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RURAL ROCKS

Newsletters

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June 2016

Southwestern Oklahoma State University

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*The SWOSU College of Pharmacy Rural Health Network,
with the Southwestern Pharmacy Foundation Continuing Education Department,
will be offering an Oklahoma State Board of Pharmacy-Approved*

Immunization Training Program

on Saturday, July 16

on SWOSU campus in Weatherford, Oklahoma.

Early Registration is due by July 1.

***Class size is limited,
so be sure to register early.***

Here is the link

to the brochure with more details including the Registration Form:

<http://www.southwesternpharmacy.com/docs/ProgramBrochure.pdf>

For more program information,

please contact Immunization Training Program Coordinator,

Randy Curry (randy.curry@swosu.edu or 580-774-3760).

Note: see attachment on SWOSU College of Pharmacy Panama Medical Mission Trip (check Facebooks for more pictures.)

RECALLS


- Hummingbird Med Devices Inc. Recalls Hummi Micro-Draw Blood Transfer Device Due to Potential for Parts to Disconnect
 - http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm503689.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery








- FDA Drug Safety Communication: FDA warns about rare but serious skin reactions with mental health drug olanzapine (Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbyax)
 - http://www.fda.gov/Drugs/DrugSafety/ucm499441.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
 - http://reference.medscape.com/features/slideshow/guidelines-review/2016/may?src=wnl_drugguide_160509_mscpref&uac=4045DY&impID=1087868&faf=1#page=2

- **FDA Panel Backs Approval of Sanofi Combination Diabetes Drug**
 - <http://www.firstreportnow.com/articles/us-panel-backs-approval-sanofi-combination-diabetes-drug>
- **Hummingbird Med Devices Inc. Recalls Hummi Micro-Draw Blood Transfer Device Due to Potential for Parts to Disconnect**
 - http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm503689.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Human Drug Product Recalls Pending Classification

- <http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm310739.htm>

 <p>Auvi-Q (epinephrine injection, USP) Auto-Injector, 0.3 mg (a) 2 prefilled auto injectors + 1 trainer (NDC 0025-5833-02) and (b) 1 prefilled auto injector + 1 trainer (NDC 0024-5833-00), Rx Only, Manufactured for Sanofi-Aventis US, LLC Bridgewater, NJ 08807 A Sanofi Company</p>	<p>Class I</p>	<p>a) 2081278, 2113841, 2113842, 2144138, exp 10/2015; 2440675, exp 04/2016; 2506456, 2506460, 2546946, 2546947, exp 05/2016; 2620206, 2620207, 2659534, exp 06/2016; 2692111, 2692112, exp 07/2016; 2716517, 2719817, 2734079, 2734080, 2734081, 2778035, 2800128, exp 08/2016; 2800130, 2824828, 2824829, 2857516, 2867928, 2870928,</p>	<p>Defective Delivery System; potential to have inaccurate dosage delivery</p>	<p>Sanofi-Aventis U.S. LLC 55 Corporate Dr Bridgewater, NJ 08807-1265</p>
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 Drugs  view details	Auvi-Q (epinephrine injection, USP) Auto-Injector, 0.15 mg (a) 2 prefilled auto injectors + 1 trainer (NDC 0024-5831-02) and (b) 1 prefilled auto injector + 1 trainer (NDC 0024-5831-00), Rx Only, Manufactured for Sanofi-Aventis US, LLC Bridgewater, NJ 08807 A Sanofi Company	Class	2867929, 2867930, 2883616, 2883617, exp 09/2016; 2883618, 2883619, 2974267, 2883620, more... a) 2144144, exp 10/2015; 2469674, exp 04/2016; 2506492, 2546978, 2546979, exp 05/2016; 2654817, 2654818, exp 06/2016; 2692143, 2692144, exp 07/2016; 2719838, exp 08/2016; 2824845, 2891021, 2857530, exp 09/2016; 2883631, 2883632, exp 10/2016; 2883633, 2945429, 3028243, exp 11/2016; 3037230, 2966680, 2974276, 2974280, exp 12/2016; and b) 2525474, exp 05/2016	Defective Delivery System; potential to have inaccurate dosage delivery	Sanofi-Aventis U.S. LLC 55 Corporate Dr Bridgewater, NJ 08807-1265
 Drugs  view details	LIPO ESCULTURA capsules, 250 mg, 60-count bottles, Distributed By: JAT Productos Naturales Corp., BROOKLYN, NY 11238, www.lipoesculturatreatment.com	Class	All lots	Marketed Without An Approved NDA/ANDA: Tainted product marketed as a dietary supplement. Product found to be tainted with sibutramine, an appetite suppressant that was withdrawn from the U.S. market in October 2010 for safety reasons, and diclofenac, a prescription non-steroidal anti-inflammatory drug, making this an unapproved drug.	Lipo Escultura Corp. 888 Wyckoff Ave Brooklyn, NY 11237-6116
 Drugs  view details	Pink Bikini capsules, (all colors and all strengths), packaged in 30-count bottle, Manufactured and Distributed by: Lucy's Weight Loss System (dba Waisted With Lucy), Arlington, TX 76010	Class	All lots, all colors and all strengths	Marketed without an approved NDA/ANDA: Product contains undeclared Sibutramine, Phenolphthalein and/or Diclofenac.	Lucy's Weight Loss (dba. Waisted With Lucy) 813 Oram St Arlington, TX 76010-2837
 Drugs	Black Ant, packaged in Big Box (20 small boxes / 4 capsules per box / 80 capsules total), Distributed by: R	Class	all lots	Marketed Without An Approved NDA/ANDA	R Thomas Marketing, LLC 3704 White



Thomas Marketing, LLC, Bronx, NY
10467

Plains Rd
Bronx, NY
10467-5710



Black Ant, packaged in Big Box (20
small boxes / 4 capsules per box / 80
capsules total), Distributed by: R
Thomas Marketing, LLC, Bronx, NY
10467

Class
I all lots

Marketed Without An Approved
NDA/ANDA

R Thomas
Marketing, LLC
3704 White
Plains Rd
Bronx, NY
10467-5710



Real Skill, packaged in 20 small boxes
/ 4 capsules per box / 80 capsules
total, Distributed by: R Thomas
Marketing, LLC, Bronx, NY 10467

SHORTAGES

June 02, 2016

- [Lindane Lotion, USP 1%](#) (*Discontinuation*)

May 24, 2016

- [Terbinafine \(Lamisil\) Oral Granules](#) (*Discontinuation*)

May 10, 2016

- [Cyclosporine Capsules](#) (*Discontinuation*)
- [Imipenem and Cilastatin for Injection, USP](#) (*Discontinuation*)

April 26, 2016

- [Fluphenazine Tablets](#) (*Discontinuation*)

April 07, 2016

- [Theophylline Extended Release Tablets and Capsules](#) (*Currently in Shortage*)

Updated

June 01, 2016

- [Cefepime Injection](#) (*Currently in Shortage*)
- [Fentanyl Citrate \(Sublimaze\) Injection](#) (*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*)

May 27, 2016

- [Tigecycline \(Tygacil\) Injection](#) (*Currently in Shortage*)

May 26, 2016

- [Methylprednisolone Sodium Succinate for Injection, USP](#) (*Currently in Shortage*)

May 25, 2016

- [Cefepime Injection](#) (*Currently in Shortage*)

May 24, 2016

- [Doxorubicin \(Adriamycin\) 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*)
- [Piperacillin and Tazobactam \(Zosyn\) Injection](#) (*Currently in Shortage*)
- [Potassium Chloride Injection](#) (*Currently in Shortage*)
- [Sodium Chloride 0.9% Injection Bags](#) (*Currently in Shortage*)
- [Sodium Chloride 23.4% Injection](#) (*Currently in Shortage*)
- [THAM Solution \(Tromethamine Injection\)](#) (*Discontinuation*)
- [Vancomycin Hydrochloride for Injection, USP](#) (*Currently in Shortage*)

HIPAA

- OCR Releases New HIPAA Audit Protocol and Other Audit-Related Materials
 - <https://www.healthlawpolicymatters.com/2016/04/20/hhs-office-for-civil-rights-releases-new-hipaa-audit-protocol/>

PHARMACIST ED & PATIENT SAFETY

- Clues to How Popular Heartburn Drug Might Harm Arteries
 - https://www.nlm.nih.gov/medlineplus/news/fullstory_158754.html
- New Guidelines Recommend Prophylaxis, Antiretroviral Medications in HIV-Exposed Persons
 - <http://www.firstreportnow.com/articles/New-Guidelines-Recommend-Prophylaxis-Antiretroviral-Medications-HIV-Exposed-Persons>

IMMUNIZATIONS



- <http://www.immunize.org/express/issue1245.asp>
- **[Vaccines & Immunizations](#)**
 - <http://www.cdc.gov/vaccines/index.html>

INSURANCE



- [Cortisporin Otic](#) (May 11, 2016)
- [Aggrenox](#) (May 4, 2016)
- [Migranal/DHE 45](#) (May 4, 2016)
- [Noxafil/Cresamba](#) (April 13, 2016)
- [Nuelasta/Granix/Zarxio](#) (March 15, 2016)
- [APAP/IBU/Compounded Medications](#) (March 6, 2016)
- [Tetracycline/Fluoroquinolone](#) Update (March 2, 2016)

HOSPITAL

- Active Shooter Preparedness for Healthcare:
- Maturing Your Plans and Procedures
 - http://go.everbridge.com/active-shooter-preparedness-healthcare-maturing-your-plans-and-procedures.html?trk=FH_AS2_JUNE&mkt_tok=eyJpIjoiWmpnMU9XWXpaV013TVdJNCIsInQiOiJZRW1ZTENCMklhVk5FSWFmbXVlb010ODViM21CVmZaeFhjN3JOaW5tVUhUNHJsSVhqOFA0aXlsc3ZlVHBUR0RybzB1YW9ZYjRHY2p4byt6cEVhMWE2ZVRqWTg1MGtZZW1jSmpPaml3bzhlMD0ifQ%3D%3D
-

FDA approval alert:

- **Mylan launches first 200-mg Doryx generic**
 - http://www.drugstorenews.com/article/mylan-launches-first-00-mg-doryx-generic?tp=i-H55-Q5U-lm-ZSvM-1v-wGU-1c-Bi1-ZR8j-29Lz59&utm_campaign=Generics&utm_source=Experian&utm_medium=email&cid=2962&mid=8452668
- **FDA approves Aurobindo's Tricor generic**
 - http://www.drugstorenews.com/article/fda-approves-aurobindos-tricor-generic?tp=i-H55-Q5U-lm-ZSvM-1v-wGU-1c-Bi3-ZR8j-dNiQq&utm_campaign=Generics&utm_source=Experian&utm_medium=email&cid=2962&mid=8452668
- ISMP news
 - <http://www.ismp.org/newsletters/acutecare/issues/20160602.pdf>

NEWS

- **Do I need to worry about my teen getting hooked on Imodium?**
 - <http://www.univadis.com/viewarticle/do-i-need-to-worry-about-my-teen-getting-hooked-on-imodium-402909>
- **Hard' Tap Water Linked to Eczema in Babies**
 - Skin condition seems more likely in areas with high mineral content in water, study finds
 - https://www.nlm.nih.gov/medlineplus/news/fullstory_159150.html
- **FDA Calls for Less Salt in Processed Foods**
 - Agency sets short- and long-term goals in effort to cut Americans' risk of high blood pressure, heart disease, stroke
 - https://www.nlm.nih.gov/medlineplus/news/fullstory_159136.html
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- [Concealed compliance info lands ex-Ranbaxy owners \\$385m costs](http://www.in-pharmatechnologist.com/Regulatory-Safety/Concealed-compliance-info-lands-ex-Ranbaxy-owners-385m-costs)
- By [Dan Stanton+](#), 10-May-2016
- The former owners of Indian drugmaker Ranbaxy have been ordered to pay Daiichi Sankyo \$385m for concealing quality problems across its manufacturing network before selling the business.

<http://www.in-pharmatechnologist.com/Regulatory-Safety/Concealed-compliance-info-lands-ex-Ranbaxy-owners-385m-costs>