Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: November 17, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Children's Medical Ventures - RECALL [Medical Device]

AFFECTED PRODUCT: **Gel-E Donut gel pillow and Squishon 2 gel cushion products**

SUMMARY: **Unclassified Recall; The recall is due to due to potential mold contamination of the products.**

This action follows a previous recall for these products announced in May 2014. Refer to the table below for a listing of recalled model numbers and quantities, which were manufactured and distributed between July 2012 and August 2014. The model number is printed directly on the product.

Model Number	Quantity Affected
92025-A	96,311
92025-B	109,732
92025-C	50,456
91033-2	80,196
Grand Total	336,695

The products were distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. Customers who have questions about the recall or require further information or support concerning this issue, may contact their local Philips representative at (770) 510-4681 or (770) 510-4684.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Philips Healthcare Announces Recall of Children's Medical Ventures Gel-E Donut / Squishon 2 Products

Contacts

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FOR IMMEDIATE RELEASE — November 14, 2014 — Andover, MA — Children's Medical Ventures, a Philips Healthcare business, today announced that the company has issued a recall of all Gel-E Donut gel pillow and Squishon 2 gel cushion products due to potential mold contamination of the products. This action follows a previous recall for these products announced in May 2014. Refer to the table below for a listing of recalled model numbers and quantities, which were manufactured and distributed between July 2012 and August 2014. The model number is printed directly on the product.

Model Number	**Quantity Affected**
92025-A	96,311
92025-B	109,732
92025-C	50,456
91033-2	80,196
Grand Total	**336,695**

Customers are being asked to discontinue use and dispose of all Gel-E Donut gel pillow and Squishon 2 gel cushion products in their facility, even if mold is not visible. Following these actions, customers will be asked to return a reply form indicating that these actions have been completed. Customers will be given credit for all products scrapped.

In May 2014, Children's Medical Ventures initiated a recall due to mold contamination of some products, which occurred during the manufacturing process. The mold types detected on the products have been identified as types which are commonly found in indoor and outdoor environments. There is potential for the mold to be transferred to patient environments once the outer pack is opened. There is the possibility of fungal infection should patients come in contact with the mold, which could be superficial or invasive and life threatening.

At the time of the initial recall, Children's Medical Ventures implemented a process intended to reduce the presence of viable mold on the products prior to shipment. Since then, Philips has received one new report of the presence of mold on product. Because the process to eliminate the potential for mold growth has not been fully effective, the company is announcing this new recall.

The Children's Medical Ventures Gel-E Donut gel pillow and Squishon 2 gel cushions are intended to help support an infant's head or body in a hospital environment. The products are intended to be used in Neonatal Intensive Care Units (NICU), Pediatric Intensive Care Units (PICU), and neonatal care centers.

Countries where affected devices have been shipped include the United States, Australia, Austria, Belgium, Canada, France, Germany, Iceland, Ireland, Italy, Japan, Kuwait, Netherlands, New Zealand, Norway, Portugal, Reunion, Romania, Saudi Arabia, South Africa, Spain, Sweden, Switzerland, Thailand and United Kingdom.

Customers who have questions about the recall or require further information or support concerning this issue, may contact their local Philips representative at (770) 510-4681 or (770) 510-4684. Distributors outside of the U.S. should contact their local Philips representative.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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Photo