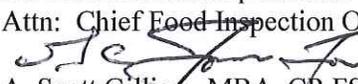




Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 2, 2013
TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Beacon Hill Medical Pharmacy d/b/a/ Rxtra Solutions Recall [Drug]

SUGGESTED ACTION: Unclassified Recall; All lots of certain sterile products to the user level. There is a question of sterility assurance for the affected products raised by the FDA; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The products were distributed nationwide to outlets including hospitals, clinics, and patients who have received orders by directly placing phone calls or faxed prescriptions to the Beacon Hill Medical pharmacy facility in Southfield, Michigan. 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.

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.

Beacon Hill Pharmacy d/b/a Rxtra Solutions Issues Voluntary Nationwide Recall of Certain Sterile Products Due to a Question of Sterility Assurance

Contact:
Consumer:
Dr. Wissam Alawieh, Pharm.D.
(800) 518-9831



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

FOR IMMEDIATE RELEASE - July 31, 2013 – Southfield, MI, Beacon Hill Medical Pharmacy d/b/a/ Rxtra Solutions (Beacon Hill) is voluntarily recalling all lots of certain sterile products to the user level. There is a question of sterility assurance for the affected products raised by the FDA.

Microbial contamination of products intended to be sterile can lead to serious infections, which may be life-threatening. Beacon Hill has not received any reports of adverse events related to this recall and to date, there is no evidence of contamination in the recalled products or any previously prepared products.

Below is the list of sterile injectable products compounded by Beacon Hill/Rxtra Solutions prescribed by physicians to individual patients according to their prescription order in alphabetical order, organized by Drug name and strength:

ACETYLCYSTEINE 100 MG/ML INJ SOLN	APOMORPHINE HCL 3 MG/ML INJECTABLE	ASCORBIC ACID (CORN SOURCE) 500 MG/ML INJECTABLE
ASCORBIC ACID (NON CORN SOURCE) 500 MG/ML INJECTABLE	B-12 REJUV 25 MG/ML INJECTABLE	B-12/LIDOCAINE 25/10MG/ML INJECTABLE
B-COMPLEX/LIDO/B-12 25MG/ML INJECTABLE	B-COMPLEX/LIDOCAINE 2% INJECTION INJECTABLE	BI-TROPIN S-2 INJECTABLE
BUPRENORPHINE 0.3 MG/ML INJECTABLE	BUPRENORPHINE 0.5 MG/ML INJECTABLE	CALCIUM CHLORIDE 100 MG/ML
CALCIUM EDTA 200 MG/ML INJECTABLE	CALCIUM EDTA 300 MG/ML INJECTABLE	CHROMIUM 4 MCG/ML INJECTABLE
COPPER 0.4MG/ML INJECTABLE	CYANOCOBALAMIN 1000 MCG/ML INJ SOLN	CYCLOSPORIN (A) 2% (PF) AQUEOUS SUSP
DEXAMETHASONE SODIUM PHOSPHATE 10 MG/ML INJECTABLE	DEXPANTHENOL 250 MG/ML INJECTABLE	DEXTROSE PF 50% INJECTABLE
DIAZEPAM 5MG/ML INJECTABLE	DMPS P/F 50 MG/ML INJECTABLE	DMSO 50% INJ 50 ML VIAL INJECTABLE
DUAL-TESTOSTERONE 10ML VIAL(COTTON SEED OIL) 200 MG/ML OIL INJ SOLN	DUAL-TESTOSTERONE 2 ML VIAL 20 MG/ML OIL INJ SOLN	DUAL-TESTOSTERONE 4 ML VIAL 50 MG/ML OIL INJ SOLN
DUAL-TESTOSTERONE 5 ML VIAL 50 MG/ML OIL INJ SOLN	EDETATE DISODIUM 150 MG/ML INJECTABLE	ESTRADIOL CYP/PROG/TEST CYP 0.5/10/10 MG/ML OIL INJ SOLN
OXYTOCIN 10 UNITS/ML INJECTABLE	ESTRIOL 5 MG/ML OIL INJ SOLN	AMINO ACID III (COMPARE TO FREAMINE III) ALT. 8.5% INJECTABLE

ARGININE 100MG/ML INJECTABLE		
FUROSEMIDE 10MG/ML INJECTABLE	GLUTATHIONE 200 MG/ML (PF) INJ SOLN	GLUTATHIONE/LIDO 100MG/2%/ML (PF) INJ SOLN
GLUTATHIONE/METHYL/LI DO 1 00/25/20 MG/ML INJ SOLN	GLUTATHIONE/METHYL/LI DO 100/25/20MG/ML (PF) INJ SOLN	GLYCINE 50 MG/ML INJECTABLE
GLYCYRRHIZIC ACID 8 MG/ML INJECTABLE	HYALURONIDASE 150U/ML INJECTABLE	HYALURONIDASE 200U/ML INJECTABLE
HYDROXOCOBALAMIN (VITAMIN B12A) 1 MG/ML INJECTABLE	L-CARNITINE HCL 50 MG/ML INJECTABLE	LIDOCAINE MDV 1% INJECTABLE
LIDOCAINE MDV 20 MG/ML INJECTABLE	LIDOCAINE PF 20 MG/ML INJECTABLE	LIPOIC ACID 100 MG/ML INJECTABLE
LIPOIC ACID 200 MG/ML INJECTABLE	LIPO-PLEX INJECTABLE	LIPO-PLEX/LIDOCAINE 2% INJECTABLE INJECTABLE
L-TRYPTOPHAN 300 MG/ML INJECTABLE	MAGNESIUM CHLORIDE HEXAHYDRATE 20% INJECTABLE	MAGNESIUM SULFATE 50% INJECTABLE
MANGANESE SULFATE 0.1 MG/ML INJECTABLE	MELOXICAM 10 MG/ML INJECTABLE	MELOXICAM 5MG/ML INJECTABLE
METHYLCOBALAMIN (PF) 1 MG/ML INJ SOLN	METHYLCOBALAMIN (PF) 25 MG/ML INJECTABLE	METHYLCOBALAMIN 1 MG/ML INJ SOLN
METHYLCOBALAMIN 10 MG/ML INJ SOLN	METHYLCOBALAMIN 25 MG/ML INJECTABLE	METHYLCOBALAMIN 5 MG/ML INJ SOLN
METHYLPREDNISOLONE ACETATE 40 MG/ML INJECTABLE	METHYLPREDNISOLONE ACETATE 80 MG/ML INJECTABLE	MIC-CARN + B6/B12/LIDOCAINE 25/50/50/175MCG/1/0.1MG/ ML INJECTABLE
MIC-CARN MAX (WITH METHYLCOBALAMIN) 15/100/50/1 MG/ML INJECTABLE	MIC-CARN MAX 15/100/50/1 MG/ML INJECTABLE	MIC-CARN MAX PLUS LIDOCAINE 15/100/50/1 MG/5MG/ML INJECTABLE
PHOSPHATIDYLCHOLINE 50 MG/ML INJECTABLE	POTASSIUM CHLORIDE 2 MEQ/ML INJECTABLE	PROCAINE P/F 20 MG/ML INJECTABLE
PROG/TEST CYP 15/7.5 MG/ML OIL INJ SOLN	PROGESTERONE 50 MG/ML OIL INJ SOLN	PUMICE/LIDOCAINE HCL 1.5%/1% INJ SUSP
PYRIDOXINE HCL P/F 100 MG/ML INJECTABLE	QUAD AMINO BLEND 150/75/150/75 MG/ML INJECTABLE	SELENIUM 400 MCG/ML INJECTABLE
SERMORELIN ACETATE 10	SERMORELIN ACETATE 3	SODIUM BICARBONATE

MG INJECTABLE	MG INJECTABLE	PF 8.4% INJECTABLE
TACROLIMUS SOLUTION 0.02% OPHTHALMIC	TEST. HYPOALLRGNC 200 MG/ML INJECTABLE	TESTOSTERONE AQUEOUS 100 MG/ML INJECTABLE
TESTOSTERONE CYPIONATE 10 ML VIAL 100 MG/ML OIL INJ SOLN	TESTOSTERONE CYPIONATE 2 ML VIAL 20 MG/ML INJECTABLE	TRIAMCINOLONE ACETONIDE 80 MG/ML INJ SUSP
TRI-MIX 10 MCG/30 MG/1 MG/ML INJ SOLN	TRI-MIX 30 MCG/15 MG/2 MG/ML INJ SOLN	TRIPLE-TESTOSTERONE 10 ML VIAL 250 MG/ML OIL INJ SOLN
TRIPLE-TESTOSTERONE 5 ML VIAL 200 MG/ML OIL INJ SOLN	TRIPTROPIN PLUS INJECTABLE	VITAMIN B- COMPLEX INJECTABLE
VITAMIN B-COMPLEX SL SOLTN	VITAMIN B-COMPLEX (PF) INJECTABLE	VITAMIN D 50,000 I.U./ML INJECTABLE
ESTRADIOL CYPIONATE 10 MG/ML OIL INJ SOLN	ESTRADIOL CYPIONATE 40 MG/ML OIL INJ SOLN	ESTRADIOL CYPIONATE 5 MG/ML OIL INJ SOLN
TRACE ELEMENTS-5 INJECTABLE	NALBUPHINE HCL 20MG/ML INJECTABLE	NANDROLONE DECANOATE 200 MG/ML OIL INJ SOLN
NANDROLONE DECANOATE 100 MG/ML OIL INJ SOLN	ALPROSTADIL 100 MCG/ML INJ SOLN	NALTREXONE 1 MG/ML INJECTABLE
NALTREXONE 200 MG/ML INJECTABLE	HYDROCHLORIC ACID 10% INJ SOLN	
ZINC SULFATE 1 MG/ML INJECTABLE	ALPROSTADIL 50 MCG/ML INJ SOLN	AMMONIUM MOLYBDATE 25 MCG/ML INJECTABLE
B12/E2/E3/PROG/TEST 1/3.75/2.5/50/45 MG/ML OIL INJ SOLUTION	BI-MIX PHENTOLAMINE/PAPAVERI NE 0.5 MG/30 MG/ML INJECTABLE	BI-MIX PHENTOLAMINE/PAPAVE RIN E 1 MG/30 MG/ML INJECTABLE
BUPRENORPHINE 0.1/0.05 MG/ML CREAM	DUAL-TESTOSTERONE 100 MG/ML OIL INJ SOLUTION	DUAL-TESTOSTERONE 150 MG/ML OIL INJ SOLUTION
DUAL-TESTOSTERONE 200 MG/ML OIL INJ SOLUTION	DUAL-TESTOSTERONE 50 MG/ML OIL INJ SOLUTION	ESTRADIOL VALERATE W/LIDOCAINE 1% 40MG/ML OIL INJ SOLN
GLUTAMINE 100 MG/ML INJ SOLN	H.C.G. (COMPOUNDED) 10,000 UNIT VIAL INJECTABLE	H.C.G. (COMPOUNDED) 11,000 UNIT VIAL INJECTABLE
H.C.G. (COMPOUNDED) 12,000 UNIT VIAL INJECTABLE	H.C.G. (COMPOUNDED) 5,000 UNIT VIAL INJECTABLE	H.C.G. (COMPOUNDED) 8,000 UNIT VIAL INJECTABLE

HYDROGEN PEROXIDE 3% INJECTABLE	HYDROCYPROGESTERONE CAPROATE 250 MG/ML OIL INJ SOLN	KETOROLAC TROMETHAMINE 60 MG/ML INJECTABLE
PARABEN WATER FOR INJECTION	SODIUM HYDROXIDE 10% (W/V) WATER FOR INJECTION	SODIUM PHOSPHATE DIBASIC/WATER FOR INJECTION 10%
SODIUM PHOPHATE MONOBASIC/WATER FOR INJECTION 10%	TESTOSTERONE CYPIONATE (COTTONSEED) 200 MG/ML OIL INJ SOLN	TESTOSTERONE PROPRIONATE 100 MG/ML OIL INJ SOLN

Physicians prescribe these products to patients receiving IV solutions and hormone replacement therapy.

These products are packaged in clear or amber sterile injectable vials ranging in size of 1 ml to 100 ml containing liquid solution, suspension or lyophilized powder. The products are packaged in either individual patient prescription vials or single units in a cardboard box container. The products can be identified via the label format, which will include lot numbers initiating with code 01012013@1 to 07262013@99. The vials will contain a label indicating the drug name, strength, and quantity of product in the vial, the lot number with the codes indicated above, and a recommended use by date, product ingredients, storage instructions and the facility information and address. A sample vial label and prescription label is attached that includes the exact format for all products dispensed. The products were distributed nationwide to outlets including hospitals, clinics, and patients who have received orders by directly placing phone calls or faxed prescriptions to the Beacon Hill Medical pharmacy facility in Southfield, Michigan.

Beacon Hill began notifying its customers on July 26th 2013 via telephone, and will begin initiating recall mailers including formal letters, and will continue to call its patients and providers, and schedule office visits to discuss with physicians further. Beacon Hill is arranging for **return** of all recalled products. Health care providers, hospital staff and patients should immediately check their inventory, identify products in their possession, which are being recalled, stop utilizing product and contact Beacon Hill Medical Pharmacy at 800.518.9831 to further assist with product replacement, continuity of care and further instructions on product return.

Beacon Hill recognizes FDA's observations of sterile practices and 211 guidelines and has already initiated its facility upgrade in an effort to deliver at the highest manufacturing standard. Beacon Hill has initiated testing on products in the recall in quarantine in an effort to assess its validation process of prior sterility practices and will continue to cooperate with the FDA to establish 211 guided standards of practice.

Beacon Hill is dedicated to this voluntary recall and has set up a task force of pharmacists and personnel ready to establish a transition for product replacement and urges patients to contact the pharmacy for any assistance.

Consumers with questions regarding this recall can contact Beacon Hill by calling 800.518.9831 during the business hours of 10 am and 6 pm eastern standard time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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.htm¹
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm². Mail to address on the pre-addressed form.
- **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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[RSS Feed for FDA Recalls Information](#)³ [[what's this?](#)⁴]

Photo: [Product Labels](#)⁵