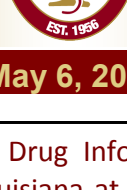


# FYDI

FOR YOUR DRUG INFORMATION



May 6, 2013

## ULM COLLEGE OF PHARMACY Drug Information Center



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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.**

##### 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.

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##### 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.

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##### 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-PAACK unit with incorrect labeling.

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##### 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.

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##### 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.

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##### 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.

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##### 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.

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##### Recall of One Touch Verio IQ Blood Glucose Meter

The VERA 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.

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##### 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.

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##### 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.

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##### Sterility Assurance Concerns Results in Recall of NuVision Pharmacy Products

NuVision Pharmacy is recalling all compounded lyophilized products containing HcG and Sermorelin/GHRH6.

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##### Sterility Assurance Concerns Results in Recall of ApotheCure Products

All sterile products compounded by ApotheCure, Inc. have been recalled due to sterility concerns.

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##### 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.

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##### Recall of Affirm XL, Dietary Supplement

The dietary supplement marketed for sexual enhancement contained an undeclared ingredient, a sildenafil analogue.

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##### 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.

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##### 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.

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##### Recall of Intravenous Immune Globulin

Visible particles have been observed in BIVIGAM (immune globulin injection).

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##### Recall of Hospira's Sodium Chloride Injection, Flexible Container

Brass particulates have been identified in the primary container.

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##### 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.

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##### 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.

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##### FDA Rejects New Drug for Migraine

Levadox (dihydroergotamine) was denied FDA approval due to manufacturing concerns.

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##### 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.

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##### 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.

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##### National Shortage of Tuberculin Skin Test

The CDC has issued recommendations for addressing the tuberculin skin test antigen shortage.

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##### 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.

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##### 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.

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##### 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).

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##### 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).

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##### 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.

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##### 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.

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##### 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.

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#### Drug Approvals

##### Procybsi (Cysteamine Bitartrate) Approved for Nephropathic Cystinosis

Procybsi 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.

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##### 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.

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##### Amitiza (Lubiprostone) for Opioid-Induced Constipation

Sucampo and Takeda Pharmaceuticals introduce Amitiza for patients who suffer from opioid-induced constipation.

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##### 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.

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##### New Warner Chilcott has Gained Approval to Add a 200 mg 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.

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##### FDA Approves Quartette – Oral Contraceptive

Quartette (levonorgestrel/ethinyl estradiol and ethinyl estradiol) is approved as an ascending-dose, extended regimen oral contraceptive.

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##### FDA Approves Sitavig

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

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##### FDA Approves Diclegis

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

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##### 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.

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##### Tecfidera (dimethyl fumarate) Approved for Relapsing Forms of Multiple Sclerosis

Tecfidera capsules reduce the number of relapses for patients with multiple sclerosis.

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##### 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.

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##### 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*.

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##### Dotarem (Gadotericate 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.

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##### 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.

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##### 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.

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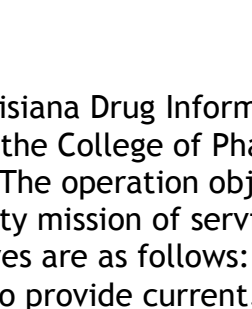
##### Guidelines Released for Parenchymal Neurocysticercosis

The American Academy of Neurology guideline includes the recommended use of albendazole and a steroid for the treatment of neurocysticercosis.

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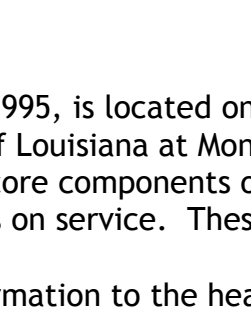
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## ULM COLLEGE OF PHARMACY Drug Information Center

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
- 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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For comments and suggestions please email [druginfo@ulm.edu](mailto:druginfo@ulm.edu).

Disclaimer: No information source can replace clinical judgment applied to a specific case. Some of the drug therapy we write about will be outside the labeled indications for specific products. References will be provided when possible. Consult these references, product 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.