Indiana State Department of Health
An Equal Opportunity Employer

Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

DATE: January 21, 2010

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

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Nipro Medical Corporation Recall

SUGGESTED ACTION: **Unclassified Recall; GlucoPro Insulin Syringes; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. These syringes may have needles that detach from the syringe. If the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into the syringe, or remain in the skin after injection. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

****

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.

Nipro Medical Corporation Issues a Voluntary Recall of All GlucoPro Insulin Syringes

Contact:
Jessica Oswald
305.599.7174 x249
(EST: 9 am – 5 pm)

FOR IMMEDIATE RELEASE - January 21, 2010 - Nipro Medical Corporation, Miami FL, is initiating a nationwide recall of all GlucoPro Insulin Syringes (This does not include the GlucoPro syringe specific for use with the Amigo Insulin pump). These syringes may have needles that detach from the syringe. If the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into the syringe, or remain in the skin after injection.

Consumers who have GlucoPro Insulin Syringes should stop using and return them to point of sale for reimbursement.

This recall includes all product codes and lot numbers with expiration dates before 2011-11 (Nov 1, 2011).

Product Code	Lot #	Expiry date
JD+01U3008-5C	A08022	2011-11
JD+01U3013-5C	A08013	2011-06
JD+01U3013-5C	A08017	2011-08
JD+01U3108-5C	A08013	2011-06
JD+01U3108-5C	A08017	2011-08
JD+03U3008-5C	C08022	2011-11
JD+03U3013-5C	C08013	2011-06
JD+03U3013-5C	C08017	2011-08
JD+03U3108-5C	C08013	2011-06
JD+03U3108-5C	C08017	2011-08
JD+05U3008-5C	B08022	2011-11
JD+05U3013-5C	B08013	2011-06
JD+05U3013-5C	B08017	2011-08
JD+05U3108-5C	B08013	2011-06
JD+05U3108-5C	B08017	2011-08

The firm voluntarily recalled the products after learning of the possibility of needle detachment. FDA has been apprised of this action.

No injuries have been reported to date.

Product was distributed nationwide, including Puerto Rico.

Company is notifying its distributors and customers by Fax and Email and is arranging for return of all recalled products.

Consumers with questions may contact the company at 305.599.7174 x249.

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.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm.
  Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

RSS Feed for FDA Recalls Information [what's this?]