

August 2006



Missouri Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

PO Box 625, Jefferson City, MO 65102

Correction From May Newsletter

An error occurred in providing the dates of time that continuing education (CE) needs to be accrued within. The correct dates for acquiring CE for the purpose of renewing a license for the period running 2006 to 2008 is September 1, 2004, to **August 31, 2006**.

Executive Director Retires

Kevin E. Kinkade, RPh, retired as of July 1, 2006. He had been employed by the Missouri Board of Pharmacy for over 22 years and served as executive director for the entire period. During a reception held June 20, 2006, in his honor, Kevin was presented framed proclamations/resolutions from Governor Matt Blunt, Missouri Senate, Missouri House of Representatives, National Association of Boards of Pharmacy®, and the Task Force on the Use, Misuse, and Abuse of Prescription Drugs, each noting his years of dedicated service as a state employee and to the profession of pharmacy. The Board is seeking applicants for the executive director position; the job announcement is posted on its Web site at www.pr.mo.gov/pharmacists.asp.

Board of Pharmacy Licensing Statistics

The Board currently licenses/registers a total of 25,056 individuals and businesses. This is an increase of 2,010 compared to the 2005 report. The following provides a breakdown for each category of license/registration. The number in parenthesis reflects the amount of increase/decrease observed from last year:

Drug Distributor License (Temporary/Permanent)	1,172 (-59)
Drug Distributor Registrations (Out-of-state Manufacturers)	92 (-8)
Pharmacists (Active = 7,464; Inactive = 241)	7,705 (+279)
Pharmacies	1,763 (-21)
Interns	1,136 (+206)
Technicians	13,188 (+1,613)

Gold Certificates

The following pharmacists will receive gold certificates in honor of maintaining a license with the Board for 50 years. Each gold certificate is signed by the Board members, executive director, and Governor Matt Blunt and is accompanied with a letter of congratulations from the Board. Congratulations to those who have served the public for 50 years as a licensed pharmacist.

- Fayette S. Baker – Webb City, MO
- Gilbert D. Bell – Pleasant Hill, MO

- Jack D. Devine – Metamora, IL
- David L. Dove – St Clair, MO
- James W. Frederich – Parkville, MO
- Patricia L. Groh – Smithville, MO
- Wallace W. Johnson – Kansas City, MO
- Bernard R. Letassy – Poplar Bluff, MO
- Robert L. Little – Arnold, MO
- James F. McCalpin – Brentwood, MO
- Earl S. Meyer – Glenview, IL
- Steve S. Oslica – Chesterfield, MO
- Sanford M. Palans – Chesterfield, MO
- Edward Rosen – Kansas City, MO
- Richard Silberg – Leawood, KS
- Donald G. Stogsdill – Henderson, NV
- Gerald Twitchell – St Louis, MO
- Kenneth J. Unnerstall – Cape Girardeau, MO
- Robert L. Wolf – Raymore, MO

E-mail Addresses

Renewal notices will contain an area for each pharmacist to provide their personal e-mail address so that a new database can be created. This database will be used to send out communications from the Board office to all pharmacists licensed by the Board. Eventually, the *Newsletter* will be sent out in this fashion but for now, once the addresses can be added into the new database, it will be used to increase communication by the office to licensees on issues considered important where the use of e-mail would be the quickest and most appropriate way of sending out information. Anything from alerts; information from Food and Drug Administration, Drug Enforcement Administration, and Bureau of Narcotics and Dangerous Drugs; actions taken by the Board; or upcoming issues or events of importance could be subjects that would be sent via e-mail.

Internet Solicitations to Pharmacies

Board staff has been fielding more questions about the legality of pharmacies acting as fulfillment centers for Internet businesses that are attempting to provide prescription drugs to consumers. Pharmacists who may consider accepting prescriptions from these businesses need to exercise due diligence by fully researching how and where the prescriptions originate. Prescriptions that are based on an Internet questionnaire, an Internet-based consultation, or a telephonic consultation without a valid preexisting patient-practitioner relationship are not considered legal. More contact to pharmacies and pharmacists is being made by businesses that, due to their business practices, could cause prescriptions

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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.dea diversion.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.

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to be dispensed that would cause them to be misbranded. When considering business connections to act as a fulfillment center, use caution and refer to state law and to your inspector prior to any final agreement.

PIC Responsibilities

An issue that periodically surfaces deals with the security of drug inventories. Some pharmacies are using inventory crews and cleaning crews in the pharmacy. The Board has reports of situations where these crews have stolen inventory while cleaning or taking inventory in pharmacies. In addition, persons who represent reverse distributor companies may be allowed to inventory drug returns and in the process steal some of the drugs meant for delivery to the distributor. Some situations are difficult to control but are still the responsibility of the pharmacist-in-charge (PIC) to ensure that drug inventories are always under proper supervision and security is appropriate. Another situation that has been found to be connected to the theft of drugs in rare instances is "shadowing." This is where a high school or college student observes pharmacy activities but does not participate or assist in any pharmacy functions. All of these scenarios require vigilance on behalf of the pharmacy staff and the PIC.

Licensing Report

Pharmacists:

Bonfiglio, Ralph A., #042950, Chesterfield, MO; April 12, 2006.

Pharmacist license placed on probation for two years. Failed to ensure maintenance of adequate and accurate inventory records; failed to ensure maintenance of adequate and accurate prescription records and labeling of prescriptions; terminated from employment due to misconduct involving a coworker in the pharmacy. Section 338.055.2(5), (13), and (15) RSMo.

Chandler, Paul C., #2003003450, Springfield, MO; May 13, 2006.

Pharmacist license placed on probation for two years. Multiple dispensing errors. Section 338.055.2(13) and (15), RSMo.

Kettelhut, Jeffrey L., #2002030459, Valley Park, MO; April 3, 2006.

Violation of previous discipline. Pharmacist license suspended for six (6) months followed by probation for five (5) years. Consumption of alcohol in violation of disciplinary order. Section 338.055.2(1), (6), (13).

Kucukarslan, Suzan N., #041532, Northville, MI; April 21, 2006.

Pharmacist license placed on suspension for thirty (30)

days followed by two (2) years probation. Failed to obtain the thirty (30) continuing education hours required for renewal of license for the period of August 1, 2002 through October 31, 2004. Section 338.055.2(3), (5), and (6), RSMo 2000.

Slack, Jay Duane, #2002006434, Four Seasons, MO; March 28, 2006.

Pharmacist license placed on probation for five years. Personal use or consumption of a controlled substance without a valid prescription. Section 338.055.2 (5), (6), (13), (15), and (17), RSMo.

Interns:

Smock, Laura E., #2004018004, Kirkwood, MO; June 9, 2006.

Intern license suspended for three (3) months, followed by five (5) years probation. Employment terminated for stealing merchandise and controlled substances and for working under the influence of controlled substances; and plead guilty to a felony drug charge. Section 338.065.1, RSMo (2000).

Pharmacies:

Agri-Med South, LLC, dba AMP, #2006017005, Troy, MO; June 16, 2006.

Restricted pharmacy permit issued on probation for two years. Distributed legend drugs without appropriate licensure as a drug distributor; dispensed a human legend drug pursuant to a veterinarian's prescription without appropriate licensure as a pharmacy, and was selling legend drugs via the Internet without licensure from the Board of Pharmacy. Section 338.055.1 and .2(5), (6), (13), and (15), RSMo.

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The *Missouri Board of Pharmacy News* is published by the Missouri Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Matt Blunt - Governor

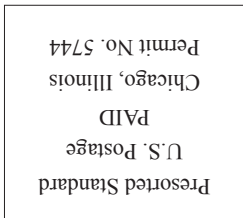
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