

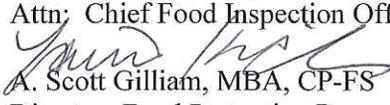


Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 28, 2013

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

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

SUBJECT: Wellness Pharmacy, Inc. Recall [Drug]

AFFECTED PRODUCT(S) Dexpanthenol 250 mg/ml Lot #130605@52 Exp. 12/02/2013
Magnesium Sulfate 50% Lot #130613@38 Exp. 12/10/2013
Methylcobalamin 1 mg/ml Lot #130612@49 Exp. 12/09/2013 & 10/19/2013
Sodium Phenybutyrate 200 mg/ml SDV PF Lot #130621@28 Exp. 10/19/2013
R.L. Glutathione 100 mg/ml SUV PF Lot #130710@27 Exp. 01/06/2014
Ascorbic Acid (cassava) 500 mg/ml PF SUV Lot #130711@13 Exp. 01/07/2014
Due to Lab Results Indicating Microbial Contamination

SUGGESTED

ACTION: Unclassified Recall; This recall was initiated after Wellness Pharmacy was notified that in a recent inspection of Front Range Labs, FDA investigators observed methods used by Front Range Labs to assess sterility and other qualities (e.g., strength and stability) may have resulted in Wellness Pharmacy receiving inaccurate sterility test results on these lots. FDA has concerns that test results obtained from Front Range Labs may not be reliable; Patients and physicians should immediately discontinue use of these lots of medications, and return the recalled unexpired medications to Wellness Pharmacy. Information is provided in case of a consumer inquiry.

From the information provided by FDA, the product being recalled was distributed to individual patients and to physician offices nationwide. To return medication or request assistance related to this recall, patients and physicians should contact Wellness Pharmacy at 205-879-6551 or 800-227-2627, Monday through Friday, between 9 a.m. and 4 p.m. CDT. In addition, if any recalled products are found, please notify this office at 317-233-3213.



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To promote and provide
essential public health services.

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.

Wellness Pharmacy, Inc. Issues Nationwide Voluntary Recall of Certain Sterile Products due to Laboratory Results Indicating Microbial Contamination

Contact

Consumer:
800-227-2627

FOR IMMEDIATE RELEASE - August 26, 2013 - Birmingham, AL – Wellness Pharmacy, Inc. is voluntarily recalling the following medications:

Product Name	Lot#	Expiry
Dexpanthenol 250mg/ml	130605@52	12/2/2013
Magnesium sulfate 50%	130613@38	12/10/2013
Methylcobalamin 1mg/ml	130612@49	12/9/2013 10/19/2013
Sodium Phenylbutyrate 200mg/ml SDV PF	130621@28	10/19/2013
R.L. Glutathione 100mg/ml SUV PF	130710@27	1/6/2014
Ascorbic acid (cassava) 500mg/ml PF SUV	130711@13	1/7/2014

This recall was initiated after Wellness Pharmacy was notified that in a recent inspection of Front Range Labs, FDA investigators observed methods used by Front Range Labs to assess sterility and other qualities (e.g., strength and stability) may have resulted in Wellness Pharmacy receiving inaccurate sterility test results on **these lots**. FDA has concerns that test results obtained from Front Range Labs may not be reliable.

If there is microbial contamination in medications intended to be sterile, patients are at risk of serious infections which may be life threatening. To date Wellness Pharmacy has not received **any** reports of adverse events related to this recall.

Recalled medications were distributed to individual patients and to physician offices nationwide. These liquid medications are in either clear or amber sterile vials ranging in size from 1ml to 50ml. The medications can be identified by the label on each vial, which will have the name of the drug, strength or concentration, lot number, use by date, and vial size.

Wellness Pharmacy is notifying its customers by telephone and regular mail of this recall. Patients

and physicians should immediately discontinue use of these lots of medications, and return the recalled unexpired medications to Wellness Pharmacy.

To return medication or request assistance related to this recall, patients and physicians should contact Wellness Pharmacy at 205-879-6551 or 800-227-2627, Monday through Friday, between 9 a.m. and 4 p.m. CDT.

Patients should contact their physician or health care provider if they have experienced any problems that may be related to taking these medications.

Adverse reactions experienced with the use of these medications 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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