December 2008

Kentucky Board of Pharmacy

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Spindletop Administration Building
2624 Research Park Dr, Suite 302
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Happy Holidays!!!!
From the
Kentucky Board of Pharmacy
Board Members and Staff

Continuing Education Reminder

A pharmacist shall complete a minimum of one and five-tenths (1.5) CEUs (15 contact hours) annually between **January 1 and December 31** pursuant to 201 KAR 2:015 Section 5(1). A pharmacist first licensed by the Kentucky Board of Pharmacy within twelve (12) months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

2009 Pharmacist Renewals

Pharmacist licenses expire on February 28, 2009. The Board will send out a **postcard** the first week of January 2009 as a reminder (in addition, a pharmacist that renewed online last year will be sent a reminder via e-mail). Again this year you may renew your license online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's Web site:** *www.pharmacy.ky.gov.*

2009 Pharmacy Technician Registration

Effective April 1, 2009, a person assisting in the practice of pharmacy shall be registered with the Board as a pharmacy technician. The Board office is currently developing the registration process, which will be available after the first of the year. A pharmacy technician will be able to register online, and this registration will expire on March 31, 2010. The Board will notify pharmacists and pharmacies via e-mail, mail, the Web site, and through pharmacy associations of the exact date registration will begin.

New Board Members

Larry A. Hadley and Joel C. Thornbury were appointed by Governor Steven L. Beshear to the Kentucky Board of Pharmacy. These appointments shall be effective January 2, 2009, and their terms will expire on January 1, 2013.

New Board of Pharmacy Employee

On September 16, 2008, Bryan M. Proctor started as an administrative specialist I with the Board of Pharmacy. Bryan has previously worked in a community chain and independent pharmacy and with the Kentucky Department of Agriculture.

Rule Requires 1-800 Number for Pharmacies by July 1, 2009

The Food and Drug Administration (FDA) Amendments Act of 2007 (Public Law 110-85) directed the Secretary of Health and Human Services to implement a 2004 proposed rule regarding adverse event reporting. The rule requires **pharmacies** and other authorized dispensers to distribute the 1-800 number "side-effects statement" to consumers with prescription medications and over-the-counter products that do not already list the manufacturer's contact information. Side-effects statement means the following verbatim statement: "Call your doctor for medical advice about side-effects. You may report side-effects to FDA at 1-800-FDA-1088." The side-effects statement must be distributed with new and refill prescriptions. **Pharmacists** and other authorized dispensers may distribute the side-effects statement in one of five ways:

1. distribute the side-effects statement on a sticker attached to the unit package, vial, or container of the drug product;
2. distribute the side-effects statement on a preprinted pharmacy prescription vial cap;
3. distribute the side-effects statement on a separate sheet of paper;
4. distribute the side-effects statement in consumer medication information; or
5. distribute the appropriate FDA-approved Medication Guide that contains the side-effects statement.

Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

Testing Medication Names Prior to Marketing

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with USP and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!®*** ***Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper (*www.fda.gov/cder/drug/MedErrors/meeting_names.pdf*) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of

errors and potential errors caused by look-and sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc®, has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to *www.med-errs.com* and click on "Become a Reviewer."

Coalition Looks to Pharmacies, Regulators to Reduce Diversion

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain statewide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

FDA Encourages Pharmacists to Use Patient Safety News

FDA Patient Safety News is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at *www.fda.gov/psn* or by sending an e-mail to PSNews@cdrh.fda.gov.

Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair® HFA Inhalation Aerosol, Proventil® HFA Inhalation Aerosol, and Ventolin® HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex® HFA Inhalation Aerosol. More information is available on the FDA Web site at *www.fda.gov/cder/mdi/albuterol.htm*.

Do You Drink Too Much?

Submitted by Brian Fingerson, RPh, Chair, Pharmacist Recovery Network Committee

The one or two glasses of wine you drink at the occasional meal when you dine out are no big deal, but what about the standard two glasses of wine you have with every dinner? Could this love of Chardonnay mean that you drink too much? Many people wonder whether or not their drinking habits are over the top. To find out if your drinking habits are out of control, answer these questions honestly in this brief quiz sometimes called the CAGE test:

1. Have you ever felt you should **C**ut down on your drinking?
2. Have people **A**nnoyed you by criticizing your drinking?
3. Have you ever felt bad or **G**uilty about your drinking?
4. Have you ever had a drink first thing in the morning to steady your nerves or get over a hangover (**E**ye opener)?

The holidays are an especially stressful time in the lives of many people, especially with the current economic climate. This may be a time for you to take a look at your use of alcohol or other mood-altering substances. For help you may call Brian Fingerson with the Kentucky Professionals Recovery Network at 502/749-8385 or by e-mail at kyprn@insightbb.com.

2009 CAPTASA Conference

The 2009 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 23-24, 2009, at the Embassy Suites in Lexington, KY. For information on this conference please visit *www.CAPTASA.org* or contact Sandy Patrick at sandy@captasa.org or 502/425-7761.

Contact Number of State Boards and Federal Agencies

Board of Dentistry	502/429-7280(o)
	502/429-7282(fax)
Board of Medical Licensure	502/429-7150(o)
	502/429-7158(fax)
Board of Nursing	502/429-3300(o)
	502/429-3311(fax)
Board of Optometric Examiners	859/246-2744(o)
	859/246-2746(fax)
Board of Respiratory Care	859/246-2747(o)
	859/246-2750(fax)
Office of Drug Enforcement	502/564-7985(o)
	502/696-3880(fax)
FDA (Cincinnati)	513/684-3501(o)
DEA (Louisville)	502/582-5905(o)

For more information on these and other state agencies please visit *www.ky.gov*, click on Government, and then click on State Agency List.

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