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RURAL ROCKS

Newsletters

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4-15-2016

## April 2016

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### Recommended Citation

Curry, Randy and Brooks, Cindy, "April 2016" (2016). *RURAL ROCKS*. 2.  
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# SWOSU College of Pharmacy Rural Health Network

## RURAL ROCKS

RURAL ROCKS	
<p><b>RECALLS</b></p> <ul style="list-style-type: none"> <li>• 50% Magnesium Sulfate Injection, USP</li> <li>• Super Herbs Capsules, Weight Loss Dietary Supplement</li> <li>• Marketed as a dietary supplement</li> <li>• 5% Dextrose Injection USP</li> <li>• 8.4% Sodium Bicarbonate Injection, USP</li> <li>• Amikacin sulfate injection USP, 1 gram/4mL (250 mg/mL)</li> <li>• Fluconazole Injection, USP, (in 0.9% Sodium Chloride) 200mg per 100mL</li> </ul> <p><b>SHORTAGES</b></p> <ul style="list-style-type: none"> <li>• Numerous products</li> </ul> <p>FDA Drug Safety Communication:</p> <ul style="list-style-type: none"> <li>• FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin</li> </ul> <p>HIPAA update</p> <ul style="list-style-type: none"> <li>• Ready or Not, It's Time For Phase 2 HIPAA Audits</li> </ul> <p>INSURANCE</p> <ul style="list-style-type: none"> <li>• New Medicare Payment Model Aims To Improve Primary Care</li> <li>• Pharmacy Drug Pricing</li> </ul> <p>IMMUNIZATIONS</p> <ul style="list-style-type: none"> <li>• CDC Vaccine Price List</li> </ul> <p>HOSPITAL</p> <ul style="list-style-type: none"> <li>• Joint Commission Resources</li> </ul>	<p><b>UPDATES</b></p> <ul style="list-style-type: none"> <li>• CARDIOLOGY USPSTF: Update to Aspirin Use Guidelines</li> <li>• Depression May Compound Diabetes Risk (from consultant360)</li> <li>• New research investigates the association between depression and metabolic risk factors and the likelihood of developing type 2 diabetes</li> <li>• New Prostate Technique May Help Men's Nighttime Urination</li> </ul> <p><b>NEWS</b></p> <ul style="list-style-type: none"> <li>• For Consumers: Seven Things Pregnant Women and Parents Need to Know About Arsenic in Rice and Rice Cereal</li> <li>• Scientists Try to Stop Another Deadly Virus</li> <li>• Doctors Often Overestimate Promise of Newly Approved Drugs</li> <li>• Many misinterpret FDA 'breakthrough' designation, survey finds</li> <li>• 3 Findings on Colds You May Have Missed</li> <li>• Prediabetes May Damage Nerves More Than Thought</li> </ul>

**RECALLS**

- **Dexcom Inc. Recalls G4 Platinum and G5 Mobile Continuous Glucose Monitoring System Receivers Due to Audible Alarm Failure**

[http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm495448.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm495448.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery)

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|--|---|--|---|---|
| <ul style="list-style-type: none"> <li>• 04/13/2016</li> </ul> | <ul style="list-style-type: none"> <li>• <a href="#">Hospira</a></li> </ul>     | <ul style="list-style-type: none"> <li>• 50% Magnesium Sulfate Injection, USP</li> </ul>                 | <ul style="list-style-type: none"> <li>• Particulate Matter</li> </ul>  | <ul style="list-style-type: none"> <li>• Hospira, Inc.</li> </ul> |
| <ul style="list-style-type: none"> <li>• 04/11/2016</li> </ul> | <ul style="list-style-type: none"> <li>• <a href="#">Super Herbs</a></li> </ul> | <ul style="list-style-type: none"> <li>• Super Herbs Capsules, Weight Loss Dietary Supplement</li> </ul> | <ul style="list-style-type: none"> <li>• Unapproved new drug- FDA laboratory testing found SUPER HERBS to contain sibutramine, desmethylsibutramine, and/or phenolphthalein.</li> </ul> | <ul style="list-style-type: none"> <li>• Super Herbs</li> </ul>   |

- 04/05/2016 • [Continuum Labs](#) • Marketed as a dietary supplement • Contains Ligandrol • INVISIBLU International LLC
- 03/28/2016 • [B. Braun Medical Inc.](#) • 5% Dextrose Injection USP • Leakage and visible particulate matter (microbial growth) • B. Braun Medical Inc.
- 03/18/2016 • [Hospira](#) • 8.4% Sodium Bicarbonate Injection, USP • Presence of particulate matter • Hospira Inc.
- 03/09/2016 • [Teva Pharmaceuticals](#) • Amikacin sulfate injection USP, 1 gram/4mL (250 mg/mL) • Due to the potential presence of particulate matter identified as glass in one vial • Teva Pharmaceuticals
- 03/01/2016 • [Sagent Pharmaceuticals, Inc.](#) • Fluconazole Injection, USP, (in 0.9% Sodium Chloride) 200mg per 100mL

- SHORTAGES

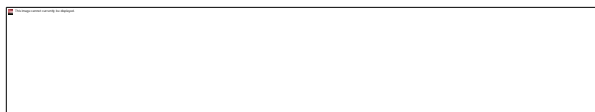
- April 07, 2016
- [Theophylline Extended Release Tablets and Capsules](#) (*Currently in Shortage*)
- April 05, 2016
- [Theophylline Extended Release Tablets and Capsules](#) (*Currently in Shortage*)
- March 17, 2016
- [Rivastigmine Tartrate Capsules](#) (*Discontinuation*)
- March 11, 2016
- [Didanosine Delayed-Release Capsules USP](#) (*Discontinuation*)
- [Telithromycin \(Ketek\) Tablets](#) (*Discontinuation*)
- March 04, 2016
- [Enoxaparin Sodium Injection](#) (*Discontinuation*)
- Updated
- April 13, 2016
- [Piperacillin and Tazobactam \(Zosyn\) Injection](#) (*Currently in Shortage*)
- April 11, 2016
- [Calcium Gluconate Injection](#) (*Currently in Shortage*)
- [Cefepime Injection](#) (*Currently in Shortage*)
- [Cefotetan Disodium Injection](#) (*Currently in Shortage*)
- [Imipenem and Cilastatin for Injection, USP](#) (*Currently in Shortage*)
- [Lidocaine Hydrochloride \(Xylocaine\) Injection](#) (*Currently in Shortage*)
- [Methylprednisolone Sodium Succinate for Injection, USP](#) (*Currently in Shortage*)
- [Potassium Chloride Injection](#) (*Currently in Shortage*)
- [Sodium Chloride 23.4% Injection](#) (*Currently in Shortage*)
- [Theophylline Extended Release Tablets and Capsules](#) (*Currently in Shortage*)

- [Tigecycline \(Tygacil\) Injection](#) (Currently in Shortage)
- [Tiopronin \(Thiola\)](#) (Resolved)
- [Tobramycin Injection](#) (Currently in Shortage)
- [Vancomycin Hydrochloride for Injection, USP](#) (Currently in Shortage)
- April 07, 2016
- [Chloroquine Phosphate Tablets](#) (Resolved)
- [Potassium Acetate Injection, USP](#) (Currently in Shortage)
- April 05, 2016
- [Dexamethasone Sodium Phosphate Injection](#) (Currently in Shortage)
- [Fentanyl Citrate \(Sublimaze\) Injection](#) (Currently in Shortage)
- [Meropenem for Injection, USP](#) (Resolved)
- [Sufentanil Citrate \(Sufenta\) Injection](#) (Currently in Shortage)
- April 04, 2016
- [Atropine Sulfate Injection](#) (Currently in Shortage)
- [Calcium Chloride Injection, USP](#) (Currently in Shortage)
- [Doxorubicin \(Adriamycin\) Injection](#) (Currently in Shortage)
- [Fentanyl Citrate \(Sublimaze\) Injection](#) (Currently in Shortage)
- [Imipenem and Cilastatin for Injection, USP](#) (Currently in Shortage)
- [Lidocaine Hydrochloride \(Xylocaine\) Injection](#) (Currently in Shortage)
- [Multi-Vitamin Infusion \(Adult and Pediatric\)](#) (Currently in Shortage)
- [Piperacillin and Tazobactam \(Zosyn\) Injection](#) (Currently in Shortage)
- [Sodium Bicarbonate Injection, USP](#) (Currently in Shortage)
- [Sodium Chloride 23.4% Injection](#) (Currently in Shortage)
- [Tobramycin Injection](#) (Currently in Shortage)
- [Vancomycin Hydrochloride for Injection, USP](#) (Currently in Shortage)

FDA Drug Safety Communication:

**FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin**

- o <http://www.fda.gov/Drugs/DrugSafety/ucm486096.htm>



<http://hmpemail.net/blaster/display.php?M=1816169&C=650bc7500c0804127d80187cd978ea9e&S=5899&L=243&N=6097>

#### **FDA ACTIVITY**

- **FDA Approves Biosimilar of Johnson and Johnson's Blockbuster Drug Remicade**
- The FDA has approved Inflectra (infliximab-dyyb, Celltrion Inc) for the treatment of multiple conditions, including rheumatoid arthritis and inflammatory bowel disease.

#### **• FDA APPROVALS**

- **FDA Approves Venclexta for Patients With Chronic Lymphocytic Leukemia With 17p Deletion**
- The FDA has approved Venclexta (venetoclax, AbbVie Inc) for the treatment of chronic lymphocytic leukemia in patients with a chromosomal abnormality called 17p deletion who have been previously treated with at least one therapy.
- **FDA ACTIVITY**
- **FDA Expands Use of Metformin to Include Patients With Renal Impairment**
- Metformin-containing medications can be used in certain patients with diabetes who have mild-to-moderate kidney dysfunction.

## HIPAA update

- **Ready or Not, It's Time For Phase 2 HIPAA Audits**
  - o <http://www.jdsupra.com/legalnews/ready-or-not-it-s-time-for-phase-2-78715/>
- **\$1.55 million settlement underscores the importance of executing HIPAA business associate agreements**
  - o <http://www.hhs.gov/about/news/2016/03/16/155-million-settlement-underscores-importance-executing-hipaa-business-associate-agreements.html>

## INSURANCE

- **New Medicare Payment Model Aims To Improve Primary Care**
  - o <http://www.consultant360.com/exclusives/new-medicare-payment-model-aims-improve-primary-care>
- **Pharmacy Drug Pricing**
  - o <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Pharmacy-Pricing.html>

## UPDATES

- **CARDIOLOGY USPSTF: Update to Aspirin Use Guidelines**
  - o <http://www.consultant360.com/exclusives/uspstf-update-aspirin-use-guidelines>
- **Depression May Compound Diabetes Risk** (from consultant360)
  - o New research investigates the association between depression and metabolic risk factors and the likelihood of developing type 2 diabetes
  - o <http://www.consultant360.com/topic/mental-health>
- **New Prostate Technique May Help Men's Nighttime Urination**

- o [https://www.nlm.nih.gov/medlineplus/news/fullstory\\_158125.html](https://www.nlm.nih.gov/medlineplus/news/fullstory_158125.html)

## IMMUNIZATIONS



- <http://www.immunize.org/express/issue1241.asp>
- **CDC Vaccine Price List**
  - o <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>
- **Zika fears escalate: Virus is scarier than previously thought, CDC says**
  - o [http://www.fiercehealthcare.com/story/zika-fears-escalate-virus-scarier-previous-thought-cdc-says/2016-04-14?utm\\_medium=nl&utm\\_source=internal&mkt\\_tok=eyJpIjoiTjJKak5XUTNOBU5rTmtpsaCIsInQiOiJtcuVub0l6K05HSFVJQXFYejY5aWh4ZzVhSldNQ0psbWRnaHNkXC94T3RKdlNzaUluMXVEaUZXSkkpMXBCQkxtQ11DVVR2dm5MREkrTnBTTWNEUThnOTIxR2NtT0pKeVN6WVpuUzU3MUNpRUU9In0%3D](http://www.fiercehealthcare.com/story/zika-fears-escalate-virus-scarier-previous-thought-cdc-says/2016-04-14?utm_medium=nl&utm_source=internal&mkt_tok=eyJpIjoiTjJKak5XUTNOBU5rTmtpsaCIsInQiOiJtcuVub0l6K05HSFVJQXFYejY5aWh4ZzVhSldNQ0psbWRnaHNkXC94T3RKdlNzaUluMXVEaUZXSkkpMXBCQkxtQ11DVVR2dm5MREkrTnBTTWNEUThnOTIxR2NtT0pKeVN6WVpuUzU3MUNpRUU9In0%3D)

## HOSPITAL

- **Joint Commission Resources**
- **Patient safety**
- April 13, 2016
- **New Quick Safety focuses on implicit bias**
  - o [http://www.jointcommission.org/issues/article.aspx?Article=TjgKCr9s%2b3VowCidQsb%2bE4yZbhTavTj%2fu0vzpKVtAHk%3d&j=2869101&e=randygc2011@yahoo.com&l=94\\_HTML&u=77598806&mid=1064717&jb=63](http://www.jointcommission.org/issues/article.aspx?Article=TjgKCr9s%2b3VowCidQsb%2bE4yZbhTavTj%2fu0vzpKVtAHk%3d&j=2869101&e=randygc2011@yahoo.com&l=94_HTML&u=77598806&mid=1064717&jb=63)
- **Upcoming events to help better understand Joint Commission requirements**
- Several events are coming up in mid-May to help health care organizations with accreditation. All of the events will be held at the Westin Lombard, 70 Yorktown Shopping Center, in Lombard, Illinois:
- **Hospital Accreditation Essentials:** May 16-17. This interactive, solutions-based seminar is designed to provide health care professionals with implementation tips for using Joint Commission hospital requirements.
- **Maximizing Hospital Tracer Activities:** May 18. This single-day event is for hospital professionals seeking an advanced workshop that includes the latest information on tracers, as well as recommendations and strategies that can be implemented at their organizations.
- **Home Care Accreditation Essentials:** May 19-20. This is a strategy-based seminar aimed at helping organizations with The Joint Commission's home care requirements.

## NEWS

- **For Consumers: Seven Things Pregnant Women and Parents Need to Know About Arsenic in Rice and Rice Cereal**

- o <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm493677.htm#1>

- **Scientists Try to Stop Another Deadly Virus**

- o [https://www.nlm.nih.gov/medlineplus/news/fullstory\\_158128.html](https://www.nlm.nih.gov/medlineplus/news/fullstory_158128.html)

- **Doctors Often Overestimate Promise of Newly Approved Drugs**

- o Many misinterpret FDA 'breakthrough' designation, survey finds
- o [https://www.nlm.nih.gov/medlineplus/news/fullstory\\_158267.html](https://www.nlm.nih.gov/medlineplus/news/fullstory_158267.html)

- **3 Findings on Colds You May Have Missed**

- o [http://www.pharmacytimes.com/resource-centers/cough-cold/3-findings-on-colds-you-may-have-missed?utm\\_source=Informz&utm\\_medium=Pharmacy+Times&utm\\_campaign=PT\\_eNews\\_Daily\\_Nasacort\\_4-5-16](http://www.pharmacytimes.com/resource-centers/cough-cold/3-findings-on-colds-you-may-have-missed?utm_source=Informz&utm_medium=Pharmacy+Times&utm_campaign=PT_eNews_Daily_Nasacort_4-5-16)

- **Prediabetes May Damage Nerves More Than Thought**

- o Early pain and tingling in hands, feet may be 'canary in the coal mine,' researchers say
- o [https://www.nlm.nih.gov/medlineplus/news/fullstory\\_158274.html](https://www.nlm.nih.gov/medlineplus/news/fullstory_158274.html)

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- o [Spanish regulators suspend Inmunotek's manufacturing license and order recall](#)
- o By [Gareth MacDonald](#), 13-Apr-2016
- o Inmunotek has been ordered to recall vaccines made at a facility in Madrid after Spanish regulators identified a number of GMP deficiencies.
- o <http://www.in-pharmatechnologist.com/Regulatory-Safety/Spanish-regulators-suspend-Inmunotek-s-manufacturing-license-and-order-recall>

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- o [Pill attaches to GI tract lining for slow release](#)
- o By Melissa Fassbender, 11-Apr-2016
- o Researchers have developed a new tablet that attaches to the lining of the GI tract and slowly releases medication.
- o <http://www.in-pharmatechnologist.com/Drug-Delivery/Pill-attaches-to-GI-tract-lining-for-slow-release>

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- o [Oasmia looking to license Vitamin A-derived drug delivery tech](#)
- o By [Dan Stanton+](#), 12-Apr-2016
- o Oasmia Pharmaceutical has announced clinical results for its XR17 nanotechnology it says validates the excipient as a potential drug delivery system.
- o <http://www.in-pharmatechnologist.com/Drug-Delivery/Oasmia-looking-to-license-Vitamin-A-derived-drug-delivery-tech>