FYDI

FOR YOUR DRUG INFORMATION

May 6, 2013

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.

ULM
COLLEGE OF PHARMACY
Drug Information Center

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In this issue…

FDA MedWatch and Other Safety Alerts

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

Valproate Products Contraindication for Pregnant Women
The FDA is advising of a contraindication based on evidence of decreased IQ scores in children of mothers who have taken anti-seizure medications valproate sodium and related products, valproic acid and divalproex sodium for prevention of migraine headaches.
View Alert

Kadcyla (ado-trastuzumab emtansine): Name Confusion Could Lead to Errors
The FDA has issued a Drug Safety Communication to notify that the incorrect nonproprietary name for Kadcyla (ado-trastuzumab emtansine) may appear in some electronic systems, which could potentially lead to medication errors.
View Alert

Labeling Issue Leads to Urgent Product Recall by Fenwal
Fenwal has issued a voluntary urgent recall on one lot of anticoagulant citrate phosphate dextrose solution, USP BLOOD-PACK unit with incorrect labeling.
View Alert

Piperacillin/Tazobactam for Injection Recalled
Fifteen lots of Piperacillin/Tazobactam for Inj., USP 40.5 grams, were recalled due to precipitation/ crystallization in IV bag or IV line after reconstitution.
View Alert

Samsca (tolvaptan): FDA Limits Use Due to Possible Liver Injury
The FDA has limited the duration and usage of the drug due to evidence suggesting possible severe adverse effects possibly leading to liver transplant or death.
View Alert

FDA Warns of Adverse Effects Linked to Anti-Seizure Medication
Potiga (Ezogabine) has been linked to pigment changes of the retina and blue skin discoloration.
View Alert

Multivitamin Supplement Recalled Due to Contamination
Saratoga Therapeutics LLC recalled 900 bottles of ebA Multivitamin Supplement due to undeclared milk components, though the label lists the product as free of milk components.
View Alert

Recall of One Touch Verio IQ Blood Glucose Meter
The Veria IQ meter has been discovered to turn off, rather than display high glucose warning when readings are greater than or equal to 1024 mg/dL.
View Alert

Sterility Assurance Concerns Leads to Recall of Nora Apothecary Products
Nora Apothecary & Alternative Therapies issued a recall on all compounded sterile compounded drug products due to concerns with quality control processes.
View Alert

Recall of Balanced Solutions Sterile Compounded Products
Concerns with quality control have resulted in recall on all lots of sterile products compounded by the pharmacy.
View Alert

Sterility Assurance Concerns Results in Recall of NuVision Pharmacy Products
NuVision Pharmacy is recalling all compounded lyophilized products containing HcG and Sermorelin/GHRH6.
View Alert

Sterility Assurance Concerns Results in Recall of ApotheCure Products
All sterile products compounded by ApotheCure, Inc. have been recalled due to sterility concerns.
View Alert

Quality Control Concerns Results in Recall of Green Valley Drugs Products
All Green Valley Drugs sterile products have been recalled due to concerns of quality control.
View Alert

Recall of Affirm XL, Dietary Supplement
The dietary supplement marketed for sexual enhancement contained an undeclared ingredient, a sildenafil analogue.
View Alert

Undeclared Ingredient Leads to Male Enhancement Product Recall
A product recall has been issued due to the presence of hydroxythiohomosildenafil, a sildenafil analogue, in ROCK-It MAN Male Enhancement Capsules marketed by Consumer Concepts, Inc.
View Alert

Recall of Insulin Infusion Pump
A false alarm or warning sound may prompt consumer to "rewind, load, and prime," which could potentially result in dose-related hypoglycemia.
View Alert

Recall of Intravenous Immune Globulin
Visible particles have been observed in BIVIGAM (immune globulin injection).
View Alert

Recall of Hospira's Sodium Chloride Injection, Flexible Container
Brass particulates have been identified in the primary container.
View Alert

Recall of Pallimed Solutions, Inc. Sterile Compound Products
All Pallimed Pharmacy sterile compound products dispensed since Jan. 1, 2013 are being recalled due to visible particulates.
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News Items

FDA Lowers Age for Plan B Access to 15 Years
The FDA approves Plan B One-Step without prescription for women 15 years of age and older.
View Item

Proposal for Greater FDA Regulation Over Compounding Practices
The proposal would clarify FDA authority over "high-risk compounding" in order to improve protections for patients using these products.
View Item

FDA Rejects New Drug for Migraine
Levadex (dihydroergotamine) was denied FDA approval due to manufacturing concerns.
View Item

SSRI Therapy Around Time of Surgery Tied to Increased Complications
Selective Serotonin Reuptake Inhibitor (SSRI) use may increase surgery-associated risks, according to a recent study.
View Item

Effective Treatment for Distal Subungual Onychomycosis
Two separate trials show effectiveness of topical efinaconazole treatment for toenail fungal infection and slightly more than one-half of the subjects achieved mycological cure.
View Item

National Shortage of Tuberculin Skin Test
The CDC has issued recommendations for addressing the tuberculin skin test antigen shortage.
View Item

HIV Vaccine Study Halted by Investigators
An HIV vaccine trial was halted due of lack of efficacy and an increased risk of HIV infections among those who received the vaccine.
View Item

Valproate Therapy During Pregnancy Linked to Autism
A 10 year study in Denmark showed increased risk of childhood autism in babies born to mothers on valproate therapy.
View Item

Dutasteride Associated With Slower Progression of BPH
A post hoc analysis of the REDUCE study evaluated the possible benefit of treating asymptomatic or mildly symptomatic men with benign prostatic hypertrophy (BPH).
View Item

OxyContin Label Updated
The new labeling contains a warning that the product has physical and chemical properties that are intended to make abuse via injection difficult and decrease abuse via the intranasal route (snorting).
View Item

Multiple Sclerosis Drug Possibly Beneficial in Stroke Patients
A study found that the multiple sclerosis drug, Acorda, might also help stroke patients with impaired motor function.
View Item

Staphylococcus Aureus Vaccine Trial Terminated Due to Poor Clinical Outcomes
Subjects that received the vaccine had more infections and higher mortality than those that did not receive the vaccine.
View Item
View Article Abstract

ACE Inhibitor and Beta-Blocker for Cardiotoxicity Prevention in Chemotherapy
In the OVERCOME trial, enalapril and carvedilol may prevent left ventricular systolic dysfunction related to treatment with intensive chemotherapy.
View Item

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Drug Approvals

Procysbi (Cysteamine Bitartrate) Approved for Nephropathic Cystinosis
Procysbi has been granted orphan drug status for the treatment of cystinosis, a rare genetic disease that affects approximately 500 individuals in the United States and 3,000 persons worldwide.
View Item

Kcentra Approved for Urgent Reversal of Vitamin K Antagonist Anticoagulation
The prothrombin complex is the first drug approved for urgent reversal of the effects of vitamin K antagonist anticoagulation.
View Item

Amitiza (Lubiprostone) for Opioid-Induced Constipation
Sucampo and Takeda Pharmaceuticals introduce Amitiza for patients who suffer from opioid-induced constipation.
View Item

Simbrinza (Brinzolamide and Brimonidine) Approved for Glaucoma
Simbrinza is the first fixed-dose combination therapy available for glaucoma in the United States that does not include a beta-blocker.
View Item

New Higher Strength, Delayed-Release Dosage Form for Doryx (Doxycycline) Approved
Warner Chilcott has gained approval to add a 200 mg delayed-release formulation to the 75-mg, 100-mg and 150-mg strengths already available.
View Item

FDA Approves Quartette – Oral Contraceptive
Quartette (levonorgestrel/ethinyl estradiol and ethinyl estradiol) is approved as an ascending-dose, extended regimen oral contraceptive.
View Item

FDA Approves Sitavig
Sitavig (acyclovir) buccal tablet is indicated for the treatment of recurrent herpes labialis in immunocompetent adults.
View Item

FDA Approves Diclegis
Diclegis (doxylamine succinate and pyridoxine hydrochloride) has been approved for nausea and vomiting in pregnant women.
View Item

FDA Approves Invokana for Type-2 Diabetes
A first-in-class sodium-glucose co-transporter-2 inhibitor, Invokana (canagliflozin), has been approved for the treatment of Type 2 Diabetes.
View Item

Tecfidera (dimethyl fumarate) Approved for Relapsing Forms of Multiple Sclerosis
Tecfidera capsules reduce the number of relapses for patients with multiple sclerosis.
View Item

FDA Approves First Heptavalent Botulism Antitoxin
The antitoxin neutralizes all seven known botulinum nerve toxin serotypes and will be stored in the Strategic National Stockpile for emergency preparedness.
View Item

TOBI Podhaler for Cystic Fibrosis Therapy Approved
TOBI (tobramycin inhalation powder) Podhaler broadens the available delivery mechanism options for cystic fibrosis patients needing treatment for *Pseudomonas aeruginosa*.
View Item

Dotarem (Gadoterate Meglumine) MRI Agent Approved
A new magnetic resonance imaging agent, Dotarem has been approved to help radiologists identify CNS abnormalities.
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New Guidelines

Updated Recommendation for HIV Screening
U.S. Preventive Services Task Force (USPSTF) recommends screening adolescents and adults aged 15 to 65 years for HIV.
View Guideline

New Diabetes Algorithm: American Association Of Clinical Endocrinologists
The new guidelines address prediabetes, glycemic control, diabetes medication management, weight management therapies, and cardiovascular risk reduction.
View Guideline

Prostate Cancer Screening Guidelines Reviewed
The guidance statement from the American College of Physicians advises of limited potential benefits and substantial harms in prostate cancer screening.
View Guideline

Guidelines Released for Parenchymal Neurocysticercosis
The American Academy of Neurology guideline includes the recommended use of albendazole and a steroid for the treatment of neurocysticercosis.
View Guideline

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ULM COLLEGE OF PHARMACY Drug Information Center

318-342-5501
Online Requests

The Louisiana Drug Information Center (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 professionals.
- To teach pharmacy students, pharmacists, and other healthcare providers the skills of efficient 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
Complimentary 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**
Online Requests

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