Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 6, 2013

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

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

SUBJECT: Medaus Pharmacy Recall [Drug]

AFFECTED PRODUCT **Certain Pharmacy Products Due to Questions Surrounding an Independent Third Party's of the Sterility Testing**

SUGGESTED ACTION: **Unclassified Recall; Medaus Pharmacy is voluntarily recalling certain sterile compounded consumer products (see table) due to our inability to confirm that the quality control testing performed on these specific lots by an independent, third party laboratory was conducted in a manner consistent with the highest standards of excellence we demand from ourselves and on behalf of our patients. Though Medaus received test results indicating that these lots met all safety standards, they are being recalled because the independent testing lab's sterility testing practices as applied to these lots indicate that the product's sterility cannot be confirmed; A list of the recalled products is listed below. Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products were distributed in the State of Indiana. Products were dispensed between March 12 and July 22nd, 2013 nationwide throughout the United States. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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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.

Medaus Pharmacy Initiates a Nationwide Recall of Certain Pharmacy Products due to Questions Surrounding an Independent Third Party's Sterility Testing

Contact:
Consumer:
800-526-9183

Media
205-837-7197

FOR IMMEDIATE RELEASE - September 4, 2013 - Birmingham, Alabama, Medaus Pharmacy is voluntarily recalling certain sterile compounded consumer products (see table) due to our inability to confirm that the quality control testing performed on these specific lots by an independent, third party laboratory was conducted in a manner consistent with the highest standards of excellence we demand from ourselves and on behalf of our patients. Though Medaus received test results indicating that these lots met all safety standards, they are being recalled because the independent testing lab's sterility testing practices as applied to these lots indicate that the product's sterility cannot be confirmed. Therefore, Medaus decided to conduct this voluntary recall out of an abundance of caution.

The use of a non-sterile injectable product exposes patients to the risk of contracting serious life-threatening infections. Medaus has not received any reports of adverse events related to the products affected by this recall to date. In fact, Medaus has never in its history experienced a single adverse patient reaction attributable to a failure of Medaus safety standards or quality control.

Product Name	Lot #	Expiry
Testosterone CYP 200 mg/mL	130508-1	11/16/2013
Lipo injection with lidocaine	130510-26	11/16/2013
Lipo injection with lidocaine	130610-24	12/7/2013
Taurine 50 mg/mL PF	130618-64	12/15/2013
L-Glutathione 200 mg/mL	130617-10	12/14/2013
Pyridoxine HCl 100 mg/mL NS PF	130531-31	11/27/2013
Magnesium CHI 200 mg/mL	130307-60	9/3/2013
Sodium ascorbate 500 mg/mL PF	130702-1	12/29/2013
Lipo injection with lidocaine	130709-68	1/5/2014
Sodium ascorbate 500 mg/mL non- corn PF	130613-8	12/10/2013

These products were dispensed between March 12 and July 22nd, 2013 nationwide throughout the United States. We are contacting all patients and doctors offices that received these lots by phone to recall any unused medications from these lots.

Medaus is notifying its customers by telephone and email, and is arranging for return of affected products. Health care facilities and customers that have products which are being recalled should stop using the product and call Medaus at 800-526-9183 for instructions on returning the product for a full refund.

To return medication or request assistance related to this recall, patients and physicians should contact Medaus Pharmacy at (800) 526-9183 , Monday through Friday, between 9 a.m. and 5 p.m. CDT.

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

- **Online:** http://www.fda.gov/MedWatch/report.htm[1]
- **Mail:** use postage-paid, pre-addressed Form FDA 3500 at http://www.fda.gov/MedWatch/getforms.htm[2]
- **Fax:** 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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