Class 2 Device Recall Playtex Nurser Deluxe Double Electric Breast Pump

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See Related Information[21]

Date Posted	April 04, 2014
Recall Status[1]	Open
Recall Number	Z-1336-2014
Recall Event ID	67597[22]
Premarket Notification 510(K) Number	K061013[23]
Product Classification	Pump, Breast, Powered[24] - **Product Code** HGX[25]
Product	Playtex Nurser Deluxe Double Electric Breast Pump Product Usage: The Playtex electric breast pump is a small, quiet, safe and effective system for expressing milk from a lactating mothers breast(s). This device is comprised of 3 major assemblies: a pump assembly, a breast cup assembly, and some commercially available items (i.e., bottles, bottle liners, etc). The device is designed with 1 pre-set speed level and 3 pre-set suction settings, which are selectable by the user via a rotating dial. The device is powered by a 12V DC power supply, which is included with the package.
Code Information	Suspect date codes for Breast Pumps: P12324-91667C to P13205-30673C. Suspect adaptor date codes: 1241 to 1324.
Recalling Firm/ Manufacturer	Energizer Personal Care 6 Research Dr Shelton, Connecticut 06484-6228
Manufacturer Reason for Recall	Some of the power adapters outer casing may become loose and separate, resulting in a potential for electric shock.
FDA Determined Cause [2]	CHANGE CONTROL (GMP - GOOD MANUFACTURING PRACTICE): Component Change Control
Action	Energizer sent and Voluntary Retail Recall Notice letter dated March 18, 2014 to retail customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to stop sale and return the affected product. The letter provides instruction to customers to return the affected product. For questions or concerns, contact Energizer Personal Care at 1-888-207-1492 or visit www.playtexproducts.com.
Quantity in Commerce	35,803
Distribution	USA Nationwide Distribution in the states of: AL, AZ, CA, CO, CT, DE, FL, GA, IA, IL, IN, KS, KY, MD, MI, MN, MO, NC, NJ, NV, NY, OH, ON, OR, PA, SC, TN, TX, VA, VT, WA, WI Canada - one consignee, Energizer (recalling firm's) company store
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = HGX and Original Applicant = PLAYTEX PRODUCTS, INC.[28]