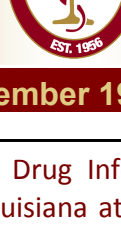


FYDI

FOR YOUR DRUG INFORMATION



November 19, 2013

ULM COLLEGE OF PHARMACY

Drug Information Center



PharmD Candidates: Margaret Broussard, Hai Bui, An Nguyen and Chuong Nguyen; Gregory W. Smith, PharmD, Director
Drug Information Services
318.342.5501
druginfo@ulm.edu

Greetings from the Drug Information Center at the University of Louisiana at Monroe College of Pharmacy!

We hope you find this newsletter helpful in staying well-informed.

Please contact us and let us assist you with any drug information needs, such as full-text article retrieval. In this issue, find out more about the services the DIC has to offer.

In this issue...

FDA MedWatch and Other Safety Alerts
News Items
Drug Approvals
New Guidelines

FDA MedWatch and Other Safety Alerts

Access to full-text articles may require subscription. Contact the Drug Information Center for literature retrieval assistance.

Nature's Pharmacy and Compounding Center Products: Recalled

Nature's Pharmacy and Compounding Center of Asheville, NC is voluntarily recalling all lots of sterile products compounded by the pharmacy that are not expired.
[View Alert](#)

Over-the-Counter Topical Antiseptics: Drug Safety Communication

FDA is requesting changes made to labeling and packaging to increase safe use of certain over-the-counter topical antiseptic products.
[View Alert](#)

Vega Shakes and Protein Products Recalled

Certain Vega products containing trace amounts of Chloramphenicol are being recalled due to the possibility of causing severe hypersensitivity reactions in people with allergies to chloramphenicol.
[View Alert](#)

OxyElite Pro Recalled

The recalled products contained aegeline, a new dietary ingredient that lacks a history of use or evidence of safety.
[View Alert](#)

Low Molecular Weight Heparins: Drug Safety Communication

The FDA gives new recommendations for patients on anticoagulants for dosing, timing of spinal catheter placement and removal in order to decrease risk of spinal column bleeding and paralysis.
[View Alert](#)

Perrigo Acetaminophen Infant Suspension Recalled

Some recalled packaging may include oral syringe without dose markings, which can result in inaccurate dosing.
[View Alert](#)

MedStream Programmable Infusion Pump and Refill Kits: Class 1 Recall

Codman and Shurtieff, Inc. notifies health professionals of Class 1 recall on MedStream Programmable Pump and Refill Kits.
[View Alert](#)

Hospira's Lidocaine and Marcaine Recalled

Hospira voluntarily recalls user-level lot of 0.25% Marcaine injection due to discoloration and particulate matter found inside vials.
[View Alert](#)

Compounding Pharmacy Recalls Human and Veterinary Products

Specialty Medicine Compounding Pharmacy recalls all lots of unexpired medications due to particulates found in vials of compounded dextrose injections.
[View Alert](#)

Albuterol Inhalation Solution 0.083% Recalled

Nephron Pharmaceuticals recalls ten lots of the product as a precaution to aseptic process monitoring.
[View Alert](#)

Cefepime for Injection USP and Dextrose Injection USP Recalled

B. Braun Medical Inc. voluntarily recalls 1g Cefepime for Injection USP and Dextrose Injection USP due to organic particulate in a reserve sample unit.
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FDA Issues Drug Safety Concern: Inclisig (Ponatinib)

FDA issues a warning regarding drug safety for Inclisig (Ponatinib) due to reports of serious adverse effects after administration of medication.
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FDA Notification: Perfect Body Solution and Burn 7

FDA advises consumers not to purchase Perfect Body Solutions and Burn 7 due to the product containing a controlled substance, Sibutramine.
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FDA Notification: Dr. Mao Slimming Capsules

FDA advises consumers not to purchase Dr. Mao Slimming Capsules due to the product containing a controlled substance, Sibutramine.
[View Alert](#)

FDA Notification: Be Inspired

FDA advises consumers not to purchase or use the product Be Inspired due to the presence of the controlled substance, Sibutramine.
[View Alert](#)

FDA Notification: Bella Vi Insane Amp'd And Bella Vi Amp'd Up

FDA advises consumers not to purchase or use Bella Vi Insane and Bella Vi Amp'd Up due to the products containing the controlled substance, Sibutramine.
[View Alert](#)

Dietary Supplements: Slim Fortune, Lidy, and Slim Expert Recalled

B@B Trade, Inc. is voluntarily recalling all lots of Slim Fortune, Lidy, and Slim Expert because the products contain the controlled substance, Sibutramine.
[View Alert](#)

Metoclopramide and Ondansetron Injection Recalled Due

Hospira, Inc. voluntarily recalls lot of Metoclopramide and Ondansetron injections due to glass particulate contamination.
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[Back to Top](#)

News Items

FDA Grants Special Status to GW Pharmaceuticals' Drug for Rare Epileptic Disorder

FDA gave Epidiolex the orphan drug designation for Dravet syndrome.
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FDA Approves Medical Device to Treat Epilepsy

The RNS Stimulator consists of a small neurostimulator implanted in the skull under the scalp to help reduce the frequency of seizures in epilepsy patients who have not responded well to medications.
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New Guidelines Could Increase Statin Use

Recommendations from new guidelines could result in as many as 70 million people on statin therapy.
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Novel Drug May Work in Hyperkalemia

An inorganic cation exchanger agent selectively traps potassium ions, making the novel drug a candidate for treating hyperkalemia in patients with chronic kidney disease.
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U.S. Preventive Services Task Force Finds Evidence Lacking for Supplement Use

According to the USPSTF, there is not enough evidence regarding the use of vitamin and mineral supplementation in primary prevention of cardiovascular disease or cancer.
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Novel Drug to Reduce LDL Cholesterol

A new approach using RNA interference to inhibit the synthesis of PCSK9 in the liver may contribute to lowering LDL cholesterol levels.
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Medical Qigong: Alternative for Pain

Medical Qigong, a branch of traditional Chinese medicine, is an alternative when traditional medical pain treatments have failed.
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Tamsulosin for BPH Associated with Severe Hypotension Risk

Tamsulosin for BPH has a doubled risk for severe hypotension when used for BPH symptoms, according to a U.S. insurance claims database.
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Head-to-head HIV Study Showing HeDolutegravir Regimen is Superior to Efavirenz Regimen

A study showed that dolutegravir plus abacavir-lamivudine had a better safety profile and more effective through 48 weeks than efavirenz-tenofovir DF-emtricitabine.
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Epilepsy Drug Potential in Alcohol Dependence Treatment

The results of a clinical trial suggest that gabapentin is beneficial in treating alcohol dependence when compared to placebo.
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FDA Moves to Reduce Trans Fats in Processed Foods

The FDA announces preliminary determination that partially hydrogenated oils are not "generally recognized as safe" for use in food.
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Three-Drug Combo Effectively Treats HCV Infection

Efficacy in treating HCV has been demonstrated with an investigational three-drug oral combination that avoids the use of both interferon and ribavirin.
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OTCs Now Eligible FSA Expenses

New legislation repeals the portion of Obamacare that prohibits participants from using their flexible spending account funds to buy OTC medications.
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Janssen Pharm to Plead Guilty For Misleading Marketing

The U.S. Department of Justice entered a guilty plea agreement with Janssen Pharmaceuticals, Inc to pay over \$1.6 billion over misleading marketing messages for its schizophrenia drug Risperdal.
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Qsymia for Weight Loss

In a 28 week study funded by VIVUS, overweight people who took the diet drug Qsymia (phentermine/topiramate) were shown to lose more weight than those on a placebo or either drug alone.
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Stem-Cell Recipients on Statin Reduces GVHD

A small study showed that stem-cell transplant recipients had low rates of acute graft-versus-host disease when taking prophylactic atorvastatin.
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New Inhaled Phosphodiesterase Inhibitor Looks Promising For Asthma and COPD

A series of preliminary studies shows that an inhaled dual phosphodiesterase inhibitor, inhibiting phosphodiesterases 3 and 4, is promising against asthma and chronic obstructive pulmonary disease.
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FDA to Tighten Schedule of Hydrocodone Rx

The FDA will send its formal recommendation to the Department of Health and Human Services to tighten the restrictions on hydrocodone combination drugs such as Vicodin by early December.
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Contaminated Steroid Injections Causes a Spectrum of Ailments

Patients made sick by contaminated steroid shots were found to have illnesses varying in severity from strokes to abscesses.
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Pancreatic Cancer Life Extension with Chemo Combo

Results of a phase III trial showed that a combination of Abiraxane and Gemzar significantly improved survival in patients with metastatic pancreatic cancer.
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Nasacort Cleared for OTC Sale

Sanofi announced that triamcinolone acetonide (Nasacort AQ) should be expected to be available OTC by spring 2014.
[View Item](#)

HIV Vaccine Candidate Fails to Protect

A placebo-controlled clinical trial of the latest vaccine ended early due to temporary results showing that the drug would probably not work.
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New Treatment Option for Parkinson's Psychosis

Pimavanserin is shown to be beneficial in alleviating symptoms of psychosis in patients with Parkinson's disease.
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[Back to Top](#)

Drug Approvals

FDA Approves Luiconazole

A one-week antifungal drug, Luzu (luiconazole) 1% cream, was FDA approved for the treatment of athlete's foot, jock itch, and ringworm in adults.
[View Letter](#)
[View Label](#)

FDA Approves Imbruvica

Imbruvica (brutinib) approved for use to treat patients with mantle cell lymphoma, a rare and aggressive type of blood cancer.
[View Approval](#)

FDA Approves Aptiom

Aptiom (eslicarbazepine acetate) was approved as an add-on medication to treat seizures associated with epilepsy.
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FDA Approves Gazyva

The FDA approved obinutuzumab for use together with chlorambucil to treat patients with previously untreated chronic lymphocytic leukemia (CLL).
[View Approval](#)

FDA Approves Opsumit

The FDA has approved macitentan (Opsumit, Actelion) for the treatment of pulmonary arterial hypertension in adults.
[View Approval](#)

Novovight FDA Approved

Turoctogog alpha (Novovight) is a recombinant coagulation factor VIII recently FDA approved for patients with hemophilia A.
[View Approval](#)

Adempas FDA Approved

Adempas (Riociguat) was FDA approved to treat adults with pulmonary hypertension.
[View Approval](#)

Duavee FDA Approved

Duavee (Conjugated Estrogens/Bazedoxifene) has been FDA approved for women who suffer from moderate-to-severe hot flashes associated with menopause and to prevent osteoporosis after menopause.
[View Approval](#)

[Back to Top](#)

New Guidelines

Primary Care Guidelines for the Management of Persons Infected with HIV: 2013 Update from the HIV Medicine Association IDSA

Guidelines focusing on the preventative care for common health problems as patients with HIV live longer.
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2013 AHA/ACC Guidelines on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults

Changes in appropriate use of statins in patients at risk cause movement away from hard treatment targets of ATPIII Guidelines.
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2013 AHA/ACC Guidelines on Lifestyle Management to Reduce Cardiovascular Risk

The new guidelines focus on healthy dietary habits for lifestyle management.
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2013 AHA/ACC Guideline for the Management of Overweight and Obesity in Adults

This update addresses five critical questions on managing overweight and obesity in adults.
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2013 AHA/ACC Guideline on the Assessment of Cardiovascular Risk

The guidelines called for a change in approach to assessing cardiovascular risk with a new equation for cardiovascular risk estimation.
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BSR Guidelines on Psoriatic Arthritis

The British Society of Rheumatology published Psoriatic Guidelines for Treatment with Biologics.
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Pediatric HIV Guidelines Updated

The new guidelines include the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children from the Department of Health and Human Services.
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CDC: Provisional Guideline for Multidrug-Resistant TB

FDA-approved bedaquiline is included in the new guideline as part of a combination therapy for adults with pulmonary multi-drug-resistant TB.
[View Guideline](#)

2013 ACCF/AHA Guideline for the Management of Heart Failure

The update to the guidelines refreshed concepts for recommendations in managing heart failure.
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EAU Guidelines on Primary Urethral Carcinoma

The European Association of Urology has released guidelines on the diagnosis and treatment of patients with primary urethral carcinoma.
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[Back to Top](#)



ULM COLLEGE OF PHARMACY

Drug Information Center

318-342-5501

[Online Requests](#)



The Louisiana Drug Information Pharmacy (DIC), which became operational in 1995, is located on the first floor of the College of Pharmacy (COP) Bienville Building of the University of Louisiana at Monroe (ULM). The operation objectives of the DIC are centered around the three core components of the University mission of service, teaching and scholarship, with a primary focus on service. These objectives are as follows:

- ◆ To provide current, comprehensive, objective and need-specific information to the healthcare professional community of the State of Louisiana for clinical decision making and for the delivery of quality patient care.
- ◆ To serve as an information resource center for faculty, students, and healthcare providers of efficient.
- ◆ To teach pharmacy students, pharmacists, and other healthcare providers the skills of literature retrieval, critical evaluation of the information, and accurate communication of a response.
- ◆ To conduct research for the advancement of drug information and pharmacy practice.

The service component makes up the largest portion of the DIC operation and includes providing assistance with areas such as literature retrieval, evidence-based recommendations and off-label use of medications. We respond to drug information requests from healthcare professionals regarding the following areas:

- Adverse Drug Events
- Availability of Products
- Complementary and Alternative Medicine
- Clinical Kinetics
- Drug Dosage and Scheduling
- Drug Identification
- Drug Interactions
- Drug Regulations/Laws
- Drug Use Evaluation Support
- Institutional Review Board Support
- Investigational/Foreign Drugs
- IV Compatibility
- Laboratory Interpretation
- Pharmacoeconomics
- Pharmacy and Therapeutics Committee Support
- Pregnancy and Lactation
- Product Compounding
- Therapeutic Drug Monitoring
- Therapeutic Uses/Drugs of Choice
- Toxicology
- Travel/Health Information

The DIC has a new phone number and provides information services exclusively to the healthcare professionals of the State of Louisiana. Additionally, this service is available to Medicaid providers through support from the Louisiana Medicaid Pharmacy Benefits Management Program.

Please contact us and let us assist you with any drug information needs at our new number for **Healthcare Professionals Drug Information Service: 318-342-5501**

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[Back to Top](#)

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[Drug Information Center](#)

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For comments and suggestions please email druginfo@ulm.edu.

Disclaimer: No information source can replace clinical judgment applied to a specific case. Some of the drug product we write about will be outside the labeled indications for specific products. References will be provided when possible. Consult these references, therapy labeling, and/or give us a call if we can help with specific cases. This newsletter is supported by the University of Louisiana at Monroe College of Pharmacy and is not intended for commercial promotion.