September 2006

# Kentucky Board of Pharmacy

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Spindletop Administration Building
2624 Research Park Dr, Suite 302
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## Drug Manufacturer and Wholesaler Renewal Deadline September 30, 2006

Drug manufacturer and wholesaler permits expire on September 30, 2006. A drug manufacturer or wholesaler may renew and pay the fee online. Renewal applications will not be mailed out; however, a renewal form may be printed from the Kentucky Board of Pharmacy's Web site at www.pharmacy.ky.gov. If you have any questions concerning the renewal process please contact the Board office. A drug manufacturer or wholesaler application with only a United States Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is September 30, 2006.

## Board Meeting Date Change

The October 11, 2006 Board meeting has been changed to October 20, 2006. The meeting will be held at the Louisville Marriott Downtown in Louisville, KY. The meeting will begin at 10 AM. As a reminder these dates and any changes are available on the Board's Web site.

## Board Retreat 2006

The Board will be hosting a Board retreat on Saturday and Sunday, October 21-22, 2006, at the Louisville Marriott Downtown in Louisville, KY. The following are some of the agenda items: (1) wholesaler rules/pedigree legislation; (2) central fill/refill legislation; and (3) sterile compounding (United States Pharmacopeia Chapter 797). If you have a suggested item for the agenda, please forward it to the Board office, or if you have questions please contact the Board office. All pharmacists and individuals are invited to attend.

## ARNP Correction on Prescriptive Authority

In the June 2006 Board of Pharmacy *Newsletter* it was reported that an advanced registered nurse practitioner (ARNP) could prescribe controlled substances (CS) for Schedule IV and V as a 30-day supply with up to six (6) months refills. **However, an ARNP may prescribe CS for Schedule IV or V, which shall be limited to the original prescription and refills not to exceed a six (6) month supply**. If you have any questions, please contact the Board office at your convenience.

## Pseudoephedrine Update

Effective September 30, 2006, (pursuant to federal law) **all** pseudoephedrine products must be placed behind the pharmacy counter or locked up. Also, the time of the transaction must be included with the date on the pseudoephedrine log.

## Kentucky Medicaid News Updates

To receive e-mail updates regarding Kentucky Medicaid pharmacy topics, sign up at http://kentucky.fhsc.com/pharmacy/default.asp. Go to the "Providers" tab to register. Automatic electronic updates will allow you to be among the first to know about changes and the introduction of new policies and programs. With today's evolving health care system, there has never been a better time to be informed.

## Did You Know . . .

*Submitted by Brian Fingerson, RPh*

Kentucky Revised Statute (KRS) 315.125(1): When the Board has probable cause to believe a pharmacist, certificate holder, or permit holder is suffering from a mental or physical condition that might impede that person's ability to practice competently, the Board may order the individual to undergo a mental or physical examination by an appropriately trained professional designated by the Board.

**and**

KRS 315.126(1): The Board shall establish a Pharmacist Recovery Network [PRN] Committee to promote early identification, intervention, treatment, and rehabilitation of pharmacists and pharmacist interns who may be impaired by reason of illness, alcohol or drug abuse, or as a result of any other physical or mental condition.

The PRN Committee does not only help those who have drug or alcohol problems. If you or anyone you know would be in need of help for any condition that may impede an ability to practice, please call me before something happens that may harm someone. Help is available by contacting Brian Fingerson, RPh, at 502/749-8385 or via e-mail at kyprn@insightbb.com.

## New Board Members

**W. Michael Leake** was appointed to the Board effective January 1, 2006, by Governor Ernie Fletcher. The appointment shall be effective through January 1, 2010. Mr Leake is a 1973 graduate of the Mercer University Southern School of Pharmacy. Mr Leake has owned and operated pharmacies since 1973. He currently owns Louisville Pharmacy in Louisville, KY.

Mr Leake is a member of the Kentucky Pharmacists Association (KPhA) (past president), International Academy of Compounding Pharmacists (past president), International Academy of Compounding Pharmacists Foundation, National Community

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## Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex® tablets, who recently released Zanaflex Capsules™ (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune® (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL® (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

## Preventing Errors Linked to Name Confusion

*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (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, then publishes its recommendations. 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: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.

- When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

## Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006, for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.deadiversion.usdoj.gov/meth/cma2005.htm.

## Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

(a) Each partial filling is recorded in the same manner as a refilling,
(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

## Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

## Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

*Continued from page 1*

Pharmacists Association, American College of Apothecaries, American Pharmacists Association (APhA), and the Jefferson County Academy of Pharmacy. He is an adjunct professor for the University of Kentucky (UK) College of Pharmacy where he was also a member of the Task Force on Long Range Curriculum Planning. He is a former chairperson of the Technical Advisory Committee on Drugs for the Kentucky Department for Medicaid Services.

He and his wife, Vicki, reside in Danville, KY. They have two children, Samantha and Spencer.

**Dr Catherine L. Shely** was appointed to the Board of Pharmacy effective January 1, 2006, by Governor Ernie Fletcher. The appointment shall be effective until January 1, 2010. Dr Shely is a graduate of the UK College of Pharmacy where she received a bachelor of science degree in 1977 and a doctor of pharmacy degree in 1980. She has been employed at St Claire Medical Center in Morehead, KY, in various positions ranging from a staff pharmacist to clinical pharmacist to coordinator of outreach pharmacy and has been director of pharmacy since 1997. She is also the director for an American Society of Health-Systems Pharmacists (ASHP) accredited Pharmacy Practice Residency Program.

Dr Shely has been most active in a number of pharmacy organizations serving in various appointed and elected positions. Presently, she is a member of the Advisory Board to the Ashland Technical College Pharmacy Technician Program and the Advisory Board for the Northeast Kentucky Area Health Education Center. She is a member of APhA, ASHP, KPhA, Kentucky Society of Health-System Pharmacists, and was the president for three different terms for the Cave Run Pharmacists Association. At the present time she is the program chair for the Gateway Pharmacists Association.

Dr Shely is married to Bill Shely, also a graduate of the UK College of Pharmacy and the owner of Cave Run Pharmacy. They have served as preceptors in the College's experiential program for 20 years. They have two grown children, Ashley, who is a veterinary student at Auburn University, and Ryan, who is a pre-engineering student at Georgetown University.

**Sandra M. "Sandy" Simpson** was appointed to the Board of Pharmacy effective April 4, 2006, by Governor Ernie Fletcher as a consumer member. The appointment shall be effective until January 1, 2010. Mrs Simpson is a graduate of Tompkinsville High School and later attended Bowling Green Business College and Western Kentucky University.

Mrs Simpson is a field representative for US Congressman Ed Whitfield (R-KY) and has been assisting constituents and local officials in the first district for 12 years. She was previously employed at Kentucky Farm Bureau Insurance Agency (Monroe County) and for 16 years prior to that she was a legal secretary for the Monroe County Attorney.

She and her husband, Benny, reside on a small farm in Tompkinsville, KY. Benny is an agent for Kentucky Farm Bureau Insurance and an avid golfer. They have two grown children, Whitney and Haley, and two shih-tzus, Fudge and Cheney.

## *Official Method of Notification*

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read carefully. The Board encourages you to keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.



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