U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

August 24, 2020

PRESIDENT
ZEN MAGNETS LLC
P O BOX 1744
BOULDER, CO 80306

RE: 200527CCC1546

Dear PRESIDENT:

Enclosed is information concerning one of your company's products. Please read this cover letter carefully because it contains important guidance about your rights and obligations regarding the enclosed information.

The U.S. Consumer Product Safety Commission (CPSC) provides firms with consumer complaints and reports of CPSC in-depth investigations concerning injuries or incidents associated with products within the Commission's jurisdiction that the firms manufacture or private label. To assure that these firms have access to information CPSC receives, we send all complaints and investigation reports we receive, whether or not the reported problem appears to be safety-related or the product appears to be at fault. We provide these reports to firms because they often provide an early warning of potential safety problems.

I have also enclosed a fact sheet that describes the Commission's information disclosure procedures under section 6(b) of the Consumer Product Safety Act that apply to the enclosed report(s). Even though the Commission has not yet received a request for public disclosure of the report(s), this letter provides you with the opportunity to comment on the information in the report(s), pursuant to section 6(b). You are not required to comment; however, if you do, please submit your comments to me within 15 days. It's most helpful if you include the incident or investigation report number(s) with your response. It is not necessary to send a copy of the report iteself. If, in your comment, you tell us that:

1) you believe that the information in the enclosed report(s) is inaccurate, or
2) you want to be notified if the Commission receives a request under the Freedom of Information Act for disclosure of the information,

the Commission will notify you when we receive such a request. In that case, the Commission will not release the information to the public until at least 15 days after the date of notification.

The reports we have provided you may - either alone or with other information you now have or may later receive - reasonably support a conclusion that the product contains a defect which could create a substantial product hazard, or creates an unreasonable risk of death or

serious injury. If so, you are required under section 15(b) of the CPSA, 15 U.S.C.2064(b), to notify the Office of Compliance and Field Operations at the CPSC.

For more information on reporting under section 15(b) of the CPSA, please visit CPSC's website at www.cpsc.gov and click on Businesses under Report Unsafe Products or write to the U.S. Consumer Product Safety Commission, Defect Investigations Division, Office of Compliance and Field Operations, 4330 East West Highway, Bethesda, MD 20814.

If you have any questions regarding this letter, please email us at clearinghouse@cpsc.gov. We can process your reply more quickly if we receive it only once. You may write to us at U.S. Consumer Product Safety Commission, National Injury Information Clearinghouse, 4330 East West Hwy., Room 502, Bethesda, MD 20814 or fax your reply to (301) 504-0025. If you want to email your reply, please address it to clearinghouse@cpsc.gov.

In the interest of improving product safety, we will continue to provide these types of reports to your firm. In addition, if any of the information used to address this letter to you requires updating, please note the necessary changes on the bottom of this letter and return it to me.

National Injury Information Clearinghouse
Division of Hazard & Injury Data Systems
Data Intake & Injury Information Branch
Clearinghouse@cpsc.gov
301-504-7921

Contact Name: _____ Title: _____

Company Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone Number: _____

Fax: _____ Email: _____

U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814-4408

CPSA Section 6(b) FACT SHEET

The Consumer Product Safety Commission (Commission) has unique restrictions that govern its public disclosure of information. This fact sheet summarizes these unique restrictions. Our rules, which you can find at 16 C.F.R. § 1101 or § 1015, provide more information. If you have questions about these restrictions, call (301) 504-7923, or facsimile (301) 504-0127.

1. What are the restrictions on the disclosure of information by the Commission?

Section 6(b), 15 U.S.C. § 2055(b), a provision of the Consumer Product Safety Act (CPSA), establishes procedures for and restrictions on the Commission's public disclosure of information. The Commission rule interpreting the requirements of section 6(b) is published in Title 16 of the Code of Federal Regulations in Part 1101 (16 C.F.R. § 1101). In addition, Section 6(a) of the CPSA prohibits the Commission from disclosing confidential business information.

2. To what information does Section 6(b) apply?

Section 6(b) applies to <u>any information</u> from which the public can readily ascertain the identity of a manufacturer or private labeler of a consumer product.

3. What are the requirements and prohibitions of Section 6(b)?

Section 6(b) prohibits the Commission from disclosing information about a consumer product that identifies a manufacturer or private labeler unless the Commission has taken "reasonable steps" to assure 1) that the information is accurate, 2) that disclosure of the information is fair in the circumstances, and 3) that disclosure of the information is reasonably related to effectuating the purposes of the CPSA and of the other laws administered by the Commission. Before disclosure of such information, the Commission must provide the manufacturer or private labeler with an opportunity to comment on the accuracy of the information. The Commission may not disclose such information for at least 15 days after sending it to the company for comment.

4. What happens when a firm submits comments on information that the Commission proposes to disclose?

The Commission must review and analyze the information in light of the comments received. The weight given to the comments and the degree of review by the Commission depends on the specificity, completeness, and credibility of the comments and any supporting documentation. Based on the comments, the Commission will decide whether to release the information.

5. If a firm submits comments, will I be able to obtain them when I receive a response to my Freedom of Information Act ("FOIA") request?

Unless the firm expressly objects to disclosure of its comments, the Commission provides those comments to the FOIA requester.

6. What happens if a firm fails to comment on information that the Commission proposes to disclose?

The Commission staff must nevertheless review the information. The degree of review, however, generally is less stringent than when a firm has submitted substantive comments.

7. What happens if the Commission decides to release information over a firm's objections?

Section 6(b) requires the Commission to notify the firm of its decision and to wait another five days before disclosing the information. During this time, the firm could file a lawsuit seeking to block disclosure of the information.

8. How long can the processing of my request take?

The initial process of giving notice to a firm and providing it an opportunity to comment on information usually takes 30 to 60 days, depending on the amount of material that is responsive to an FOIA request, the nature of the material, and the number of firms that must be notified. (Some FOIA requests involve multiple manufacturers or private labelers.) Depending on the availability of the requested records, the initial processing may take longer. If the Commission receives detailed, complex comments, the Commission's legal and technical staff must review the information closely and this can extend the processing time. On the other hand, if the firm fails to comment, the information is reviewed and released shortly after the 15 days given to the firm for comment.

9. What can I do to speed up the process?

Other than simply asking for less information, you may consult with the Commission's FOI Officer to see if you can redefine your request in a manner that will allow the release of the information without identifying a manufacturer or private labeler. Call (301) 504-7923 or facsimile (301) 504-0127.

10. Are there any other steps that I can take to get the information I requested?

Not unless you are in litigation and thus have available to you various discovery devices. Discussion of litigation discovery devices is beyond the scope of this fact sheet.

11. Are there any specific types of information that I cannot obtain?

Yes. Section 6(b)(5), 15 U.S.C. § 2055(b)(5), prohibits the disclosure of any information that a firm has reported to the Commission under Section 15 of the CPSA, 15 U.S.C. § 2064(b), unless the Commission has sued the manufacturer, has accepted a voluntary corrective action plan from the firm, has the firm's permission to release the information or the Commission publishes a finding that public health and safety requires public disclosure. (CPSA section 15(b) requires manufacturers to report to the Commission and provide information regarding their products and potential substantial product hazards.) In addition, in most cases, unconfirmed complaints are not released. The Commission requests consumers who have submitted complaints to the Commission to confirm the accuracy of the information in their complaints. If the consumer has not done so, the Commission will not release it unless the information in the complaint is corroborated by other information in the Commission's possession. Finally, as noted earlier, you cannot obtain confidential business information or trade secrets.

1. Task Number	2. Investigator's ID	EPIDEMIOLOGIC INVESTIGATION REPORT
200527CCC1546	9108	

3. Office Code	4. Date of Accident YR MO DAY	5. Date Initiated YR MO DAY
800	2020 05 19	2020 05 29

6. Synopsis of Accident or Complaint **UPC**

A nine-year-old girl was hospitalized after swallowing three magnetic balls. Surgery was required to remove the magnets from her intestines and the victim was expected to make a full recovery.

7. Location (Home, School, etc)	8. City	9. State
1 - HOME	MILLIS	MA

10A. First Product	10B. Trade/Brand Name	10C. Model Number
1345 - BUILDING SETS	NEOBALLS	UNKNOWN

10D. Manufacturer Name and Address
ZEN MAGNETS, INC.
P.O. BOX 1744
BOULDER, CO 80306

11A. Second Product	11B. Trade/Brand Name	11C. Model Number
0	NONE	NONE

11D. Manufacturer Name and Address
NONE

12A. Hispanic or Latino	12B. Race	12C. Race Source
2 - No	1 - White Other:	2 - Respondent-Other

13. Age of Victim	14. Sex	15. Disposition	16. Injury Diagnosis
9	2 - Female	4 - Hospitalized (admitted	41 - Ingested F.O.

17. Body Part(s) Involved	18. Respondent	19. Type of Investigation	20. Time Spent (Operational / Travel)
0 - INTERNAL	3 - 2nd Hand Info Only	2 - Telephone	14.00 / 0.00

21. Attachment(s)	22. Case Source	23. Sample Collection Number
9 - Multiple Attachments	09 - Doctor's Office	

24. Permission to Disclose Name (Non NEISS Cases Only)

○ Yes ◉ No ○ Yes for Manuf. Only ○ Verbal ○ Written

25. Review Date	26. Reviewed By	27. Regional Office Director
07/01/2020	9093	Beverly J. Kohen

28. Distribution	29. Source Document Number
Joseph Tsai; Stephen Harsanyi	I2050332A

This in-depth investigation was initiated as a follow-up to a magnet ingestion incident reported by a healthcare professional via SaferProducts.gov. The information contained within this report was obtained from the victim's physician (complainant) during a telephone interview (exhibit 1). There has been no response to attempts to contact the victim's family (exhibit 2). The victim's medical records were requested but have not been provided to CPSC as of this reporting date (exhibit 3).

According to the physician, the victim was a 9-year-old girl who resided with her brother and parents. On May 12, 2020 (the incident date), the victim and her brother (age unknown) were playing inside their home with small, ball-shaped magnets.

While playing, the victim accidently swallowed three magnetic balls.

The victim did not report the magnet ingestion to anyone at this time. The victim began to experience abdominal pain (date unknown). When the pain worsened, she complained about the pain to her mother but still didn't tell her about the magnet ingestion. During the evening of May 16, 2020, four days after the ingestion, the victim was brought to a local emergency room. The medical staff initially believed that she was suffering from appendicitis. Subsequent X-rays revealed three round foreign objects lodged in her intestines. Upon further questioning by the medical staff, the victim admitted to accidently swallowing magnets. The victim's mother was not aware of the ingestion, and the victim did not explain the reason for not telling anyone about the ingestion.

Shortly after midnight (May 17, 2020), emergency surgery was conducted to remove the magnets which had created two holes in her intestines and was considered life threatening. According to the physician, the surgery, which was approximately two hours in duration, was successful and a full recovery was expected. After six days in the hospital, the victim was discharged on May 22, 2020.

The physician believed that the incident magnets were washed and provided to the victim's family. No further product history was known.

During this investigator's telephone interview with the physician on June 2, 2020, the victim's contact information was provided. The physician reportedly forwarded the medical release form to the victim's family and informed them that CPSC would be contacting them in the near future. There have been numerous attempts to contact the victim's family, however as of this reporting date, there has been no response. When, or if, additional information is obtained, an addendum will be submitted.

PRODUCT INFORMATION

The product was a magnet. The victim's physician was informed by the victim's mother that the incident product were **Neoballs-brand magnet balls manufactured by Zen Magnets, LLC.** There was no further product information available.

The product was reportedly manufactured by:

Zen Magnets, LLC
P.O. Box 1744
Boulder, CO 80306
Tel. 303-669-1610
contact@zenmagnets.com

SAMPLE COLLECTION

There were no samples collected.

ATTACHMENTS

Exhibit 1: Contact list (1 page)
Exhibit 2: Written request with no response (1 pages)
Exhibit 3: Missing Document form (1 page)

Contact List

Incident date: 5/12/20

Victim: [redacted], 9-year-old girl
Victim's parents: [redacted] & [redacted]
[redacted]
Tel. [redacted]

Telephone attempt, left message, on 6/4/20 (no reply); 2nd telephone attempt, left message, and mailed letter on 6/18/20 (no reply).

[redacted], MD
Boston Children's Hospital
300 Longwood Avenue, Fegan 3
Boston, MA 02115
Tel. [redacted] / [redacted]
Email. [redacted]

Written request for victim's contact info and medical records sent to physician on 5/29/20; telephone interview with physician on 6/2/20.

U.S. Consumer Product Safety Commission

Saving Lives and Keeping Families Safe

Office of Compliance and Field Operations

[redacted]

[redacted]
Product Safety Investigator

Phone: [redacted]
Fax: [redacted]
Email [redacted]@cpsc.gov

June 18, 2020

[redacted] and [redacted]

Re: magnet ingestion incident on 5/12/20

Dear Mr. and Mrs. [redacted]:

My name is [redacted]. I am a Product Safety Investigator with the U.S. Consumer Product Safety Commission (CPSC), an independent federal regulatory agency charged with protecting the public against unreasonable risks associated with consumer products.

I was sorry to hear about the incident with your daughter, [redacted]. Dr. [redacted] at Children's Hospital indicated that you might be willing to discuss [redacted]'s incident with me, however I have been unable to contact you by phone.

CPSC collects incident and injury data on magnet ingestions in an attempt to reduce and/or prevent future incidents. Accordingly, CPSC would like to obtain additional information pertaining to the product, incident scenario, symptoms/treatments, and victim's medical records.

Would you kindly contact me to discuss. I've attached a medical release form to allow CPSC to collect [redacted]'s medical records. Thank you for your anticipated cooperation in this matter.

Sincerely,

[redacted]

U.S. Consumer Product Safety Commission

Task Number: 200527CCC1546

Date: 6-30-20

Status of Missing Document(s)

The official records below were requested for this investigation report, but could not be obtained:

1. Victim's medical records
2.
3.
4.
5.
6.