intra-abdominal scar tissue form that can interfere with gut movement and can cause obstruction) may occur as a short-term or long-term (years) complication, frequently resulting in bowel obstructions requiring additional surgeries, and thus, creating a cycle. In females, there also can be future fertility concerns related to abdominal scar tissue and adhesions. In cases where long segments of injured bowel have to be removed, digestive function of victims can be impaired permanently, resulting in malabsorption, diarrhea, cramping, total parental nutritional feeding (and consequent frequent bouts of sepsis), need for a bowel transplant, and even death.

D. Statutory Authority

This proceeding 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. *See* 15 U.S.C. 2052(a).

The Commission is authorized, under section 7 of the CPSA, to promulgate a mandatory consumer product safety standard that sets forth certain performance requirements for a consumer product or that sets forth certain 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. In addition, if the Commission finds that no feasible consumer product standard under section 7 would adequately protect consumers from an unreasonable risk or injury associated with hazardous

magnet sets, the Commission may promulgate a rule under section 8 of the CPSA declaring hazardous magnet sets to be banned products. 15 U.S.C. 2057.

Section 9 of the CPSA specifies the procedure the Commission must follow to issue a consumer product safety standard under section 7. In accordance with section 9, the Commission may commence rulemaking by issuing an NPR including the proposed rule and a preliminary regulatory analysis in accordance with section 9(c) of the CPSA and requesting comments with respect to the risk of injury identified by the Commission, the regulatory alternatives being considered, and other possible alternatives for addressing the risk. *Id.* 2058(c). Next, the Commission will consider the comments received in response to the proposed rule and decide whether to issue a final rule and a final regulatory analysis. *Id.* 2058(c)–(f).

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, concerning 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 need of the public 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) means to achieve the objective of the rule while minimizing adverse effects on competition, manufacturing, and commercial practices. *Id.* 2058(f)(1).

According 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 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 expected benefits of the rule bear a reasonable relationship to its costs and that the rule imposes the least burdensome requirements that would adequately reduce the risk of injury. *Id.* 2058(f)(3)(E)&(F).

The Commission seeks input on whether it should be regulating under section 7 and 9 of the CPSA or seeking

a ban under section 8 of the CPSA or under similar provisions of the Federal Hazardous Substances Act.

E. Relevant Existing Standards

Currently, there is no voluntary standard applicable to magnet sets. The Consumer Product Safety Improvement Act of 2008 (CPSIA) mandated ASTM F963–11, *Standard Consumer Safety Specification for Toy Safety*, as a consumer product safety standard (Section 106 of the CPSIA). Whether the toy standard is applicable to magnet sets is not the subject of this rulemaking.

F. Description of the Proposed Rule

The Commission is proposing a rule that would prohibit certain high-powered magnet sets. As described in previous sections of this preamble, we are aware of serious injuries resulting from children ingesting such magnets. Magnets that do not have the prohibited characteristics and magnets that are not parts of magnet sets would still be allowed.

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

This section of the proposed rule would state that the proposed requirements in 16 CFR part 1240 are intended to reduce or eliminate an unreasonable risk of injury to children who ingest magnets that are part of hazardous magnet sets. The standard would apply to all magnet sets, as defined in § 1240.2, that are manufactured or imported on or after the date 180 days after publication of a final rule.

2. Definitions—§ 1240.2

This section of the proposed rule would define the term “magnet set” to mean “any aggregation of separable, permanent magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief.” This definition would not include other magnetic products that do not meet the definition, 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, *Standard Consumer Safety Specification for Toy Safety*, which is a mandatory CPSC standard. The Commission seeks comment on the scope of the products proposed to be covered by this proposed rule and, in particular, whether risks are presented by magnets in science kits or craft and

hobby kits no matter how they are age graded and labeled.

The Commission also seeks comment on whether the definition of “magnet set” should include single, i.e., individual, magnets in order to ensure that the regulation prohibits the sale of individual magnets for use as aggregated manipulative or construction desk toys. This is because the hazard posed by magnets attracting in the body can occur when magnets are purchased individually or as a set.

3. Requirements—§ 1240.3

This section would set 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, magnets from that set would be required to have a flux index of 50 or less. The Commission recognizes the possible hazard that could be posed by magnets that are purchased individually and subsequently aggregated. Therefore, the proposed language in § 1240.3(a) applies to magnet sets that contain a single magnet that fits completely within the small-parts cylinder described in 16 CFR 1501.4.

The Commission seeks comment regarding whether the proposed language in § 1240.3(a) applies to magnet sets that contain one magnet, or more than one magnet, that fits completely within the small-parts cylinder described in 16 CFR 1501.4.

The small parts cylinder referenced in the proposed 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 is too large to fit within the small parts cylinder, it would not be prohibited, regardless of the magnet’s flux index. Thus, it might be possible for manufacturers to make magnet sets that contain strong magnets so long as the magnets are sufficiently large, although the large size could reduce their utility.

Small magnets (*i.e.*, those that fit within the small parts cylinder) that are part of a magnet set must have a flux index of 50 or less. This limit is based on the level that is specified in ASTM F963–11, *Standard Consumer Safety Specification for Toy Safety*, which is a mandatory CPSC standard. As discussed in section A.1 of this preamble, the flux index of a magnet is an empirical value

developed by ASTM as a way to estimate the attraction force of a magnet.

The flux index limit of 50 was developed by ASTM, with CPSC staff's participation, to address injuries resulting from strong magnets that separated from toys. The limit was based on an analysis of magnets that were involved in incidents. The Commission seeks input on the limit particularly as to whether there may be health risks should a large number of magnets be ingested even if such magnets are at or below the flux limit of 50.

4. Test Procedure for Determining Flux Index—§ 1240.4

This section of the proposed rule would describe 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 would be selected for testing. The flux index of the selected magnets would be measured in accordance with the procedure set forth in section 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 mm²). 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.

We are proposing to use the methodology specified in ASTM F963–11 to measure the flux index of magnets that are part of a magnet set. The test method was developed to address hazards posed by magnets that are part of a toy. Such magnets are likely to be individual magnets that separate from a toy. Magnet sets may contain hundreds of magnets. Thus, such magnets are more likely to be aggregated than magnets separated from toys. When magnets are aggregated, their magnetic strength may increase. Children exposed to magnets from these magnet sets may ingest more magnets than they would if a magnet separates from a toy. Thus, it may be desirable to develop a method for testing the strength of aggregated magnets. We are interested in receiving comments that would address this issue.

5. Findings—§ 1240.5

In accordance with the requirements of the CPSA, we are proposing to make the findings stated in section 9 of the

CPSA. The proposed findings are discussed in section N of this preamble.

G. Alternatives

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

1. Voluntary Recalls

Although several of the companies that manufacture or import magnet sets have voluntarily agreed to recall (and in some cases, stop selling) these products, and several retailers have agreed to stop sale, the Commission has been unsuccessful in negotiating voluntary recalls and stop sales with several companies that control a significant portion of the magnet set market, including the company that sells more than 70 percent of the magnet sets purchased in the United States. It is extremely unlikely that all manufacturers/importers will voluntarily agree to stop selling and recall their magnet sets. Moreover, recalls would not prevent new entrants into the market in the future.

2. Voluntary Standard

Currently, there is no applicable voluntary standard in effect. A group of magnet set importers and distributors have requested that ASTM International develop a voluntary standard for the labeling and marketing of these products. Specifically, these companies have requested the formation 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 not selling the magnet sets in proximity to children's products. However, despite companies' marketing and labeling to attempt to limit children's exposure to magnets, ingestion incidents involving children continue to occur and the labeling does not change the attractiveness of the product to children or the intrinsic play value of the magnet sets. From the date that the firm with the largest share of the market undertook certain labeling enhancements and marketing restrictions through June of 2012, the Commission has learned of 47 additional incidents involving ingestion of magnets from hazardous magnet sets, 26 involving ingestion of the company's hazardous 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 this product.

3. Warnings

It is unlikely that additional or different 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 designing out the hazard 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 adequately reduce or eliminate the ingestion of these magnets.

Warnings are especially unlikely to be effective among 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. In addition, warning design guidelines and literature commonly recommend that the text of warnings intended for the general public be written at no higher than the 6th grade reading level, which is equivalent to a child about 11 years old. A warning that met this guideline presumably would not be understood by many children younger than 11.

Older children, more advanced cognitively, are able to appreciate better the hazards described in a warning. However, these children value peer acceptance more than parental guidelines, and social influences and peer pressure can drive adolescent behavior more strongly than their own independent thought processes. Furthermore, adolescents are at a developmental stage in which they test limits and bend rules. Therefore, warnings about keeping the product away from children could have the unintended effect of making the product more appealing to some children. Older children might view such warnings as attempts to restrict personal freedom or self-expression, which could result in responses that are contrary to the warning's recommendations. For example, warnings about not using the product in the specific ways that might place them at risk, such as mimicking piercings, might have the unintended effect of encouraging this behavior among these children. Repeated use of the product in this way, without ingesting the magnets, most likely will convince these children that the hazard is not especially likely or is not relevant to them.

The ingestion warnings that currently accompany these products appear to be aimed at adults, primarily parents and other caregivers. Staff generally found the content of these warnings to be lacking in the following ways. The warnings often refer to children swallowing the magnets, without describing the incident scenarios that might lead to ingestion among older children and adolescents, whom caregivers may not believe are likely to put magnets into their mouths. Some warnings refer to the potential for swallowed magnets to stick to intestines, without referring to other magnets or ferromagnetic objects. Other warnings refer to magnets sticking together or attaching to other metallic objects inside the body, but they fail to explain that the magnets can attract through the walls of the intestines and forcefully compress these tissues. Without detailed information such as this, consumers may not understand how swallowing magnets differs from swallowing other small parts, or how magnets sticking together could pose a hazard rather than simply pass through the child's system. In sum, without a clear, explicit, and accurate description of the nature of the hazard and its consequences, consumers may have difficulty developing an accurate mental model of the hazard scenario and might find the warning implausible. In such situations, consumers are unlikely to comply with the action recommended in the warning.

Even if warnings could communicate the ingestion hazard, its consequences, and appropriate hazard-avoidance measures in a way that would be understood by most parents and other caregivers, the resulting warnings may not be effective at substantially reducing the incidence of magnet ingestions if consumers do not concur with what the warning states. Avoiding the ingestion hazard requires consumers to keep the product away from all children, or at least children in the incident age group, which is 15 years old and younger. Caregivers who read and understand the warnings may attempt to keep this product out of the hands of young children, but are not likely to be so diligent about heeding the warning with older children and adolescents. Unless caregivers are convinced that their child is likely to mimic lip, nose, or similar piercings or to perform other activities that might lead them 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.

Even if caregivers believe the warnings, several factors may prevent

compliance. Some children, especially those who are older, may have peers who already own and use magnets from magnet sets. Some personally may have used the product before. Knowing this, caregivers might feel significant social pressure from the child, other family members and friends, to purchase the product for their children, or allow their children to use the product, especially if magnet sets are very popular among the child's peers. 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.

Moreover, securing the product from a child after every use requires time and effort, and warnings research has shown that even small increases in time and effort can prevent compliance with warnings. If the caregiver cannot secure the product properly—without dismantling the shapes and forms created during use—and the caregiver has created especially challenging or interesting designs with the magnets, the caregiver might feel compelled to keep the forms intact and, as a result, fail to secure the product properly. In addition, the difficulty of attempting to identify 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.” Attempts to secure the product also may fail because the caregiver underestimates the abilities of their child and places the product in locations that seem secure but are still accessible to the child. Teens may have cognitive and motor skills similar to an adult's, making it extremely challenging to keep the magnet sets out of their hands. Furthermore, if caregivers know that their children have friends who own and use magnet sets, caregivers are likely to conclude that securing their magnet set will not prevent exposure to other identical or similar products. This may lead caregivers to reject the warning message.

Based on these concerns about the likely effectiveness of warnings for magnet sets, we do not believe that warning labels would adequately reduce the risk of injury presented by these products. We are interested in receiving comments on the warnings issues.

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, or a package that

is child resistant. Aside from the evident challenges in developing such containers, their effectiveness at reducing ingestions is doubtful. Such approaches would depend on consumers securing the packaging after each use. As discussed above, consumers may be reluctant to place the product back in its packaging after they have created designs with the magnets.

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 them away from toy stores, children's sections of stores, and other such locations. It is not clear that the Commission would have the regulatory authority to impose such sales restrictions by rule. In any event, such restrictions are unlikely to reduce ingestions significantly. As discussed in section B.2 of this preamble, children access these magnets from sources other than stores. The magnet sets may be available in the home after a caregiver has purchased them. Such sales restrictions are unlikely to deter teens. Moreover, restrictions on in-store sale of magnet sets would not affect Internet sales.

6. No Action

Another option is for the Commission to take no regulatory action to address the risk of injury posed by magnet sets. 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, but would likely be smaller than if the Commission issues the proposed rule.

H. Preliminary Regulatory Analysis

The Commission is proposing to issue a rule under sections 7 and 9 of the CPSA. The CPSA requires that the Commission prepare a preliminary regulatory analysis and that it be published with the text of the proposed rule. 15 U.S.C. 2058(c). The following discussion is extracted from staff's memo, “Preliminary Regulatory Analysis of a Proposed Rule that Would Prohibit Certain Small Powerful Magnet Sets.”

1. Introduction

The Commission has preliminarily determined to issue a rule prohibiting magnet sets that have been involved in incidents resulting in serious injuries to children who have ingested magnets that are part of these magnet sets. Some of these incidents have required surgery to remove individual magnets ingested

by children. Reported incidents of magnet ingestion involved young children who put the magnets in their mouth and adolescents and teens who paired magnets to mimic tongue or lip piercings. This behavior has led to the powerful magnets being swallowed, resulting sometimes in severe medical consequences, including significant damage to the gastrointestinal tract.

The proposed rule would prohibit magnet sets that do not meet the requirements of the proposed rule. Thus, for magnet sets that contain more than one magnet, if any of the magnets would fit within the small parts cylinder, the magnet set would be prohibited, unless the small magnets meet the specified flux index limit. This performance standard for magnet sets would effectively ban current designs of magnetic desk sets of the type that have become popular in recent years.

2. Description of the Product and Market

Magnetic desk sets that would be affected by the scope of the proposed 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 the first year with significant sales to U.S. consumers was 2009.⁵ Most 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, and others have sold large sets of more than 1,000 magnetic balls. Based on product information provided by marketers, the most common magnet size is approximately 5 mm in diameter; although balls as small as about 3 mm have been sold, as have sets of larger magnet balls (perhaps 15 mm to 25 mm in diameter).⁶ In addition to magnetic ball sets, desk sets of small magnetic cubes have also been sold, although they have comprised a relatively small share of the market. The leading marketer of such magnet sets has recently added small magnetic rods—intended to be used with balls to make geometric shapes—to its desk toy product line.

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 have been sold to U.S. consumers since 2009, the first year of

significant sales, may have totaled about 2.7 million sets, with a value of roughly \$50 million. This value range 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 suggest prices typically ranging from about \$20 to \$45, with an average price of about \$25.

The small powerful magnets most likely to be affected by this proposed rule are made from alloys of neodymium, iron, and boron. 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 now are mined in China, which also reportedly holds a nearly worldwide monopoly on the production of neodymium-iron-boron magnets. 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.⁷

As noted above, none of the magnetic sets within the scope of the proposed rule are produced domestically. All of the firms that have marketed the products are believed to import 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; and there are no major barriers to market entry for firms wishing to source products from China for sale in the United States. For example, some of the firms with smaller sales volumes reported to Compliance staff that they mainly marketed products (sourced from manufacturers in China) through sales arrangements with a leading Internet retailer, which held stock for them and processed orders. A review of the product listings of the Internet retailer found that several other firms have similar business models. Other U.S. firms and individuals sell magnetic sets they have imported from China through “stores” they maintain on another major Internet shopping site.

To date, the Directorate for Economic Analysis has identified about 25 U.S. firms and individuals who have recently

imported magnetic desk sets for sale in the United States. The combined sales of the top seven firms have probably accounted for the great majority (perhaps over 98%) of units sold. Due to resource constraints, the compliance division targeted 13 firms for corrective action. Eleven agreed to stop sale pending negotiations for a corrective action plan, two are now the subject of administrative cases recently initiated by the Commission. One firm is believed to have held a dominant position in the market for magnetic desk sets since it entered the market in 2009. 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. 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, many of which market products through “stores” on a leading Internet shopping site.⁸

3. Evaluation of the Proposed Rule

Societal Costs and the Potential Benefits of a Rule Prohibiting Certain Magnetic Desk Sets

Estimated Societal Costs of Injuries

The purpose of the proposed rule is to prevent serious intestinal injuries that can result when children ingest two or more of the magnets in the subject magnet sets (or one magnet and another ferromagnetic object) (Inkster, 2012). The draft proposed rule would prohibit magnet sets that do not meet specified performance requirements. Therefore, benefits of the proposed rule would be the resulting reduction in injuries. Based on a review of magnet ingestion incidents reported through CPSC databases that include the Injury or Potential Injury Incident database (IPII) and the In-depth Investigation database (INDP), CPSC staff is aware of 38 confirmed incidents involving ingestion of one or more powerful magnets from a subject magnetic desk set since the product was introduced in 2008 (Garland, 2012). An additional five incidents possibly involved magnets from such magnet sets. No fatalities involving the products are known to the CPSC.

Our analysis of the potential benefits of the proposed rule focuses on injuries

⁵ 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.

⁶ One firm's larger magnet balls are reportedly made with cores of strontium ferrite ($\text{SrO} \cdot 6\text{Fe}_2\text{O}_3$), rather than neodymium-iron-boron.

⁷ One importer reported that some of the magnet sets it sells and ships to U.S. consumers are made from bulk magnets received from its supplier in China that it repackages in its U.S. office.

⁸ More than 40 such stores shipping magnetic desk toys directly from Hong Kong or China were identified in a brief review of product offerings on the Internet site.

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. 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 72 magnet ingestions from 2009 through 2011, which 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, three of the 72 NEISS-reported cases (4.2%) did mention a brand name of magnet sets that are the magnets of interest; 69 cases (95.8%) were determined to have possibly 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, 2012).

Based on the 72 NEISS-reported magnet cases, there were an estimated 1,716 injuries treated in U.S. hospital emergency departments during the 2009 through 2011 study period. Roughly 6 percent were hospitalized injuries, as opposed to being treated and released. The benefits of the proposed rule can be estimated as the reduction in the societal costs associated with the injuries that would be prevented by the

proposed rule. The 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 it estimates the societal costs of injuries reported through NEISS. Additionally, based on empirical relationships between the number of medically attended injuries treated in emergency departments and the number of injuries treated in other settings, the ICM also estimates the number and societal costs of medically attended injuries treated outside of emergency departments, such as in doctors’ offices and clinics. The estimates of societal costs provided by the ICM depend upon (and vary by) the injury diagnosis, the body part affected, the injury disposition (*i.e.*, treated in a doctor’s office, treated and released from a hospital emergency department, or hospitalized), and the age and sex of the victim.

Table 1 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 proposed rule. As shown in the table, the 2009 through 2011 NEISS estimates suggest an estimated *annual* average of about 572 emergency department-treated injuries, including 537 injuries that were treated and released and 35 injuries that were hospitalized. About 70 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.⁹ Additionally, based on estimates from the ICM, there were another 870 injuries treated annually outside of hospital emergency departments.

After including the injuries treated outside of hospital emergency departments, there was an annual average of about 1,442 medically attended injuries involving ingestions of magnets that were defined as at least “possibly of interest.” These injuries resulted in annual societal costs of about \$24.8 million (in 2011 dollars) during the 2009–2011 time period. The average estimated societal costs per injury were about \$13,000 for injuries treated outside of emergency departments and hospitals (such as in a doctor’s office or clinics), about \$17,000 for those that were treated and released from emergency departments, and about \$112,000 for those that were admitted to hospitals for treatment. Medical costs and work losses (including work losses of caregivers) accounted for about 25 percent of these injury cost estimates, and the less tangible costs of injury associated with pain and suffering accounted for about 75 percent of the estimated injury costs (Miller et al., 2000).

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, 2009–2011

Injury disposition	Estimated No.	Estimated societal costs (\$ millions) *
Treated and Released from Hospital Emergency Department (NEISS)	537	\$9.1
Admitted to Hospital Through the Emergency Department (NEISS)	† 35	3.9
Medically Treated Outside of Hospital Emergency Department (ICM)	870	11.7
Total Medically Attended Injuries	1,442	24.8

* In 2011 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.

It should be noted that there is uncertainty concerning these estimates. Some of the cases described as “possibly” involving the magnet injuries that were included in Table 1 may not have involved the magnets that

are the subject of the NPR. As noted above, about 95.8 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 proposed rule.

⁹ In contrast to the available evidence on the number of magnets ingested from the NEISS estimates, 37 of 40 non-NEISS incidents reported to the CPSC involved the ingestion of more than one

magnet (see Garland, Table 10). The difference may be related to the number of cases upon which the NEISS estimate was based, which may have been too small to provide reliable estimates.

Alternatively, it is possible that the non-NEISS injury reports to the CPSC tended to involve the more serious cases with multiple magnets.

On the other hand, in addition to the magnet cases upon which the table was based, there were also 175 NEISS cases (representing about 1,440 emergency department-treated injuries annually) in which the magnet type was unknown. These cases included those in which the case narrative 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 those that would be covered by the proposed rule, the Table 1 results would tend to understate the societal costs associated with the magnets subject to the proposed rule.

Estimated Benefits of the Proposed Rule

As noted above, the benefits of a proposed magnet rule would be the reduction in the societal costs of the injuries that would be prevented. In general, because the proposed rule would effectively ban certain types of magnet sets, all ingestion injuries that would have involved magnets that, in the absence of the proposed rule, would have been sold after the effective date of the proposed rule, will be prevented. However, if children, adolescents, and teens cannot play with or use the prohibited magnets, they could play with or use substitute products that may also result in injury. Hence, the overall benefits of the proposed rule should be measured as the *net reduction* in injuries, and the concomitant reduction in societal costs, that would result.

These issues make it difficult to estimate with much certainty the prospective benefits of a proposed rule. However, if we assume that the injuries presented in Table 1 provide a generally accurate estimate of the annual injuries that would be prevented by the

proposed rule, and that the risk associated with the use of substitute products is small, the expected benefits might amount to roughly \$25 million annually.

Potential Costs of a Rule Prohibiting Certain Magnetic Desk Sets

The profits of firms represent a measure of the benefits to businesses that result from the production and sale of products. Similarly, the use value or “utility” that consumers receive from products represent the benefits of product use by the consuming public. Consequently, the costs of a proposed rule that effectively bans certain magnetic sets would consist of: (1) the lost profits of firms that would be barred from producing and selling the product in the future, and (2) the lost use value experienced by consumers who would no longer be able to purchase the prohibited magnets at any price.

Market Wide Profits

First consider “profits,” which would be defined as the total revenue (TR) received by firms resulting from the sale of the subject magnets, less the total costs (TC) needed to produce, distribute, and market them. We do not have firsthand knowledge of the profits of firms marketing the magnetic desk sets, but we do have information that may help us provide an upper limit.

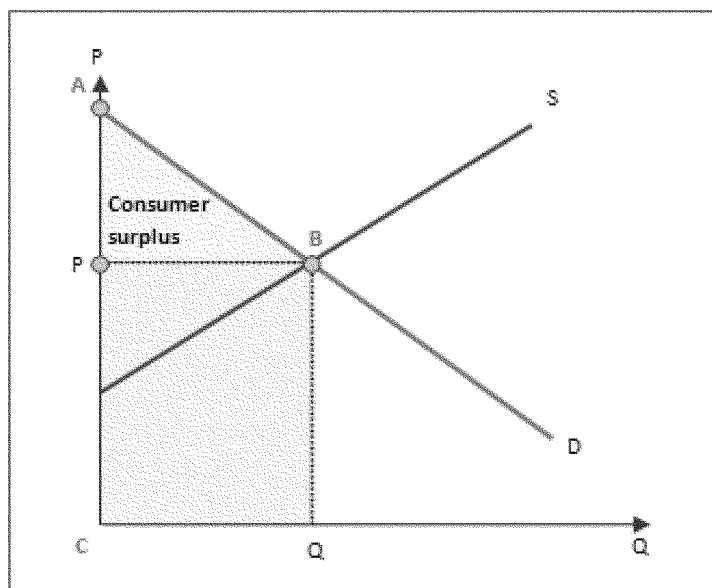
Based on the available information described earlier, sales of the magnetic desk sets may have averaged roughly 1 million annually during the 2009–2011 study period, with an average retail price of about \$25 per set. Thus, total industry revenues may have averaged about \$25 million annually (*i.e.*, 1 million sets × \$25 per set). 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 may have amounted to about \$10 per set, or an annual average of about \$10 million (*i.e.*, 1 million sets × \$10 import cost per set). Thus, total revenues, less import costs, might have averaged about \$15 million annually (*i.e.*, \$25 million – \$10 million). While the share of profits from this \$15 million in net revenues is unknown, it seems unlikely that profits would amount to more than about half, or about \$7.5 million annually. Thus, the costs of a proposed rule in terms of reduced profits might amount to as much as \$7.5 million on an annual basis.¹⁰

Lost Utility to Consumers

We cannot estimate in any precise way the use value that consumers receive from these products, but we can describe it 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 magnetic desk sets, given sales of about 1 million sets annually, and an average retail price of about \$25 per set, consumer expenditures would amount to about \$25 million annually. This \$25 million represents the minimum value that consumers would expect to get from these products. It is represented by the area of the rectangle CPBQ in the standard supply and demand graph below, where P equals \$25, and Q equals 1 million units.

¹⁰ While most of these potential profits would accrue to importers, who also sell the magnetic desk toys directly to consumers, some portion would accrue to other retailers.



The consumer surplus is given by the area of the triangle PAB 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. For example, while 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 \$50.¹¹

In general, the use value for the magnetic desk sets obtained by consumers is represented by the area of the trapezoid CABQ. However, the prospective *loss* in use value associated with the proposed rule prohibiting certain magnetic desk sets 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 \$25 million (represented by the rectangle CPBQ) that they would have spent on

magnetic sets in the absence of a ban. While they can no longer purchase magnetic desk 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, the amount of utility that would be lost from a ban of magnetic sets. While the magnetic desk sets clearly provide "utility" to purchasers, they are not necessities. Consequently, the demand for magnetic desk sets is probably *not* price inelastic, a factor that would tend to reduce estimates of utility losses.¹² Additionally, if the magnetic sets are "faddish," they may not be the type of product that will be used intensively 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 desk sets might amount to about \$10 million on an annual basis (*i.e.*, [$\$35 - \25] \times 1 million units annually).

Finally, it should be noted that the loss in consumer surplus just described represents the maximum loss of consumer utility from the proposed 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 in the place of magnetic desk sets. If, for

example, there were close substitutes for magnetic desk sets (*i.e.*, desk sets that are almost as satisfying and similarly priced), the overall loss in consumer surplus (and hence, the costs of the proposed rule) would probably tend to be small. On the other hand, if there are no close substitutes, the costs of the proposed rule would tend to be higher. Nevertheless, the proposed rule will result in some level of lost utility. By purchasing magnetic desk sets rather than other products, consumers are revealing that they have a preference for the magnetic desk sets that are likely to provide more utility than a substitute purchase.

Sensitivity of Results to Product Life Assumptions

Implicit in this analysis has been the assumption that the expected useful life of the magnetic desk 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. Magnetic desk sets are relatively durable products, purchased at an average price of about \$25. However, many consumers may find them to be novelties that soon lose much of their appeal. Thus, 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 they are purchased. On the other hand, the magnets may be put away in a place accessible by children at some later date. Although it is somewhat speculative, it seems reasonable to assume that the effective useful product life of magnetic desk sets is, on average, no more than about a year.

¹¹ If the above graph represents the market for tickets, the demand curve (AD) 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 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 B. 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.

¹² 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, meaning consumers are not likely to reduce substantially their purchase of gasoline (at least in the short run) even if the price increases substantially.

However, it should also be noted 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 magnetic desk set in use (and hence, reduce estimated societal costs per set) by about half. However, this reduced estimate of annual societal costs would itself be offset by the fact that the sets remain in use for 2 years, rather than 1 year. Thus, annual benefits would be halved, but benefits would be accrued over a 2-year period rather than 1 year. Consequently, even if we had doubled the assumed product life, the relationship between benefits and costs would have remained about the same.

Alternatives to the Proposed Rule

There are several possible alternatives that the Commission might consider instead of a proposed rule prohibiting certain magnetic desk sets.

Alternative Performance Requirements

As an alternative to the proposed rule, the Commission could consider promulgating an alternative set of requirements that could reduce the risk of injury from magnetic desk sets. Performance requirements might allow a different flux index for the magnets sold as manipulative desk sets; different specifications regarding shapes and sizes of magnets within the scope of the standard; or some other criteria that have not yet been developed (but not as stringent as in the proposed rule). The advantage of such an approach is that it could reduce the potentially unreasonable risk of injury associated with magnetic desk sets and at the same time allow adults to continue to use the product. One practical question, however, is whether such a standard would eliminate or substantially affect the physical qualities of the products that make them enjoyable for adults. Additionally, the expected injury reduction would depend upon the parameters of the performance requirements that are established.

Safer Packaging

A possible alternative might be for magnetic desk 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 an approach might prevent injuries resulting from a small number of magnets being separated from a set

without the owner knowing. In reality, though, many consumers may not use such containers because it could require time to form the magnets into a shape (e.g., a cube) to make them fit in the containers; or they might want to keep the magnets out of their container in a shape or structure that took time and effort to construct.

Alternatively (or in combination), the magnets could be sold in child-resistant packaging. Such an approach has the potential to reduce ingestion injuries, but it may result in several practical problems. Child-resistant packaging would not prevent teens and adolescents (and even some younger children) from opening the packaging. Additionally, the child-resistant 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 magnetic desk sets because of the level of inconvenience it would involve (Sedney & Smith, 2012). Also, for the reasons described above, consumers may leave magnets outside of their container.

Warnings

The Commission could require strong warnings on labels and on product instructions designed to prevent the use of the magnetic desk sets by children. The Division of Human Factors, Directorate for Engineering Sciences (HF) memorandum contains an extensive discussion concerning warnings and their potential effectiveness (Sedney & Smith, 2012). Based on HF staff's examination, the ingestion warnings that currently accompany magnetic desk sets are generally aimed at adults, but appear to be deficient in terms of their content. For example, some warn against children swallowing the magnets without describing the incident scenarios. Some warnings refer to the propensity for swallowed magnets to stick to intestines without referring to the presence of other magnets or metal objects. Others warnings did refer to magnets sticking together or attaching to other metallic objects inside the body, but without explaining that the magnets can attract through the walls of the intestines and forcefully compress these tissues, resulting in serious injuries. According to CPSC 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.

CPSC staff believes that it may be possible to develop warnings that could adequately 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. However, the effectiveness of such warnings is unknown, and CPSC staff doubts that even well-written warnings would substantially reduce the incidence of magnet ingestions. Some caregivers who read and understand the message may attempt to keep the magnets out of the hands of young children, but staff doubts many caregivers would attempt to keep the product away from older children and adolescents. Additionally, staff is doubtful that children old enough to understand the warnings would abide by them.

Restrictions on the Sale of Magnetic Desk Sets

Another option for the Commission to consider might be to prohibit sales of magnetic desk sets in toy stores, children's sections of general purpose stores, and near cash registers of stores that sell any children's products. Sales limitations or requirements for strong warnings might also be required on Web sites advertising the sale of magnets on the Internet.

The details for developing a set of sales limitations and requirements would need to be worked out, but the idea would be to make sure that magnetic desk 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 could be developed although the staff has expressed serious concern as to whether such warnings can ever overcome the attractiveness of the magnets and their intrinsic play value.

Such sales limitations, in combination with adequate and explicit warnings, may increase consumer awareness of the hazard, and possibly reduce the number of ingestions. Some parents would still allow their children (especially older children and adolescents) to play with the magnetic desk sets despite the warnings. Also, some young children will get into the packaging, even if parents try to restrict the use of the desk sets. Nevertheless, combining sales limitations with explicit warnings might educate parents about the hidden nature of the hazard, while at the same time allow adults to continue to use a

product that they apparently enjoy. We are interested in receiving comments that would address this issue.

Address Through Corrective Actions Rather Than Regulatory Action

Alternatively, the Commission could continue to address the hazard by means of Corrective Action Plans. While staff believes this approach may be deficient, such a strategy might be combined with other actions described above to achieve some reductions in the hazard.

Summary

Based on reports to the CPSC, ingestions of small magnets contained in magnetic desk sets have caused multiple, high severity injuries that require surgery to remove the magnets and repair internal damage. However, because of the lack of definitive information on the number of injuries involving magnetic desk sets that would be prevented by a proposed rule, there is uncertainty concerning the benefits that would result. If we assume that the NEISS cases identified by the Directorate for Epidemiology staff as involving high-powered and/or ball-shaped magnet ingestions actually involved the magnets that would be prohibited, then the estimated benefits of the rule might amount to about \$25 million annually.

The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, are also uncertain. However, based on annual estimates available for the 2009–2011 study period, these costs could amount to about \$7.5 million in lost profits and some unknown quantity of lost utility.

There are alternative regulatory actions that the Commission could consider that might allow the magnetic desk sets to continue to be marketed. For example, the Commission, by regulation, could issue alternative performance requirements or require warnings that explicitly describe the hazard and how to avoid it. Other options might be to develop requirements for the packaging of the magnetic desk sets (e.g., develop requirements for child-resistant packaging); and/or place limitations on how and where the magnetic desk sets can be sold. These alternative actions—which might be considered alone, or in combination—would have varying levels of effectiveness.

I. Paperwork Reduction Act

The proposed rule would not require manufacturers (including importers) to perform testing or require manufacturers or retailers to keep records. For this

reason, the proposed 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 proposed 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.

J. Initial Regulatory Flexibility Analysis

1. Introduction

The Regulatory Flexibility Act (RFA) generally requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses. Section 603 of the RFA calls for agencies to prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the proposed rule on small entities and identifying impact-reducing alternatives. The initial regulatory flexibility analysis is to contain:

(1) A description of the reasons why the action is being considered;

(2) A succinct statement of the objectives of, and legal basis for, the proposed rule;

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

(4) 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

(5) An identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

Accordingly, staff prepared an initial regulatory flexibility analysis, which is summarized below.

2. Description of the Proposed Rule and Reasons for Considering It

As discussed previously, the proposed rule would prohibit magnet sets that do not meet the specified requirements described in section F of this preamble. Some of the incidents that have come to the attention of the Commission involving ingestions of magnets from desk sets have resulted in severe medical consequences, including significant damage to the stomach or intestines. Based on a review of emergency department-treated magnet ingestions obtained through the NEISS, the Directorate for Epidemiology staff has identified 72 magnet ingestions

from 2009 through 2011, which were determined to involve, or possibly involve, the magnets of interest. Based on these injuries, staff estimates that there has been an *annual* average of about 572 emergency department-treated injuries involving the products, including 537 injuries that were treated and released and 35 injuries that were hospitalized.¹³ Additionally, based on estimates from the CPSC’s Injury Cost Model (ICM), which is integrated with NEISS, there were 870 other injuries treated annually outside of hospital emergency departments, such as in doctors’ offices and clinics. The estimated total of 1,442 medically attended injuries involving magnet ingestions, which were defined as at least “possibly of interest,” resulted in average annual societal costs of nearly \$25 million during 2009 through 2011, based on estimates provided by the ICM.

3. Products Within the Scope of the Proposed Rule

This proposed rule would cover magnet sets that are comprised of sets of small powerful magnetic balls, cubes, and/or cylinders that can be arranged in many different geometric shapes. The products have been described as desk toys, games, puzzles, and stress relievers. The small powerful magnets most likely to be affected by the proposed rule are made from alloys of neodymium, iron, and boron. We are interested in receiving comments that would address this issue both as to the type of products that should be covered and the composition of the magnets. More information concerning the product and the market is provided in section B of the preamble.

4. Small Businesses Subject to the Proposed Rule and Possible Economic Impacts

The proposed rule would impact U.S. importers and retailers of manipulative desk sets that are comprised of small powerful magnets of the size and magnetic force proscribed by the proposed rule. None of the magnetic desk sets within the scope of the proposed rule are produced domestically. All of the firms that have marketed the products are believed to import them from manufacturers in China, packaged and labeled for sale to U.S. consumers. The Directorate for Economic Analysis has identified about 25 firms and individuals in the United States who have recently

¹³ Average annual estimates are from the Injury Cost Model evaluation of 72 emergency department-treated injuries during 2009–2011 determined to have involved, or possibly having involved, magnets of interest (Garland, 2012).

imported the product for sale to consumers. All of the importers are small businesses under U.S. Small Business Administration (SBA) size standards (SBA, 2012).¹⁴

Based on information on product sales reviewed by the Directorate for Economic Analysis staff, including reports by firms to the Office of Compliance and Field Operations (Compliance), the number of manipulative magnetic desk sets that have been sold by U.S. importers since the products were introduced in 2008 may total about 2.7 million sets, with a value to the firms of roughly \$50 million. This value range 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.

Although there are about 25 U.S. importers of magnet sets that would fall within the scope of the rule, the economic impact of the rule will be most severe for the seven firms that account for the great majority (perhaps over 98%) of units sold. Perhaps five of these larger importers derive most or all of their revenues from the sale of magnetic desk toys falling within the scope of the rule, or related products, such as books and surfaces upon which magnetic designs are constructed. These firms would be severely affected by the proposed rule, which would effectively ban the magnet sets that they have been importing and selling. Consequently, they may go out of business. Two of the other leading importers of magnetic desk sets apparently have fairly broad product offerings, which could lessen the severity of the economic impact of a rule. Nevertheless, the impacts of the proposed rule could be considered significant for these small importers.

Nearly all of the perhaps 18 other recent U.S. importers of magnetic desk sets have sold relatively few of the products. These importers sourced the products from manufacturers in China and have marketed the magnet sets through online “stores” maintained on Internet retail sites. Many of these importers are individuals who may also market a variety of other products through the same Internet outlets. For individuals and firms with these business models, the discontinuance of certain magnetic desk sets as a source of revenue as a result of the rule is less likely to cause significant economic hardship, unlike the firms or

individuals who derive most, or all, of their revenue from sales of magnetic desk sets and related products.

Although a large share of magnetic desk sets are sold directly to consumers by the importers using their own Internet Web sites or other Internet shopping sites, a rule prohibiting these products would also affect retailers of the products, whether selling them online or physically in stores. However, these retailers are not likely to derive significant proportions of total revenues from sales of affected desk sets, and the impacts on individual firms should be minimal.

5. Objectives of, and Legal Basis for, the Proposed Rule

The purpose of the proposed rule is to reduce the risk of injury from ingestion of one or more small, powerful magnets that comprise the subject consumer products. As noted above, the estimated total of 1,442 medically attended injuries involving magnet ingestions that were defined as at least “possibly of interest” resulted in annual societal costs of about \$25 million during the 2009 to 2011 time period. These incident numbers may change over the course of the rulemaking because the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) has provided the Commission with some additional incident data and is currently surveying their members regarding any additional incident data they may have to share with the Commission. After receiving this data the Commission may conduct its own survey to collect additional data similar to the exposure surveys the Commission has conducted in the ATV rulemaking. However, it is expected that the proposed rule would substantially reduce the future incidence and cost to society of ingestions of the subject magnetic desk sets. As discussed in section D of this preamble, the rule is being proposed under the authority of the CPSA.

6. Other Federal Rules

We are not aware of any federal rules that may duplicate, overlap, or conflict with the proposed rule.

7. Alternatives to the Proposed Rule

There are possible alternatives to the proposed rule that would reduce the impact of a rule on small businesses. These alternatives would include the following:

a. Adoption of a Performance Standard With Different Provisions

As an alternative to the proposed rule, the Commission could consider

promulgating a different set of performance requirements to reduce the risk of injury from magnetic desk sets. Performance requirements might require a different flux index for the magnets sold as manipulative desk sets, different specifications regarding shapes and sizes of magnets within the scope of the standard, or some other criteria that have not been developed yet. The advantage of such an approach is that, theoretically, it could reduce the potentially unreasonable risk of injury associated with magnetic desk sets, and at the same time, allow adults to continue to use the product. One practical question, however, is whether such a standard would eliminate or substantially reduce the physical qualities of the products that make them enjoyable for adults.

b. Safer Packaging Options

In theory, magnetic desk sets could 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 that result from a small number of magnets becoming separated from a set without the owner knowing. In reality, though, many consumers might be unlikely to use such containers because using a container could require consumers to take time to form the magnets into a shape (e.g., a cube) in order for the magnets to fit back into the container, or consumers might wish to keep the magnets in a formation that took time and effort to construct.

Alternatively, the magnets could be sold in child-resistant packaging. Such an approach has the potential to reduce ingestion injuries, but it may suffer from several practical problems. 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 such as the magnetic desk set because of the level of inconvenience it would involve.

It is not clear that the Commission would have the authority to require either of these approaches through regulation.

c. Warnings/Labeling Requirements

The Commission could require labeling on affected magnetic desk sets to warn consumers in lieu of a rule that prohibits the products. Following its evaluation of this alternative, the

¹⁴ The SBA size standard for “Other Miscellaneous Nondurable Goods Merchant Wholesalers” (which includes importers) is 100 employees and the size standard for “Non-store Retailers—Electronic Shopping” is \$30 million in average annual receipts (SBA, 2012).

Division of Human Factors, Directorate for Engineering Sciences, concluded: “it may be possible to develop warnings that could inform parents and other caregivers better about the ingestion hazard, its consequences, and appropriate hazard-avoidance measures. Nevertheless, the resulting warnings may not be effective at motivating caregivers to comply, and therefore, they may not reduce substantially the incidence of magnet ingestions.”

d. Restrictions on the Sale of Magnetic Desk Sets

Another option might be to prohibit sales of magnetic desk sets in toy stores, children’s sections of general purpose stores, and near cash registers of stores that sell any children’s products. Advertising and sales limitations or requirements for strong warnings might also be required at Web sites advertising the sale of magnets on the Internet.

The details for developing a set of sales limitations and requirements would need to be worked out (and the legal authority to impose such restrictions by regulation is uncertain), but the idea would be to make sure that magnetic desk 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 of the sort that CPSC staff has suggested could be developed.

Such sales limitations, in combination with adequate and explicit warnings, may increase consumer awareness of the hazard, and possibly reduce ingestions. Some parents would still allow their children (especially older children and adolescents) to play with the magnetic desk sets despite the warnings. Also, some young children will get into the packaging even if parents try to restrict the use of the products. Nevertheless, combining sales limitations with explicit warnings might educate parents about the hidden nature of the hazard, while at the same time allow adults to continue to use a product that apparently they enjoy.

e. Address Through Corrective Actions Rather Than Regulatory Action

Alternatively, the Commission could continue to address the hazard by means of Corrective Action Plans. While we believe this approach may be deficient, such a strategy might be combined with other actions described above to achieve some reductions in the hazard.

f. Taking No Action

The Commission could take no regulatory action to reduce the risk of

ingestion injuries associated with magnetic desk sets. Under this alternative, future societal losses would be determined by the numbers of products in use, other factors that affect the likelihood that young children, adolescents, and teens will ingest the magnets, and the awareness and response of the medical community to the hazards presented by ingested magnets. Theoretically, over time, increased awareness of the hazards by caregivers could make it more likely that the magnets will be kept away from young children and older children, and school personnel could be made more aware of the hidden dangers of using strong magnets to mimic tongue or lip piercings. Also, the medical community seems to be taking steps to become better educated about the risks of ingested magnets, which should lead to monitoring of patients’ medical status more quickly, which would reduce the adverse medical consequences of magnet ingestions.

8. Summary

The results of this initial regulatory flexibility analysis suggest that the proposed rule would likely have a significant adverse impact on seven of the small importers of magnetic desk sets, and perhaps five of these firms that derive most or all of their revenue from the sale of magnetic desk sets might go out of business. Some possible alternatives to a rule prohibiting the products have been identified. All of these alternatives would reduce the expected impact of the rule on small businesses. However, these alternatives might not achieve the same level of benefits as the proposed rule.

K. Environmental Considerations

Usually, 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 (see 16 CFR 1021.5(c)(1)). This proposed 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 proposed rule as follows:

The regulation for hazardous magnet sets is proposed 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 non-identical 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 proposed in today’s **Federal Register** would preempt non-identical state or local requirements for magnet sets designed to protect against the same risk of injury.

M. Effective Date

The Commission proposes that this rule would become effective 180 days from publication of a final rule in the **Federal Register** and would apply to all magnet sets 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).

N. Proposed 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 that the rule must 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 its 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 discussed below.

Degree and nature of the risk of injury. Based on a review of NEISS data, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. From review of INDP and IPII databases, we are aware of 50 reported incidents occurring from January 1, 2009 through June 30, 2012, involving the ingestion of magnets by children between the ages of 1 and 15. Of those 50 incidents, 38 involved the ingestion of high-powered, ball-shaped magnets that were contained in products that meet the above definition of “magnet set,” and 5 of those 50 incidents possibly involved ingestion of this type of magnet. Hospitalization was required in order to treat 29 of the 43 incidents, with surgery necessary to remove the magnets in 20 of the 29 hospitalizations. In 10 of the 29 hospitalizations, the victim underwent colonoscopic or endoscopic procedures to remove the magnets. In 37 of the 43 incidents that likely involved magnets from hazardous magnet sets, the magnets were ingested by children younger than 4 years old, or between the ages of 4 and 12.

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 period of 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 with girls. Even those 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.

Number of consumer products subject to the rule. The market has increased substantially since magnet sets were first introduced. We estimate that the number of such 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, with a value of roughly \$50 million.

The need of the public for magnet sets and the effects of the rule on their utility, cost, and availability. We cannot estimate, in any precise way, the use value that consumers receive from these products. In general, this 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). Although the proposed rule would prohibit the magnet sets currently on the market, it is conceivable that a similar product that meets the requirements of the proposed rule could be developed that would serve a similar purpose of the magnet sets that the proposed rule would prohibit.

Other means to achieve the objective of the rule, while minimizing the impact on competition and manufacturing. Various alternatives to the proposed rule are discussed in previous sections of this preamble. We do not believe that options other than the proposed rule prohibiting certain magnet sets would sufficiently reduce the number and severity of injuries resulting from the ingestion of magnets from these magnet sets. As discussed above, 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, and as a result, they 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, 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 such a warning. Because individual magnets are shared easily among children, many end users of the product are likely to have had no exposure to any warning.

Unreasonable risk. As noted previously, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. Injuries resulting from such ingestions of magnets can be severe and life-threatening. The risk posed by these magnets may not be appreciated by caregivers and children, as they may assume, mistakenly, that the consequences of ingesting magnets would be similar to ingesting any other small object. However, once ingested, these strong magnets are mutually attracted to each other and exert compression forces on the trapped gastrointestinal tissue.

We estimate that the societal costs of resulting injuries could amount to \$25 million annually. This would be the expected benefits that could result from the proposed rule. The costs of the proposed rule would consist of the lost profits to firms that produce and sell magnet sets, plus the lost use value that consumers would experience when the product is no longer available. We estimate these costs to be about \$7.5 million in lost profits 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 proposed rule would have on firms producing and selling the product, and on consumers who would lose the utility of the product—we preliminarily conclude that magnet sets pose an unreasonable risk of injury and that the proposed rule is reasonably necessary to reduce that risk.

Public interest. This proposed rule is in the public interest because it would reduce magnet-related deaths and injuries in the future. A rule prohibiting certain magnet sets from the chain of commerce 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. The Commission seeks comment on this issue and also whether similar actions regarding lawn darts and dive sticks have had the effect of reducing injuries by reducing the access to the product.

Voluntary standards. Currently, there is no voluntary standard for magnetic sets. A group of magnet set importers and distributors have requested the formation of a voluntary standard by ASTM International for the labeling and marketing of these products. The companies have requested the formation of a voluntary standard to: (1) Provide for appropriate warnings and labeling on packages of these magnet sets, and (2) establish guidelines for restricting the sale of these magnet sets to, or for the use of children, such as: not selling to stores that sell children's products exclusively, and not selling the magnets in proximity to children's products. Such a voluntary standard would have many of the same limitations as would a labeling standard.

Relationship of benefits to costs. 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. Although there is some uncertainty concerning the benefits that would result from the proposed rule, we estimate that benefits of the rule might amount to about \$25 million annually.

The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, also are uncertain. However, based on annual estimates available for the 2009–2011 study period, these costs could amount to about \$7.5 million in lost profits and some unknown quantity of lost utility.

Least burdensome requirement. We have considered several alternatives to the proposed rule prohibiting certain magnet sets. 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. Theoretically, this might allow some current products to continue to be produced. However, it is unclear that a different flux index would permit products that have the desired physical qualities to make them sufficiently enjoyable to adults while adequately reducing the characteristics that make these strong magnets hazardous to children. Some type of special storage containers or other packaging requirements might be possible.

However, it is unlikely that consumers would use such containers, particularly if they wish to keep the magnets out of the container and maintain whatever shape they have constructed with the magnets. We have considered the possibility of requiring rigorous warnings on the products or in the instructions for the products. However, magnet sets currently on the market provide warnings concerning the potential hazard to children. 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 when adults have bought them and they are available to children. The Commission could continue to address the hazard from magnet sets through corrective actions, *i.e.*, recalls of the product. However, such action would do nothing to prevent additional companies from continuing to enter the market and import magnet sets into the country. The Commission 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 if the Commission issues the proposed rule.

O. Request for Comments

We request comments on all aspects of this proposed rule. We ask for comments concerning the risks of injury associated with these magnet sets; the regulatory alternatives discussed; other possible ways to address these risks; and the economic impacts of the various regulatory alternatives. We specifically seek comments concerning the following issues:

- The proposed definition of “magnet sets” that would be covered by the rulemaking and other issues related to scope of the proposal
- The appropriateness of the proposed flux index limit of 50 or less
- The adequacy of the proposed test procedure for determining the flux index, particularly whether it would be sufficient to account for the strength of aggregated magnets

- Alternatives to the small parts cylinder that limits the size of the magnets at issue
- The likelihood that a magnet set could function as entertainment for adults and meet the proposed requirements
- All alternatives to the proposed regulatory action
- Issues related to warnings for these products
- The options of conducting the rulemaking under section 8 of the CPSC or under provisions of the FHSA
- Whether the definition of magnet set should include magnets sold individually with the possibility that they could be aggregated into a set of two or more magnets by consumers, and if so, whether such individually sold magnets are already covered by the definition of magnet set contained in the proposed rule at 16 CFR 1240.2(b), or whether the definition should be amended with additional language such as “whether sold individually or as part of a set.”
- Proposed § 1240.3(a) would apply to magnet sets that contain a magnet that fits completely within the small-parts cylinder described in 16 CFR 1501.4. Should it instead apply to sets with at least two magnets that fit completely within the small parts cylinder?

P. Conclusion

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

List of Subjects in 16 CFR Part 1240

Consumer protection, Imports, Infants and children, Labeling, Law enforcement.

For the reasons stated in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

1. Add 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. These requirements are intended to reduce or eliminate an unreasonable risk of injury to children who ingest magnets that are part of hazardous magnet sets. This standard applies to all magnet sets, as defined in § 1240.2, that are manufactured or imported on or after [180 days after publication of a final rule].

§ 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, permanent, magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief.

§ 1240.3 Requirements.

(a) *Small parts.* Magnet sets containing a magnet that fits completely within the cylinder described in 16 CFR 1501.4, must meet the requirement in paragraph (b) of this section.

(b) *Flux index.* When tested in accordance with the method described in § 1240.4, small magnets, as determined in paragraph (a) of this section, must have a flux index of 50 or less.

§ 1240.4 Test procedure for determining flux index.

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

(b) Measure the flux index of the selected magnets 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 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) *The degree and nature of the risk of injury.* Based on a review of NEISS data, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. From review of INDP and IPII databases, we are aware of 50 reported incidents occurring from January 1, 2009 through June 30, 2012, involving the ingestion of magnets by children between the ages of 1 and 15 years. Of those 50 incidents, 38 involved the ingestion of high-powered, ball-shaped magnets that were contained in products that meet the above definition of “magnet set,” and five of those 50 incidents possibly involved ingestion of this type of magnet. Hospitalization was required in order to treat 29 of the 43 incidents, with surgery necessary to remove the magnets in 20 of the 29 hospitalizations. In 9 of the 29 hospitalizations, the victim underwent colonoscopic or endoscopic procedures to remove the magnets. In 37 of the 43 incidents that likely involved magnets from hazardous magnet sets, the magnets were ingested by children who were less than 4 years old or between the ages of 4 and 12 years old.

Once ingested, these strong magnets begin to interact in the gastrointestinal tract, which can lead to tissue death, perforations, and/or fistulas, and possibly bowel 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; however, as few as two magnets can cause serious internal damage in a very short period of 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 associated with treatment and surgery for removal of ingested magnets. There may be a risk of gastrointestinal bleeding; leakage of holes that were repaired; rupturing of resected 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 with girls. Even those 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.

Number of consumer products subject to the rule. The market has increased substantially since magnet sets were first introduced. We estimate that the number of such 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, with a value of roughly \$50 million.

The need of the public for magnet sets and the effects of the rule on their utility, cost and availability. We cannot estimate in any precise way the use value that consumers receive from these products. In general, this 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 of money that consumers would have been willing to pay for the product). Although the proposed rule would prohibit the magnet sets currently on the market, it is conceivable that a similar product that meets the requirements of the proposed rule could be developed that would serve a similar purpose as the magnet sets that the proposed rule would prohibit.

Other means to achieve the objective of the rule, while minimizing the impact on competition and manufacturing. Various alternatives to the proposed rule are discussed in previous sections of this preamble. We do not believe that options other than the proposed rule prohibiting certain magnet sets would sufficiently reduce the number and severity of injuries resulting from the ingestion of magnets from these magnet sets. As discussed above, 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 hazards associated with magnet sets, and as a result, they will continue to allow children access to the product. Children may not appreciate the hazards, and they will continue to mouth the items, swallow them, or, in the case of young adolescents and teens, mimic body piercings. Once the magnets are removed from their carrying case, the magnets bear no warnings to guard against ingestion or aspiration; and the small size of the individual magnets precludes the addition of such

a warning. Because individual magnets are easily shared among children, many end users of the product are likely to have had no exposure to any warning.

Unreasonable risk. As noted previously, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. Injuries resulting from such ingestions of magnets can be severe and life-threatening. The risk posed by these magnets may not be appreciated by caregivers and children, as they may assume, mistakenly, that the consequences of ingesting magnets would be similar to ingesting any other small object. However, once ingested, these strong magnets are mutually attracted to each other and exert compression forces on the trapped gastrointestinal tissue.

We estimate that the societal costs of resulting injuries could amount to \$25 million annually. This would be the expected benefits that could result from the proposed rule. The costs of the proposed rule would consist of the lost profits of firms that produce and sell magnet sets, plus the lost use value that consumers would experience when the product is no longer available. We estimate these costs to be about \$7.5 million in lost profits 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 proposed rule would have on firms producing and selling the product, and the impact on consumers who would lose the utility of the product, we conclude, preliminarily, that magnet sets pose an unreasonable risk of injury. Additionally, we conclude that the proposed rule is reasonably necessary to reduce that risk.

Public interest. This proposed rule is in the public interest because it may reduce magnet-related deaths and injuries in the future. A rule prohibiting certain magnet sets from the chain of commerce 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.

Voluntary standards. Currently, there is no voluntary standard for magnetic sets. A group of magnet set importers and distributors have requested the formation of a voluntary standard by ASTM International for the labeling and marketing of these products. The companies have requested the formation of a voluntary standard to: (1) Provide for appropriate warnings and labeling

on packages of these magnet sets, and (2) establish guidelines for restricting the sale of these magnet sets to, or for the use of children, such as by not selling to stores that sell children's products exclusively, and by not selling magnet sets in proximity to children's products. Such a voluntary standard would have many of the same limitations as a labeling standard.

Relationship of benefits to costs. 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. Although there is some uncertainty concerning the benefits that would result from the proposed rule, we estimate that benefits of the rule might amount to about \$25 million annually. The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, are also uncertain. However, based on annual estimates available for the 2009–2011 study period, these costs could amount to about \$7.5 million in lost profits and some unknown quantity of lost utility. We believe that there would be a reasonable relationship between the anticipated benefits and costs of the proposed rule.

Least burdensome requirement. We have considered several alternatives to the proposed rule prohibiting certain magnet sets. 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. Theoretically, this might allow some current products to continue to be produced. However, it is unclear whether a different flux index would permit products that have the desired physical qualities to make them enjoyable to adults would reduce adequately the characteristics that make these strong magnets hazardous to children. Some type of special storage containers or other packaging requirements might be possible. However, it is unlikely that consumers would use such containers, particularly if they wish to keep the magnets out of the container and maintain whatever shape they have constructed with the magnets. We have considered the possibility of requiring rigorous warnings on the products or in the instructions for the products. However, magnet sets currently on the market provide warnings concerning the potential hazard to children. 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 still may 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 in other locations when adults have bought them and they are available to children. Finally, the Commission could continue to address the hazard from magnet sets through corrective actions, *i.e.*, recalls of the product. However, such action would do nothing to prevent additional companies from continuing to enter the market and import magnet sets into the country. The Commission 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 if the Commission issues the proposed rule.

Dated: August 28, 2012.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2012–21608 Filed 8–31–12; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2011–F–0765]

Nexira; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Nexira proposing that the food additive regulations be amended to provide for the expanded safe use of acacia gum (gum arabic) in foods.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by October 4, 2012.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–