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رقم المحفوظات: ٢٩/٤٠٥
رقم الصادر : ١٣/١/١٤٦٠٠١
بيروت، في : ٢٤ نيسان ٢٠١٣

جانب نقيب الاطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Thera Pearl 3-in-1 Breast Therapy

الجهاز المعني بالمتابعة:

- Thera Pearl 3-in-1 Breast Therapy
- Trade Mark: Lansinoh Laboratories
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA الذي يحذر فيه من استعمال الصنف المذكور أعلاه نظراً لوجود خلل في طريقة عمله ، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصية الصادرة.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
وزارة الصحة العامة

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

U.S. Food & Drug Administration

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Class 2 Recall THERA PEARL 3-in-1 BREAST THERAPY

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Date Posted	February 04, 2013
Recall Number	Z-0784-2013
Product	THERA PEARL 3-in-1 BREAST THERAPY, 2 hot and cold packs in plastic box. The Thera Pearl 3-in-1 Breast Therapy is a reusable therapeutic hot and cold pack for use with pain, swelling, engorgement, plugged ducts or mastitis associated with breast feeding or to help encourage let-down while using a breast pump.
Code Information	Lot Numbers 100/12/01, 116/12/01, 108/12/01, 109/12/01, 149/12/01
Recalling Firm/ Manufacturer	Lansinoh Laboratories Inc 333 N Fairfax St Ste 400 Alexandria, Virginia 22314-2632
For Additional Information Contact	Richard Thome 703-299-6477
Reason for Recall	The Spanish translation on the Instructions for Use (IFU) insert and product package for hot and cold packs has incorrect heating instructions which would cause product to over heat.
Action	Lansinoh Laboratories, Inc. sent an Urgent Product Recall letter dated August 14, 2012, to all affected customer. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to stop distributing and quarantine the affected product. Customers were informed that a credit would be issued for the affected product and they were asked to mail the postage paid Business Reply Card even if they do not have the affected product. If necessary call 1-877-366-1182 to arrange pickup. For questions customers were instructed to call the Customer Service Center at 1-800-292-4794. For questions regarding this recall call 703-299-6477.
Quantity in Commerce	51,472 units
Distribution	Nationwide Distribution, including the states of TX, CA, NJ, NY, SD, RI, WV, IL PA, NC and MN.

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